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Presidential Documents

Title 3—

The President

Proclamation 10675 of November 17, 2023

National Family Week, 2023

By the President of the United States of America

A Proclamation

My father always said that family is the beginning, the middle, and the end. Family is everything. During National Family Week, we celebrate the love, support, and resilience of the tens of millions of American families that make our Nation strong and keep the American Dream alive.

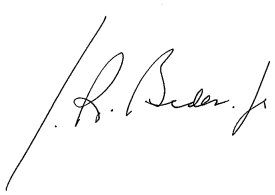
For too long, too many families in this country have lived with the prospect of an uncertain future. Too many parents have lain awake at night staring at the ceiling, wondering how they will make rent, send their kids to college, retire, or pay for medication. Too many have had to move far away from their hometowns to earn a living. I ran for President to change all that—to finally rebuild a strong middle class and grow our economy from the middle out and bottom up, giving hardworking families across the country a little more breathing room.

The historic legislation that we have since enacted is delivering, investing in American families and in America's future. The American Rescue Plan kept millions of families in their homes, food on the table, and folks on the job through the pandemic. Thanks to the Bipartisan Infrastructure Law, over 40,000 projects are currently underway to rebuild our Nation's roads, bridges, and ports, expand access to clean drinking water, and connect every home to high-speed internet. We are also working to revitalize American manufacturing—we have helped create nearly 800,000 manufacturing jobs, and through the CHIPS and Science Act, we are making historic investments across the country. The Inflation Reduction Act has made health care coverage cheaper for nearly 15 million Americans—it is set to cap out-of-pocket prescription drug costs for seniors on Medicare at $2,000 per year, and it has already slashed their insulin costs to $35 per month from as much as $400, helping families pay their monthly bills. Through the PACT Act, we are helping veterans who were exposed to toxic materials while serving get the health care and benefits that they and their families deserve. I am fighting hard to protect children and families from the scourge of gun violence—last year, I signed our Nation's most significant gun safety law in nearly 30 years, strengthening background checks, increasing the effective use of red flag laws, and expanding access to mental health services. I am fighting to ensure that all families have equal rights and dignity. That is why I was so proud to sign the Respect for Marriage Act into law, protecting the right to marriage for same-sex and interracial couples. I also signed an Executive Order that calls for the most comprehensive set of executive actions of any administration in history to increase high-quality child care, long-term care, and support for caregivers, ensuring that families have access to the support they need.

We have more to do to keep building on all of this progress, to make sure that every family in America has an equal shot at a better life of dignity and respect. During National Family Week, we celebrate the importance of spending time with loved ones, both the families that we are born into and the families that we create throughout our lives. Families are an essential part of the glue that holds our Nation together across generations, and we will never stop investing in their dreams.

NOW, THEREFORE, I, JOSEPH R. BIDEN JR., President of the United States of America, by virtue of the authority vested in me by the Constitution and the laws of the United States, do hereby proclaim November 19 through November 25, 2023, as National Family Week. I invite States, communities, and individuals to join together in observing this week with appropriate ceremonies and activities to honor our Nation's families.

IN WITNESS WHEREOF, I have hereunto set my hand this seventeenth day of November, in the year of our Lord two thousand twenty-three, and of the Independence of the United States of America the two hundred and forty-eighth.



[FR Doc. 2023–25980
Filed 11–21–23; 8:45 am]
Billing code 3395–F4–P

Presidential Documents

Proclamation 10676 of November 17, 2023

National Child's Day, 2023

By the President of the United States of America

A Proclamation

Our Nation's children are the kite strings that keep our national ambitions aloft—they are the dreamers and doers, who will determine the course of our future. From an early age, young people lead the way by volunteering in their communities, modeling compassion and tolerance, and pushing us to address the critical issues of our time like climate change and gun violence. This generation of young people is the most gifted, tolerant, talented, and educated in American history. They are the reason I am so optimistic about the future. On National Child's Day, we recommit to ensuring that every child has the resources and opportunities they need to reach their full potential.

That is why my Administration has invested billions of dollars in America's schools. These funds are putting more teachers in our classrooms, supporting tutoring programs, financing building renovations, replacing lead pipes, and more. Our Bipartisan Infrastructure Law is expanding access to reliable high-speed internet so every student can log on at any time, regardless of their zip code.

We are also prioritizing the health and safety of our children. By expanding the Child Tax Credit, my Administration cut the child poverty rate nearly in half, and I continue to call on the Congress to reinstate this expansion because no child should grow up in poverty. We are also working to lower the cost of health care and expand access to affordable, nutritious meals for millions of families. My Administration released a national strategy to end hunger and reduce diet-related diseases in America by 2030—including advancing a pathway to provide free, healthy school meals for all children. New vaccines are rolling out that protect children against COVID–19, RSV, and the flu, which you can learn more about at www.vaccines.gov. We are also supporting LGBTQI+ children and families by safeguarding access to health care and preventing harmful so-called ''conversion therapy.'' Further, we are working with State child welfare agencies to make sure LGBTQI+ youth are placed in safe and loving homes. To curb the epidemic of gun violence in America—now the leading cause of death of children in the United States—I was proud to sign into law the most significant gun safety legislation in nearly 30 years. This law will save children's lives, but we cannot stop until we finally pass an assault weapons ban.

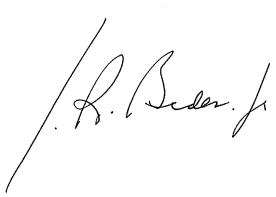
Mental health is just as important as physical health, which is why I am addressing the youth mental health crisis head-on. My Administration has advanced measures to increase the number of school psychologists and counselors available to our kids and to make it easier for schools to use Medicaid to deliver mental health care, including services under the Individuals with Disabilities Education Act. We also proposed a rule that would require insurers to finally cover mental health care just as they do physical care. Further, we must do more to make the internet a safe place for children. I have called on the Congress to limit the personal data that tech companies collect, ban targeted advertising directed at minors, and strengthen protections that safeguard children's health and safety online.

Finally, all this progress means little if our children do not inherit a healthy planet. That is why I fought so hard to pass the Inflation Reduction Act, a landmark bill that contains the largest investment to tackle climate change in history. The Act will help our children breathe cleaner air and drink cleaner water. It is also creating the jobs of the future so our kids can graduate into a strong clean energy economy.

Every child deserves the opportunity to thrive because when they dream big, our whole Nation is opened to new possibilities. The children of today are the global leaders of tomorrow. That is why this National Child's Day, we recommit to fulfilling the promise of America for every child and building a future worthy of their dreams.

NOW, THEREFORE, I, JOSEPH R. BIDEN JR., President of the United States of America, by virtue of the authority vested in me by the Constitution and the laws of the United States, do hereby proclaim November 20, 2023, as National Child's Day. I call upon all government officials, educators, volunteers, and all the people of the United States of America to observe this day with appropriate programs, ceremonies, and activities.

IN WITNESS WHEREOF, I have hereunto set my hand this seventeenth day of November, in the year of our Lord two thousand twenty-three, and of the Independence of the United States of America the two hundred and forty-eighth.



[FR Doc. 2023–25985
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Rules and Regulations

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This section of the FEDERAL REGISTER contains regulatory documents having general applicability and legal effect, most of which are keyed to and codified in the Code of Federal Regulations, which is published under 50 titles pursuant to 44 U.S.C. 1510.

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DEPARTMENT OF HOMELAND SECURITY

8 CFR Part 214

[CIS No. 2764–24]

RIN 1615–AC89

Exercise of Time-Limited Authority To Increase the Numerical Limitation for FY 2024 for the H–2B Temporary Nonagricultural Worker Program and Portability Flexibility for H–2B Workers Seeking To Change Employers; Correction

AGENCY: U.S. Citizenship and Immigration Services (USCIS), Department of Homeland Security (DHS), and Employment and Training Administration and Wage and Hour Division, U.S. Department of Labor (DOL).

ACTION: Temporary rule; correction and correcting amendment.

SUMMARY: On November 17, 2023, the Department of Homeland Security and Department of Labor jointly published a temporary rule titled ''Exercise of Time-Limited Authority to Increase the Numerical Limitation for FY 2024 for the H–2B Temporary Nonagricultural Worker Program and Portability Flexibility for H–2B Workers Seeking To Change Employers.'' The temporary rule contains errors that this document corrects.

DATES: Effective November 20, 2023, and applicable beginning November 17, 2023.

FOR FURTHER INFORMATION CONTACT: Charles L. Nimick, Chief, Business and Foreign Workers Division, Office of Policy and Strategy, U.S. Citizenship and Immigration Services, Department of Homeland Security, 5900 Capital Gateway Drive, Camp Springs, MD 20746; telephone 240–721–3000 (this is not a toll-free number).

SUPPLEMENTARY INFORMATION: This document corrects two errors contained in the *Exercise of Time-Limited Authority to Increase the Numerical Limitation for FY 2024 for the H–2B Temporary Nonagricultural Worker Program and Portability Flexibility for H–2B Workers Seeking To Change Employers* temporary final rule published at 88 FR 80394 (Nov. 17, 2023). Specifically, it corrects two incorrect citations published on p. 80457 in 8 CFR 214.2(h)(6)(xiv)(C)(*1*) by removing each instance of ''(h)(6)(xiv)(A)(*1*)(*a*)'' and replacing it each with ''(h)(6)(xiv)(A)(*1*)(*i*)''.

List of Subject in 8 CFR Part 214

Administrative practice and procedure, Aliens, Cultural exchange program, Employment, Foreign officials, Health professions, Reporting and recordkeeping requirements, Students.

Accordingly, 8 CFR part 214 is corrected by making the following correcting amendment:

PART 214—NONIMMIGRANT CLASSES

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

Authority: 6 U.S.C. 202, 236; 8 U.S.C. 1101, 1102, 1103, 1182, 1184, 1186a, 1187, 1221, 1281, 1282, 1301–1305, 1357, and 1372; sec. 643, Pub. L. 104–208, 110 Stat. 3009–708; Pub. L. 106–386, 114 Stat. 1477–1480; section 141 of the Compacts of Free Association with the Federated States of Micronesia and the Republic of the Marshall Islands, and with the Government of Palau, 48 U.S.C. 1901 note and 1931 note, respectively; 48 U.S.C. 1806; 8 CFR part 2; Pub. L. 115–218, 132 Stat. 1547 (48 U.S.C. 1806).

■ 2. In 214.2, revise the paragraph (h)(6)(xiv)(C)(*1*) heading and introductory text to read as follows:

§ 214.2 Special requirements for admission, extension, and maintenance of status.

* * * * *

(h) * * *

(6) * * *

(xiv) * * *

(C) * * *

(*1*) *Petitions filed pursuant to paragraph (h)(6)(xiv)(A)(1)(i) requesting FY 2024 employment start dates on or before March 31, 2024.* USCIS will reject petitions filed pursuant to paragraph (h)(6)(xiv)(A)(*1*)(*i*) of this section requesting employment start dates on or before March 31, 2024 that are received after the applicable numerical limitation has been reached or after September 16, 2024.

* * * * *

Christina E. McDonald,

Federal Register Liaison, U.S. Department of Homeland Security.

[FR Doc. 2023–25951 Filed 11–20–23; 4:15 pm]

BILLING CODE 9111–97–P

DEFENSE NUCLEAR FACILITIES SAFETY BOARD

10 CFR Part 1710

[Docket No. DNFSB–2023–02]

RIN 3155–AA02

Federal Employee Salary Offset Procedures for the Collection of a Debt Owed to the Federal Government

AGENCY: Defense Nuclear Facilities Safety Board.

ACTION: Final rule.

SUMMARY: This final rule adopts, without change, an interim final rule with a request for comments published in the **Federal Register** on September 19, 2023. The interim final rule created regulations governing the collection of debts owed to the Defense Nuclear Facilities Safety Board (DNFSB) and to the United States by Federal employees.

DATES: Effective November 22, 2023.

FOR FURTHER INFORMATION CONTACT: Patricia A. Hargrave, Associate General Counsel, Defense Nuclear Facilities Safety Board, 625 Indiana Avenue NW, Suite 700, Washington, DC 20004–2901, (202) 694–7000.

SUPPLEMENTARY INFORMATION: On September 19, 2023, (88 FR 64353), the Board published an interim final rule with a request for comments. This rule, which became effective October 19, 2023, implemented the debt collection procedures provided under section 5 of the Debt Collection Act (DCA), as amended, codified at 5 U.S.C. 5514. The DCA authorizes the Federal Government to collect debts by offset from the salaries of Federal employees without the employee's consent, provided that the employee is properly notified and given the opportunity to exercise certain administrative rights.

The Board determined that the regulations were interpretative because they merely implemented a definitive

statutory scheme and the requirements contained in regulations promulgated by OPM, codified in 5 CFR part 550, subpart K. Accordingly, no notice of proposed rulemaking was required pursuant to 5 U.S.C. 553(b)(A). In addition, because this rule related to agency management and personnel, no notice of proposed rulemaking was required pursuant to 5 U.S.C. 553(a)(2). The Board, however, noted that it would consider any public comments, but no comments were received. This is confirmation that the interim rule published September 19, 2023, at 88 FR 64353, is adopted as final without change.

Dated: November 13, 2023.

Joyce Connery,

Chair.

[FR Doc. 2023–25536 Filed 11–21–23; 8:45 am]

BILLING CODE 3670–01–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2023–1804; Project Identifier MCAI–2023–00675–T; Amendment 39–22596; AD 2023–22–12]

RIN 2120–AA64

Airworthiness Directives; Dassault Aviation Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: The FAA is superseding Airworthiness Directive (AD) 2023–04–18, which applied to all Dassault Aviation Model FALCON 2000 airplanes. AD 2023–04–18 required revising the existing maintenance or inspection program, as applicable, to incorporate new or more restrictive airworthiness limitations. This AD was prompted by a determination that new or more restrictive airworthiness limitations are necessary. This AD continues to require certain actions in AD 2023–04–18 and requires revising the existing maintenance or inspection program, as applicable, to incorporate new or more restrictive airworthiness limitations as specified in a European Union Aviation Safety Agency (EASA) AD, which is incorporated by reference. The FAA is issuing this AD to address the unsafe condition on these products.

DATES: This AD is effective December 27, 2023.

The Director of the Federal Register approved the incorporation by reference of a certain publication listed in this AD as of December 27, 2023.

The Director of the Federal Register approved the incorporation by reference of a certain other publication listed in this AD as of April 18, 2023 (88 FR 15607, March 14, 2023).

ADDRESSES:

AD Docket: You may examine the AD docket at *regulations.gov* under Docket No. FAA–2023–1804; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this final rule, the mandatory continuing airworthiness information (MCAI), any comments received, and other information. The address for Docket Operations is U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590.

Material Incorporated by Reference:

- For material incorporated by reference in this AD, contact EASA, Konrad-Adenauer-Ufer 3, 50668 Cologne, Germany; telephone +49 221 8999 000; email *ADs@easa.europa.eu;* website *easa.europa.eu.* You may find this material on the EASA website at *ad.easa.europa.eu.*
- You may view this material at the FAA, Airworthiness Products Section, Operational Safety Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195. It is also available in the AD docket at *regulations.gov* under Docket No. FAA–2023–1804.

FOR FURTHER INFORMATION CONTACT: Tom Rodriguez, Aviation Safety Engineer, FAA, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; telephone 206–231–3226; email *tom.rodriguez@faa.gov.*

SUPPLEMENTARY INFORMATION:

Background

The FAA issued a notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 to supersede AD 2023–04–18, Amendment 39–22365 (88 FR 15607, March 14, 2023) (AD 2023–04–18). AD 2023–04–18 applied to all Dassault Aviation Model FALCON 2000 airplanes. AD 2023–04–18 required revising the existing maintenance or inspection program, as applicable, to incorporate new or more restrictive airworthiness limitations. The FAA issued AD 2023–04–18 to address reduced controllability of the airplane. AD 2023–04–18 specified that accomplishing the revision required by that AD terminates certain requirements of AD 2010–26–05, Amendment 39–16544 (75 FR 79952, December 21, 2010) (AD 2010–26–05) for Model FALCON 2000 airplanes only. This AD therefore continues to allow that terminating action.

The NPRM published in the **Federal Register** on August 30, 2023 (88 FR 59815). The NPRM was prompted by AD 2023–0099, dated May 11, 2023, issued by EASA, which is the Technical Agent for the Member States of the European Union (EASA AD 2023–0099) (also referred to as the MCAI). The MCAI states that new or more restrictive airworthiness limitations have been developed.

In the NPRM, the FAA proposed to continue to require certain actions in AD 2023–04–18 and to require revising the existing maintenance or inspection program, as applicable, to incorporate new or more restrictive airworthiness limitations, as specified in EASA AD 2023–0099. The FAA is issuing this AD to address reduced controllability of the airplane.

You may examine the MCAI in the AD docket at *regulations.gov* under Docket No. FAA–2023–1804.

Discussion of Final Airworthiness Directive

Comments

The FAA received no comments on the NPRM or on the determination of the cost to the public.

Conclusion

This product has been approved by the aviation authority of another country and is approved for operation in the United States. Pursuant to the FAA's bilateral agreement with this State of Design Authority, it has notified the FAA of the unsafe condition described in the MCAI referenced above. The FAA reviewed the relevant data and determined that air safety requires adopting this AD as proposed. Accordingly, the FAA is issuing this AD to address the unsafe condition on this product. Except for minor editorial changes, this AD is adopted as proposed in the NPRM. None of the changes will increase the economic burden on any operator.

Related Service Information Under 1 CFR Part 51

EASA AD 2023–0099 specifies new or more restrictive airworthiness limitations for airplane structures and safe life limits.

This AD also requires EASA AD 2022–0135, dated July 6, 2022, which the Director of the Federal Register approved for incorporation by reference as of April 18, 2023 (88 FR 15607, March 14, 2023).

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

Costs of Compliance

The FAA estimates that this AD affects 168 airplanes of U.S. registry. The FAA estimates the following costs to comply with this AD:

The FAA estimates the total cost per operator for the retained actions from AD 2021–03–11 to be $7,650 (90 work-hours × $85 per work-hour).

The FAA has determined that revising the existing maintenance or inspection program takes an average of 90 work-hours per operator, although the agency recognizes that this number may vary from operator to operator. Since operators incorporate maintenance or inspection program changes for their affected fleet(s), the FAA has determined that a per-operator estimate is more accurate than a per-airplane estimate.

The FAA estimates the total cost per operator for the new actions to be $7,650 (90 work-hours × $85 per work-hour).

Authority for This Rulemaking

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

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

Regulatory Findings

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

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

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

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

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

List of Subjects in 14 CFR Part 39

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

The Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

■ 2. The FAA amends § 39.13 by:

■ a. Removing Airworthiness Directive (AD) 2023–04–18, Amendment 39–22365 (88 FR 15607, March 14, 2023); and

■ b. Adding the following new AD:

2023–22–12 Dassault Aviation: Amendment 39–22596; Docket No. FAA–2023–1804; Project Identifier MCAI–2023–00675–T.

(a) Effective Date

This airworthiness directive (AD) is effective December 27, 2023.

(b) Affected ADs

(1) This AD replaces AD 2023–04–18, Amendment 39–22365 (88 FR 15607, March 14, 2023) (AD 2023–04–18).

(2) This AD affects AD 2010–26–05, Amendment 39–16544 (75 FR 79952, December 21, 2010) (AD 2010–26–05).

(c) Applicability

This AD applies to all Dassault Aviation Model FALCON 2000 airplanes, certificated in any category.

(d) Subject

Air Transport Association (ATA) of America Code 05, Time Limits/Maintenance Checks.

(e) Unsafe Condition

This AD was prompted by a determination that new or more restrictive airworthiness limitations are necessary. The FAA is issuing this AD to address reduced controllability of the airplane.

(f) Compliance

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

(g) Retained Revision of the Existing Maintenance or Inspection Program, With No Changes

This paragraph restates the requirements of paragraph (j) of AD 2023–04–18, with no changes. Except as specified in paragraph (h) of this AD: Comply with all required actions and compliance times specified in, and in accordance with, European Union Aviation Safety Agency (EASA) AD 2022–0135, dated July 6, 2022 (EASA AD 2022–0135). Accomplishing the revision of the existing maintenance or inspection program required by paragraph (j) of this AD terminates the requirements of this paragraph.

(h) Retained Exceptions to EASA AD 2022–0135, With No Changes

This paragraph restates the exceptions specified in paragraph (k) of AD 2023–04–18, with no changes.

(1) The requirements specified in paragraphs (1) and (2) of EASA AD 2022–0135 do not apply to this AD.

(2) Paragraph (3) of EASA AD 2022–0135 specifies revising ''the approved AMP'' within 12 months after its effective date, but this AD requires revising the existing maintenance or inspection program, as applicable, within 90 days after April 18, 2023 (the effective date of AD 2023–04–18).

(3) The initial compliance time for doing the tasks specified in paragraph (3) of EASA AD 2022–0135 is at the applicable ''limitations'' and ''associated thresholds'' as incorporated by the requirements of paragraph (3) of EASA AD 2022–0135, or within 90 days after April 18, 2023 (the effective date of AD 2023–04–18), whichever occurs later.

(4) The provisions specified in paragraphs (4) and (5) of EASA AD 2022–0135 do not apply to this AD.

(5) The ''Remarks'' section of EASA AD 2022–0135 does not apply to this AD.

(i) Retained No Alternative Actions or Intervals With a New Exception

This paragraph restates the requirements of paragraph (l) of AD 2023–04–18, with a new exception. Except as required by paragraph (j) of this AD, after the existing maintenance or inspection program has been revised as required by paragraph (g) of this AD, no alternative actions (*e.g.,* inspections) or intervals may be used unless they are approved as specified in the provisions of the ''Ref. Publications'' section of EASA AD 2022–0135.

(j) New Maintenance or Inspection Program Revision

Except as specified in paragraph (k) of this AD: Comply with all required actions and compliance times specified in, and in accordance with, EASA AD 2023–0099, dated May 11, 2023 (EASA AD 2023–0099). Accomplishing the maintenance or inspection program revision required by this paragraph terminates the requirements of paragraph (g) of this AD.

(k) Exceptions to EASA AD 2023–0099

(1) This AD does not adopt the requirements specified in paragraphs (1) and (2) of EASA AD 2023–0099.

(2) Paragraph (3) of EASA AD 2023–0099 specifies revising ''the approved AMP [aircraft maintenance program]'' within 12 months after its effective date, but this AD requires revising the existing maintenance or inspection program, as applicable, within 90 days after the effective date of this AD.

(3) The initial compliance time for doing the tasks specified in paragraph (3) of EASA AD 2023–0099 is at the applicable ''limitations'' and ''associated thresholds'' as incorporated by the requirements of paragraph (3) of EASA AD 2023–0099, or within 90 days after the effective date of this AD, whichever occurs later.

(4) This AD does not adopt the provisions specified in paragraphs (4) and (5) of EASA AD 2023–0099.

(5) This AD does not adopt the ''Remarks'' section of EASA AD 2023–0099.

(l) New Provisions for Alternative Actions and Intervals

After the existing maintenance or inspection program has been revised as required by paragraph (j) of this AD, no alternative actions (*e.g.,* inspections), and intervals are allowed unless they are approved as specified in the provisions of the ''Ref. Publications'' section of EASA AD 2023–0099.

(m) Terminating Action for Certain Requirements in AD 2010–26–05

Accomplishing the actions required by paragraphs (g) or (j) of this AD terminates the requirements of paragraph (g) of AD 2010–26–05 for Model FALCON 2000 airplanes only.

(n) Additional AD Provisions

The following provisions also apply to this AD:

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

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

(o) Additional Information

For more information about this AD, contact Tom Rodriguez, Aviation Safety Engineer, FAA, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; telephone 206–231–3226; email *tom.rodriguez@faa.gov.*

(p) Material Incorporated by Reference

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

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

(3) The following service information was approved for IBR on December 27, 2023.

(i) European Union Aviation Safety Agency (EASA) AD 2023–0099, dated May 11, 2023.

(ii) [Reserved]

(4) The following service information was approved for IBR on April 18, 2023 (88 FR 15607, March 14, 2023).

(i) European Union Aviation Safety Agency (EASA) AD 2022–0135, dated July 6, 2022.

(ii) [Reserved]

(5) For EASA ADs 2023–0099 and 2022–0135, contact EASA, Konrad-Adenauer-Ufer 3, 50668 Cologne, Germany; telephone +49 221 8999 000; email *ADs@easa.europa.eu;* website *easa.europa.eu.* You may find these EASA ADs on the EASA website at *ad.easa.europa.eu.*

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

(7) You may view this material at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, visit *www.archives.gov/federal-register/cfr/ibr-locations* or email *fr.inspection@nara.gov.*

Issued on November 16, 2023.

Ross Landes,

Deputy Director for Regulatory Operations, Compliance & Airworthiness Division, Aircraft Certification Service.

[FR Doc. 2023–25832 Filed 11–21–23; 8:45 am]

BILLING CODE 4910–13–P

NATIONAL LABOR RELATIONS BOARD

29 CFR Part 103

RIN 3142–AA21

Standard for Determining Joint Employer Status

AGENCY: National Labor Relations Board.

ACTION: Final rule; delay of effective date.

SUMMARY: On October 27, 2023, the National Labor Relations Board (Board) published a final rule rescinding and replacing its rule regarding the standard for determining joint employer status under the National Labor Relations Act. The Board hereby amends that rule to change the effective date from December 26, 2023, to February 26, 2024. The purpose of this amendment is to facilitate the resolution of the legal challenges with respect to the rule.

DATES: The effective date of the final rule amending 29 CFR part 103 published at 88 FR 73946, October 27, 2023, is delayed from December 26, 2023, to February 26, 2024.

FOR FURTHER INFORMATION CONTACT: Roxanne L. Rothschild, Executive Secretary, National Labor Relations Board, 1015 Half St. SE, Washington, DC 20570–0001, (202) 273–1940 (this is not a toll-free number) or 1–844–762–NLRB (6572) (this is a toll-free number). Hearing impaired callers who wish to speak to an NLRB representative should contact T-Mobile Relay Conference Captioning by visiting its website at *https://www.tmobileaccess.com/federal* and submitting a form asking its Communications Assistant to call our toll free number at 1–844–762–NLRB (6572).

SUPPLEMENTARY INFORMATION: On October 27, 2023, the National Labor Relations Board published a final rule rescinding and replacing the final rule entitled ''Joint Employer Status Under the National Labor Relations Act,'' which was published on February 26, 2020, and took effect on April 27, 2020. The final rule establishes a new standard for determining whether two employers, as defined in the Act, are joint employers of particular employees within the meaning of the Act. The Board believes that this rule will more explicitly ground the joint-employer standard in established common-law agency principles and provide guidance to parties covered by the Act regarding their rights and responsibilities when more than one statutory employer possesses the authority to control or exercises the power to control particular employees' essential terms and conditions of employment. Under the final rule, an entity may be considered a joint employer of another employer's employees if the two share or codetermine the employees' essential terms and conditions of employment.

On November 6, 2023, a petition for review of the final rule was filed in the United States Court of Appeals for the District of Columbia Circuit. *Service Employees International Union* v. *NLRB,* No. 23–1309 (D.C. Cir.). Then, on November 19, 2023, a challenge to the final rule was filed in the U.S. District Court for the Eastern District of Texas. *Chamber of Commerce of the United States of America, et. al* v. *NLRB,* No. 6:23–cv–00553 (E.D. Tex.). The Board has determined that postponing the effective date of the rule would facilitate the resolution of the legal challenges that have been filed with respect to the

rule. 5 U.S.C. 705. Accordingly, the Board has decided to change the effective date of the rule from December 26, 2023 to February 26, 2024.

Dated: November 17, 2023.

Roxanne L. Rothschild,

Executive Secretary.

[FR Doc. 2023–25803 Filed 11–21–23; 8:45 am]

BILLING CODE 7545–01–P

DEPARTMENT OF THE TREASURY

Office of the Secretary

31 CFR Part 1

RIN 1506–AB63

Privacy Act of 1974; Exemptions

AGENCY: Financial Crimes Enforcement Network (FinCEN), Treasury.

ACTION: Final rule.

SUMMARY: In accordance with the requirements of the Privacy Act of 1974, as amended, Treasury is issuing a final rule, exempting a new system of records, entitled ''FinCEN .004—Beneficial Ownership Information System,'' from certain provisions of the Privacy Act. The Beneficial Ownership Information (BOI) System is being established to implement the beneficial ownership information reporting and access requirements set out in the Corporate Transparency Act (CTA), which was enacted on January 1, 2021, as part of the Anti-Money Laundering Act of 2020. The exemptions are intended to increase the value of the system for law enforcement purposes and to comply with the CTA's prohibitions against unauthorized disclosure of certain information.

DATES: This rule is effective January 1, 2024.

FOR FURTHER INFORMATION CONTACT: For questions about this document and privacy issues, contact: Ryan Law, Deputy Assistant Secretary for Privacy, Transparency, and Records at U.S. Department of the Treasury, 1500 Pennsylvania Avenue NW, Washington, DC 20220; telephone: (202) 622–5710.

SUPPLEMENTARY INFORMATION:

Background

On September 14, 2023, Treasury published a notice of proposed rulemaking (the ''NPRM'') in the **Federal Register**, 88 FR 63039, proposing to exempt a system of records, FinCEN .004—Beneficial Ownership Information System (the ''BOI System''), from provisions of the Privacy Act. Pursuant to the CTA, starting on January 1, 2024, FinCEN will use the BOI System to maintain BOI submitted to FinCEN by certain corporations, limited liability companies, and other entities created in or registered to do business in the United States (''reporting companies''). BOI includes identifying information associated with the reporting companies themselves, their beneficial owners, and their company applicants. The BOI System will also maintain information about individuals who apply to FinCEN for FinCEN identifiers, which beneficial owners and company applicants will be able to use in lieu of the information required to be reported about them by reporting companies.[1] Information provided to FinCEN to obtain a FinCEN identifier will be disclosed to authorized recipients for authorized purposes in the same way and to the same extent as BOI. The CTA authorizes FinCEN to disclose BOI to five categories of authorized recipients that include foreign and domestic law enforcement agencies, but do *not* include beneficial owners, company applicants, or individuals who have obtained FinCEN identifiers.

The Privacy Act contains certain requirements regarding the maintenance and disclosure of a system of records. Those requirements may differ from, or conflict with, the comprehensive requirements for maintaining and disclosing BOI specified in the CTA. In any case where the CTA conflicts with the Privacy Act, FinCEN believes that the more detailed, specific provisions of the CTA supersede any contrary provisions in the Privacy Act. Nevertheless, to the extent certain provisions of the Privacy Act were to apply, and without conceding that they do, Treasury is publishing this final rule pursuant to 5 U.S.C. 552a(j) and (k), to exempt the BOI System from those provisions.

Under 5 U.S.C. 552a(j)(2), the head of a Federal agency may promulgate rules to exempt a system of records from certain provisions of 5 U.S.C. 552a if the system of records is maintained by an agency or component thereof that performs as its principal function any activity pertaining to the enforcement of criminal laws, including police efforts to prevent, control, or reduce crime or to apprehend criminals, and the activities of prosecutors, courts, correctional, probation, pardon, or parole authorities and which consists of (a) information compiled for the purpose of identifying individual criminal offenders and alleged offenders and consisting only of identifying data and notations of arrests, the nature and disposition of criminal charges, sentencing, confinement, release, and parole and probation status; (b) information compiled for the purpose of a criminal investigation, including reports of informants and investigators, and associated with an identifiable individual; or (c) reports identifiable to an individual compiled at any stage of the process of enforcement of the criminal laws from arrest or indictment through release from supervision.

Under 5 U.S.C. 552a(k)(2), the head of a Federal agency may promulgate rules to exempt a system of records from certain provisions of 5 U.S.C. 552a if the system of records is ''investigatory material compiled for law enforcement purposes, other than material within the scope of subsection (j)(2) of this section.''

The reasons for exempting the BOI System from sections (c)(3), (c)(4), (d)(1), (d)(2), (d)(3), (d)(4), (e)(1), (e)(2), (e)(4)(G), (e)(4)(H), (e)(5), (e)(8), (f), and (g) of the Privacy Act are as follows:

(1) 5 U.S.C. 552a(d)(1), (e)(4)(H) and (f)(2), (f)(3), and (f)(5) grant individuals access to records containing information about them. An exemption from these provisions is appropriate because the CTA prohibits FinCEN from disclosing BOI except to five categories of authorized recipients;[2] these categories do not include beneficial owners, company applicants, or individuals who have obtained FinCEN identifiers. Because individuals who are the subject of the records in the BOI System are not included in any of those categories, the application of 5 U.S.C. 552a(d)(1), (e)(4)(H) and (f)(2), (f)(3), and (f)(5) to the BOI System would contravene the CTA's disclosure restrictions.

(2) 5 U.S.C. 552a(e)(4)(G) and (f)(1) enable individuals to inquire whether a system of records contains records about them. An exemption from these provisions is appropriate because allowing individuals involved in illegal activity to learn that FinCEN has information concerning those individuals that could lead to them being identified for investigation could undercut the CTA mandate that the BOI System be ''highly useful'' to law enforcement agencies. For instance, such notice could prompt individuals engaged in illegal activity to: (a) take steps to avoid detection; (b) begin, continue, or resume illegal conduct upon learning that they are not identified in the system of records; or (c)

[1] Reporting companies will not use the FinCEN identifier application to request a FinCEN identifier but instead will request a FinCEN identifier when they submit a BOI report.

[2] 31 U.S.C. 5337(c)(2).

destroy evidence needed to prove the violation.

(3) 5 U.S.C. 552a(d)(2), (d)(3) and (d)(4), (e)(4)(H), and (f)(4) permit individuals to request amendment of a record pertaining to them and require the agency either to amend the record or note the disputed portion of the record and, if the agency refuses to amend the record, to provide a copy of the individual's statement of disagreement with the agency's refusal, to persons or other agencies to whom the record is thereafter disclosed. Because these provisions depend on individuals having access to their records, and since this rule exempts the BOI System from the provisions of 5 U.S.C. 552a relating to access to records for the reasons set forth above, these provisions do not apply to the BOI System. Furthermore, an exemption from this requirement is appropriate because allowing individuals to amend certain records that pertain to them would conflict with the mechanism for reporting beneficial ownership information provided for in the CTA.

(4) 5 U.S.C. 552a(c)(4) requires an agency to inform any person or other agency about any correction or notation of dispute that the agency made in accordance with 5 U.S.C. 552a(d) to any record that the agency disclosed to the person or agency, if an accounting of the disclosure was made. Because this provision depends on individuals having access to and an opportunity to request amendment of records pertaining to them, and because this rule exempts the BOI System from the provisions of 5 U.S.C. 552a relating to access to and amendment of records for the reasons set forth above, this provision does not apply to the BOI System.

(5) 5 U.S.C. 552a(c)(3) requires an agency to make the accounting of any disclosures of records required by 5 U.S.C. 552a(c)(1) available to the individual named in the record upon his or her request. The accounting must state the date, nature, and purpose of each disclosure of the record and the name and address of the recipient. Applying this provision would impair the effective use of information collected in the BOI System. Making an accounting of disclosures available to the subject of an investigation would alert them that another agency is investigating their criminal activities and could reveal the geographic location of the other agency's investigation, the nature and purpose of that investigation, and the dates on which that investigation was active. Violators possessing such knowledge would be able to take measures to avoid detection or apprehension by: (a) altering their operations; (b) transferring their criminal activities to other geographical areas, legal entities, or ostensible beneficial owners; or (c) destroying or concealing evidence that would form the basis for arrest. Moreover, providing an accounting to the subjects of investigations would alert them to the fact that FinCEN has information relevant to their criminal activities. Access to such information, together with other available information, could reveal the operation of the information-gathering and analysis systems of FinCEN and other BOI System users, and permit violators to take steps to avoid detection or apprehension.

(6) 5 U.S.C. 552a(e)(1) requires an agency to maintain in its records only such information about an individual as is relevant and necessary to accomplish a purpose of the agency required to be accomplished by statute or Executive order. Maintenance of information, as defined in 5 U.S.C. 552a(a)(3), includes the collection and dissemination of information. An exemption from this provision is therefore appropriate because its application would require FinCEN to make determinations at the time of collection about the relevance and necessity of collected information. Speculative determinations about the relevance and necessity of collected information could negatively impact the quality of information available to law enforcement in future investigations, which would undermine the mandate in the CTA that the BOI System be ''highly useful'' to law enforcement.

(7) 5 U.S.C. 552a(e)(2) requires an agency to collect information to the greatest extent practicable directly from the subject individual when the information may result in adverse determinations about an individual's rights, benefits, and privileges under Federal programs. If such a program exists, an exemption to this provision is appropriate because applying it to the BOI System would contravene the requirement in the CTA that FinCEN collect BOI from reporting companies.

(8) 5 U.S.C. 552a(e)(5) requires an agency to maintain all records it uses in making any determination about any individual with such accuracy, relevance, timeliness, and completeness as is reasonably necessary to assure fairness to the individual in the determination. Because 5 U.S.C. 552a(a)(3) defines ''maintain'' as including ''collect'' and ''disseminate,'' applying this provision to the BOI System would hinder timely dissemination of BOI, and by extension hinder law enforcement efforts dependent upon such information. Information in the BOI System is filed by reporting companies and individual FinCEN identifier applicants, and it is not possible at the time of collection to determine whether the information in such records is accurate, relevant, timely, and complete.

(9) 5 U.S.C. 552a(e)(8) requires an agency to make reasonable efforts to serve notice on an individual when the agency makes any record on the individual available to any person under compulsory legal process when such process becomes a matter of public record. Exemption from this requirement is appropriate because applying the requirement to the BOI System could reveal to the subject of a law enforcement investigation or action that a law enforcement agency used BOI in the investigation or action, thereby revealing the agency's investigative techniques and procedures.

(10) 5 U.S.C. 552a(g) provides an individual with civil remedies when: (a) an agency wrongfully refuses to amend a record or to review a request for amendment; (b) an agency wrongfully refuses to grant access to a record; (c) any determination relating to an individual is based on records that are not accurate, relevant, timely and complete; and (d) an agency fails to comply with any other provision of 5 U.S.C. 552a so as to adversely affect the individual. The BOI System is exempt from this provision to the extent that the civil remedies relate to the provisions of 5 U.S.C. 552a from which the prior paragraphs of this section exempt the BOI System. Exemption from this provision is appropriate because there should be no civil remedies for failure to comply with provisions from which the BOI System is exempt. Exemption from this provision will also protect FinCEN from baseless civil court actions that might hamper its ability to collate, analyze, and disseminate data.

Any information from a system of records for which an exemption is claimed under 5 U.S.C. 552a(j)(2) or (k)(2) which is also included in another system of records retains the same exempt status such information has in the system of records for which such exemption is claimed.

Public Comments

Treasury received two comments on the NPRM. The first expressed support for the proposed rule, noting its ''import[ance] for protecting an individual's privacy, while also increasing the value of the [BOI System] for law enforcement purposes.''

The second addresses the proposal to exempt the BOI System from the requirements of 5 U.S.C. 552a(c)(3) and

suggests a potential alternative approach. As explained above, that provision of the Privacy Act requires an agency to make the accounting of any disclosures of records required by 5 U.S.C. 552a(c)(1) available to the individual named in the record upon his or her request. The comment's author argues that fully exempting the BOI System from these requirements ''would make the [] audit trail required by the CTA meaningless'' and that ''[a]llowing for an accounting of disclosures to be made to the public would help ensure that the right to privacy would not be violated through unauthorized disclosures.'' The commenter suggests that the BOI System should be only partially exempt from 5 U.S.C. 552a(c)(3) and that FinCEN should establish procedures under 5 U.S.C. 552a(f)(2) that would make accountings of disclosures available to requesters after some specified amount of time has passed (the commenter proposes one year).

FinCEN carefully considered this comment, particularly the commenter's claim that exempting the BOI System from the requirements of 5 U.S.C. 552a(c)(3) would make the system's audit trails meaningless. FinCEN interpreted this comment as asserting that BOI System audit trails would constitute ''accountings of disclosures'' that would only be meaningful if individuals about whom the system contains records have access to them. However, FinCEN disagrees with this view.

In its ''Sense of Congress,'' the CTA directs the Secretary of the Treasury to ''take all steps, including regular auditing, to ensure that government authorities accessing beneficial ownership information do so only for authorized purposes consistent with [the CTA] . . . .'' [3] Accordingly, FinCEN will use the BOI System's audit trails to identify potential instances of improper access to BOI by authorized system users. The audit trails will also support other aspects of the CTA compliance and enforcement regime, including the imposition of penalties, which will further help to ensure that BOI is accessed and used appropriately.

Separately, for the reasons set out in the NPRM and reiterated above regarding the potential adverse impact on law enforcement investigations, Treasury declines to adopt the suggestion to make accountings of disclosures available to requesters after a specified period of time. Law enforcement investigations may span years and share common individuals of interest with concurrent investigations of equally varying durations. Revealing information about BOI disclosures to the subjects of those disclosures—even after a seemingly lengthy delay—could put those activities at risk of disruption and jeopardize the effective use of the BOI System for law enforcement purposes. Furthermore, a delay in making an accounting of disclosures available would not address the concern that such access could reveal information about the operation of the information-gathering and analysis systems utilized by FinCEN and other BOI System users. The resulting effect would be to postpone, rather than prevent, foreseeable harms to the law enforcement activities that Congress intended the BOI System to support. Such a result would contradict the purpose of the CTA and, therefore, Treasury will adopt the rule as proposed.

Regulatory Analysis

This rule is not a ''significant regulatory action'' under Executive Order 12866, as amended.

Pursuant to the requirements of the Regulatory Flexibility Act (RFA), 5 U.S.C. 601 *et seq.,* it is hereby certified that this rule will not have a significant economic impact on a substantial number of small entities. The rule, issued under sections (j)(2) and (k)(2) of the Privacy Act, exempts certain information maintained by Treasury in the above-referenced systems of records from certain provisions of the Privacy Act. Small entities, as defined in the RFA, are not provided rights under the Privacy Act and are outside the scope of this regulation.

In accordance with the provisions of the Paperwork Reduction Act of 1995, 44 U.S.C. 3501 *et seq.,* FinCEN has determined that this rule will not impose new recordkeeping, reporting, or other types of information collection requirements.

Lists of Subjects in 31 CFR Part 1

Privacy.

For the reasons stated in the preamble, part 1 of title 31 of the Code of Federal Regulations is amended as follows:

PART 1—DISCLOSURE OF RECORDS

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

Authority: 5 U.S.C. 301, 552, 552a, 553; 31 U.S.C. 301, 321; 31 U.S.C. 3717.

■ 2. Amend § 1.36 by adding, in alphanumeric order, an entry for ''FinCEN .004'' in table 7 to paragraph (c)(1)(vii) and table 17 to paragraph (g)(1)(ix) to read as follows:

§ 1.36 Systems exempt in whole or in part from provisions of the Privacy Act and this part.

* * * * *

(c) * * *

(1) * * *

(vii) * * *

TABLE 7 TO PARAGRAPH (c)(1)(vii)

No.	Name of system
*	* * * * * * *
FinCEN .004	Beneficial Ownership Information System (not exempt from 5 U.S.C. 552 a(e)(3) and 5 U.S.C. 552a(e)(4)(I)).

* * * * *

(g) * * *

(1) * * *

(ix) * * *

[3] CTA, section 6402(7)(B).

TABLE 17 TO PARAGRAPH (g)(1)(ix)

No.	Name of system
* * * * * * *	
FinCEN .004	Beneficial Ownership Information System (not exempt from 5 U.S.C. 552a(e)(3) and 5 U.S.C. 552a(e)(4)(I)).

* * * * *

Ryan Law,

Deputy Assistant Secretary Privacy, Transparency, and Records, U.S. Department of the Treasury.

[FR Doc. 2023–25681 Filed 11–21–23; 8:45 am]

BILLING CODE 4810–02–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket Number USCG–2023–0848]

RIN 1625–AA87

Security Zone; Nantucket Memorial Airport and Abrams Point, Nantucket, MA

AGENCY: Coast Guard, Department of Homeland Security (DHS).

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing two 500-yard temporary security zones for all navigable waters adjacent to the Nantucket Memorial Airport and Straight Wharf as well as a 1,000-yard temporary security zone for all navigable waters adjacent to Abrams Point, Nantucket, Massachusetts. These security zones are needed to protect the persons under the protection of the United States Secret Service (USSS). Entry of vessels or persons into these zones is prohibited unless specifically authorized by the Captain of the Port Sector Southeastern New England or a designated representative.

DATES: This rule is effective from November 21, 2023, through 11:59 p.m. on November 26, 2023.

ADDRESSES: To view documents mentioned in this preamble as being available in the docket, go to *https://www.regulations.gov*, type USCG–2023–0848 in the search box and click ''Search.'' Next, in the Document Type column, select ''Supporting & Related Material.''

FOR FURTHER INFORMATION CONTACT: If you have questions about this rule, call or email MST2 Christopher Matthews, Sector Southeastern New England, U.S. Coast Guard; telephone 401–435–2348, email *Christopher.S.Matthews@uscg.mil.*

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

CFR Code of Federal Regulations
COTP Captain of the Port Sector Southeastern New England
DHS Department of Homeland Security
FR Federal Register
NPRM Notice of proposed rulemaking
§ Section
U.S.C. United States Code

II. Background Information and Regulatory History

The United States Secret Service (USSS) requested that the Coast Guard establish two 500-yard temporary security zones for all navigable waters adjacent to the Nantucket Memorial Airport and Straight Wharf as well as a 1,000-yard temporary security zone for all navigable waters adjacent to Abrams Point, Nantucket, Massachusetts. The purpose of the temporary security zone is to facilitate the security and safety of the persons under USSS protection.

The Coast Guard is issuing this temporary rule without prior notice and opportunity to comment pursuant to authority under section 4(a) of the Administrative Procedure Act (APA) (5 U.S.C. 553(b)). This provision authorizes an agency to issue a rule without prior notice and opportunity to comment when the agency for good cause finds that those procedures are ''impracticable, unnecessary, or contrary to the public interest.'' Under 5 U.S.C. 553(b)(B), the Coast Guard finds that good cause exists for not publishing a notice of proposed rulemaking (NPRM) with respect to this rule because the Coast Guard did not receive information regarding this event in time to publish NPRM and seek comments before the subject visit. Publishing an NPRM and delaying the effective date would be impracticable and contrary to the public interest as it would inhibit the Coast Guard's ability to fulfill its statutory missions and jeopardize the safety of the persons under USSS protection during the visit.

Under 5 U.S.C. 553(d)(3), the Coast Guard finds that good cause exists for making this rule effective less than 30 days after publication in the **Federal Register**. Delaying the effective date of this rule would be impracticable and contrary to the public interest because immediate action is needed to ensure the safety of the person under USSS protection during the visit.

III. Legal Authority and Need for Rule

The Coast Guard is issuing this rule under authority in 46 U.S.C. 70051 and 70124. The USSS requested that the Coast Guard establish two 500-yard temporary security zones for all navigable waters adjacent to the Nantucket Memorial Airport and Straight Wharf as well as a 1,000-yard temporary security zone for all navigable waters adjacent to Abrams Point, Nantucket, Massachusetts. The purpose of the temporary security zone is to facilitate the security and safety of the persons under USSS protection during their visit to the area. As a result, in consultation with the USSS, the Captain of the Port Sector Southeastern New England (COTP) has determined that the security zones are necessary to provide security for the persons under USSS protection.

IV. Discussion of the Rule

This rule establishes two 500-yard security zones for all navigable waters adjacent to the Nantucket Memorial Airport and Straight Wharf as well as a 1,000-yard temporary security zone for all navigable waters adjacent to Abrams Point, Nantucket, Massachusetts. No vessel or person will be permitted to enter the security zones from 12:01 a.m. on November 21, 2023, through 11:59 p.m. on November 26, 2023. Entry into these security zones is prohibited unless specifically authorized by the COTP or their designated representative. A designated representative is a commissioned, warrant, or petty officer of the U.S. Coast Guard assigned to units under the operational control of the U.S. Coast Guard Sector Southeastern New England.

Requests for entry will be considered and reviewed on a case-by-case basis. The COTP may be contacted by telephone at 508–457–3211 or can be reached by VHF–FM channel 16. Persons and vessels permitted to enter these security zones must transit at their slowest safe speed and comply with all lawful directions issued by the COTP or their designated representative.

V. Regulatory Analyses

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

A. Regulatory Planning and Review

Executive Orders 12866 and 13563 direct agencies to assess the costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits. This rule has not been designated a ''significant regulatory action,'' under section 3(f) of Executive Order 12866, as amended by Executive Order 14094 (Modernizing Regulatory Review). Accordingly, this rule has not been reviewed by the Office of Management and Budget (OMB).

This regulatory action determination is based on the size, location, duration, and time-of-year of the security zones. These security zones will impact small, designated areas off Nantucket, Massachusetts for approximately six days during a time of year when vessel traffic is normally low. To alleviate the effects of this rule on the public, the COTP may elect to temporary suspend enforcement of these security zones. Moreover, the Coast Guard will issue Broadcast Notice to Mariners via VHF-FM marine channel 16 about the zones, and the rule allows vessels to seek permission to enter the zones.

B. Impact on Small Entities

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

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

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

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

C. Collection of Information

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

D. Federalism and Indian Tribal Governments

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

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

E. Unfunded Mandates Reform Act

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

F. Environment

We have analyzed this rule under Department of Homeland Security Directive 023–01, Rev. 1, associated implementing instructions, and Environmental Planning COMDTINST 5090.1 (series), which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (42 U.S.C. 4321–4370f), and have determined that this action is one of a category of actions that do not individually or cumulatively have a significant effect on the human environment. This rule involves three security zones from November 21, 2023, through November 26, 2023, that will prohibit entry within 500 yards of Nantucket Memorial Airport and Straight Wharf as well as 1,000 yards of Abrams point, Nantucket, Massachusetts. It is categorically excluded from further review under paragraph L60(a) of Appendix A, Table 1 of DHS Instruction Manual 023–01–001–01, Rev. 1. A Record of Environmental Consideration supporting this determination is available in the docket. For instructions on locating the docket, see the **ADDRESSES** section of this preamble.

G. Protest Activities

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

List of Subjects in 33 CFR Part 165

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

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

PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

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

Authority: 46 U.S.C. 70034, 70051, 70124; 33 CFR 1.05–1, 6.04–1, 6.04–6, and 160.5;

Department of Homeland Security Delegation No. 00170.1, Revision No. 01.3.

■ 2. Add § 165.T01–0848 to read as follows:

§ 165.T01–0848 Security Zone; Nantucket Memorial Airport, Abrams Point and Straight Wharf, Nantucket, MA.

(a) *Location.* The following areas are security zones: All navigable waters 500 yards from Nantucket Memorial Airport and Straight Wharf as well as 1,000 yards from Abrams Point, Nantucket, Massachusetts.

(b) *Regulations.* (1) Under the general security zone regulations in subpart D of this part, you may not enter the security zone described in paragraph (a) of this section unless authorized by the Captain of the Port Sector Southeastern New England (COTP) or the COTP's designated representative. Designated representative is a commissioned, warrant, or petty officer of the U.S. Coast Guard assigned to units under the operational control of U.S. Coast Guard Sector Southeastern New England.

(2) Vessels requiring entry into the security zones must request permission from the COTP or a designated representative. To seek entry into the security zones, contact the COTP or the COTP's representative by telephone at 508–457–3211 or on VHF–FM channel 16.

(3) Persons and vessels permitted to enter the security zones must transit at their slowest safe speed and comply with all lawful directions issued by the COTP or the designated representative.

(c) *Enforcement period.* This section will be enforced from 12:01 a.m. on November 21, 2023, through 11:59 p.m. on November 26, 2023. To alleviate the effects of this section on the public, the COTP may elect to temporarily suspend enforcement of the security zones.

Clinton J. Prindle,

Captain, U.S. Coast Guard, Captain of the Port Sector Southeastern New England.

[FR Doc. 2023–25956 Filed 11–21–23; 8:45 am]

BILLING CODE 9110–04–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 73

[MB Docket No. 23–286; RM–11960; DA 23–1054; FR ID 184696]

Television Broadcasting Services Winnemucca, Nevada

AGENCY: Federal Communications Commission.

ACTION: Final rule.

SUMMARY: The Video Division, Media Bureau (Bureau), has before it a Notice of Proposed Rulemaking issued in response to a Petition for Rulemaking filed by Gray Television Licensee, LLC (Petitioner or Gray), the licensee of unbuilt television station KWNV(DT) (KWNV or Station), channel 7, Winnemucca, Nevada (Winnemucca). The Petitioner has requested the substitution of UHF channel 16 for VHF channel 7 in the Table of TV Allotments. The Petitioner filed comments in support of the petition, as required by the Commission's rules (rules), reaffirming its commitment to apply for channel 16.

DATES: Effective November 22, 2023.

FOR FURTHER INFORMATION CONTACT: Joyce Bernstein, Media Bureau, at (202) 418–1647 or *Joyce.Bernstein@fcc.gov.*

SUPPLEMENTARY INFORMATION: The proposed rule was published at 88 FR 59836 on August 30, 2023. The Petitioner filed comments in support of the petition reaffirming its commitment to apply for channel 16. No other comments were received.

The Bureau believes the public interest would be served by substituting channel 16 for channel 7 at Winnemucca. In support of its channel substitution request, Gray states that building out its new station on a UHF channel will avoid well-documented issues with indoor digital VHF reception. Gray observes that the Commission has recognized the deleterious effects manmade noise has on the reception of VHF channel signals, and the large variability in the performance of indoor antennas receiving UHF and VHF signals, with the substantial majority poorly receiving high-VHF channel signals compared to UHF channel signals. We also find that the proposal complies with all relevant technical requirements for amendment of the Table of TV Allotments, including the interference protection requirements of section 73.616 of the rules, and the proposed channel 16 facility will provide full principal community coverage to Winnemucca. In addition, proposed channel 16 noise limited service contour (NLSC) almost entirely encompasses the authorized channel 7 NLSC, and Gray does not propose a change in transmitter location. We also note that no viewers will lose any existing service because as a permittee, Gray has not commenced operations in Winnemucca.

As proposed, channel 16 can be substituted for channel 7 at Winnemucca in compliance with the principal community coverage requirements of section 73.625(a) of the rules, at coordinates 41°00′31.0″ N and 117°46′13.0″ W. In addition, we find that this channel change meets the technical requirements set forth in sections 73.616 and 73.623 of the rules. We also conclude that good cause exists to make this channel change effective immediately upon publication in the **Federal Register**, pursuant to section 553(d)(3) of the Administrative Procedure Act. An expedited effective date is necessary in this case to ensure that KWNV can operate with improved service to its viewers as quickly as possible.

This is a synopsis of the Commission's *Report and Order,* MB Docket No. 23–286; RM–11960; DA 23–1054, adopted November 7, 2023, and released November 7, 2023. The full text of this document is available for download at *https://www.fcc.gov/edocs.* To request materials in accessible formats for people with disabilities (braille, large print, electronic files, audio format), send an email to *fcc504@fcc.gov* or call the Consumer & Governmental Affairs Bureau at 202–418–0530 (voice), 202–418–0432 (tty).

This document does not contain information collection requirements subject to the Paperwork Reduction Act of 1995, Public Law 104–13. In addition, therefore, it does not contain any proposed information collection burden ''for small business concerns with fewer than 25 employees,'' pursuant to the Small Business Paperwork Relief Act of 2002, Public Law 107–198, *see* 44 U.S.C. 3506(c)(4). Provisions of the Regulatory Flexibility Act of 1980, 5 U.S.C. 601–612, do not apply to this proceeding.

The Commission will send a copy of this *Report and Order* in a report to be sent to Congress and the Government Accountability Office pursuant to the Congressional Review Act, *see* 5 U.S.C. 801(a)(1)(A).

List of Subjects in 47 CFR Part 73

Television.

Federal Communications Commission.

Thomas Horan,

Chief of Staff, Media Bureau.

Final Rule

For the reasons discussed in the preamble, the Federal Communications Commission amends 47 CFR part 73 as follows:

PART 73—RADIO BROADCAST SERVICE

■ 1. The authority citation for part 73 continues to read as follows:

Authority: 47 U.S.C. 154, 155, 301, 303, 307, 309, 310, 334, 336, 339.

■ 2. In § 73.622 (j), amend the Table of TV Allotments under Nevada by revising the entry for Winnemucca to read as follows:

§ 73.622 Digital television table of allotments.

* * * * *

(j) * * *

Community	Channel No.
* * * * *	
Nevada	
* * * * *	
Winnemucca	16
* * * * *	

[FR Doc. 2023–25394 Filed 11–21–23; 8:45 am]

BILLING CODE 6712–01–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 223

[Docket No. 231116–0271; RTID 0648–XR131]

Endangered and Threatened Wildlife and Plants; Technical Correction for the Giant Manta Ray

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

ACTION: Direct final rule.

SUMMARY: We, NMFS, announce the revised taxonomy of *Manta birostris* (giant manta ray) under the Endangered Species Act of 1973, as amended (ESA). We are revising the Enumeration of threatened marine and anadromous species for the giant manta ray to reflect the scientifically accepted taxonomy and nomenclature of this species. We revise the scientific name of the species to *Mobula birostris.* The changes to the taxonomic classification and nomenclature do not affect the species' listing status under the ESA or any protections and requirements arising from its listing.

DATES: This rule is effective January 22, 2024 without further action, unless significant adverse comment is received by December 22, 2023. If significant adverse comments are received, the NMFS will publish a timely withdrawal of the rule in the **Federal Register**.

ADDRESSES: You may submit comments on this document, identified by NOAA–NMFS–2023–0141, by the following method:

• *Electronic Submission:* Submit all electronic public comments via the Federal e-Rulemaking Portal. Go to *https://www.regulations.gov* and enter NOAA–NMFS–2023–0141 in the Search box. Click on the ''Comment'' 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 *https://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).

FOR FURTHER INFORMATION CONTACT: Maggie Miller, NMFS, Office of Protected Resources, (301) 427–8457.

SUPPLEMENTARY INFORMATION:

Purpose of This Rule

The purpose of our direct final rule is to notify the public that we are revising the Enumeration of threatened marine and anadromous species (50 CFR 223.102(e)) to reflect the scientifically accepted taxonomy and nomenclature of one fish species, the giant manta ray, listed under section 4 of the ESA (16 U.S.C. 1531 *et seq.*). The change reflects the most recently accepted scientific name in accordance with 50 CFR 223.102(b).

We are publishing this rule as a direct final rule because this is a noncontroversial action that reflects decisions already taken in the scientific community, such that prior notice and an opportunity to comment is unnecessary. This rule does not change the listing status of the species under the ESA and does not alter any protections afforded the species or any other legal requirements arising from the species' listing under the ESA. This change should be undertaken in as timely a manner as possible. This rule will be effective, as published in this document on the effective date specified in **DATES**, unless we receive significant adverse comments on or before the comment due date specified in **DATES**. Significant adverse comments are comments that provide strong scientific justification as to why the taxonomic and nomenclature changes to the Enumeration of the listed entity should not be adopted or why the rule should be changed. Please include sufficient scientific information with your comments that will allow us to verify the basis for any significant adverse comments.

If we receive significant adverse comments, we will publish a notice in the **Federal Register** withdrawing this rule before the effective date, and we will engage in notice and comment rulemaking under the applicable requirements of the Administrative Procedure Act to promulgate these changes to 50 CFR 223.102(e).

Background

Under 50 CFR 223.102(b), we use the most recently accepted scientific name of any species that we have determined to be threatened under the ESA. The ESA likewise requires that listing decisions be based solely on the best scientific and commercial data available (see 16 U.S.C. 1533(b)(1)(A)). Using the best available scientific information, our direct final rule documents a taxonomic change (scientific name) to the giant manta ray. This change is supported by a study published in a peer-reviewed journal as well as acceptance by scientists and a number of national and international renowned organizations. We revise the scientific name of the giant manta ray listed under section 4 of the ESA (16 U.S.C. 1531 *et seq.*) as follows: *Mobula birostris.* We make this change to the Enumeration of threatened marine and anadromous species (50 CFR 223.102(e)) to reflect the most recently accepted scientific name in accordance with 50 CFR 223.102(b).

Taxonomy Classification

Mobula Birostris

The scientific name change to *Mobula birostris* (giant manta ray) from *Manta birostris* is supported by genetic and morphological evidence (White *et al.* 2018). White *et al.* (2018) used molecular data from giant manta ray muscle tissues in Indonesia and the Philippines to describe the relationship of this species to ten other mobulid rays. Results from the phylogenetic analysis identified giant manta rays, as well as reef manta rays (previously *Manta alfredi*), to be nested within the genus *Mobula,* forming a sister relationship with *Mobula mobular* (White *et al.* 2018). Prior to this comprehensive genetic analysis, both manta rays were considered to be under a separate genus, *Manta,* as they both had a distinct morphological character—a terminal mouth. The other mobulid rays, under the genus *Mobula,* all had subterminal

mouths. However, the mitochondrial genome and nuclear exon data show the inclusion of *Manta* under the genus *Mobula,* suggesting the terminal mouth is a derived character within *Mobula* (White *et al.* 2018). Additionally, White *et al.* (2018) point out that another morphological character, the spiracle position relative to the plane of the disc, is dorsal for the manta rays but also for the sister species, *Mobula mobular,* whereas the remaining smaller Mobula species have it located ventrally. As such, this morphological distinction also supports the finding of the genetic analysis that *M. birostris* forms a clade with *M. mobular.* Based on this study, many scientists have accepted the taxonomic change for giant manta rays and used the updated taxonomy in recent research publications (*e.g.,* Cabral *et al.* 2023; Carpenter *et al.* 2023; Garzon *et al.* 2023; Rambahiniarison *et al.* 2023). Additionally, many national and international organizations have adopted the taxonomy, including the American Fisheries Society, Eshmeyer's Catalog of Fishes, FishBase, the International Union for Conservation of Nature, the Food and Agriculture Organization of the United Nations, and the Convention on International Trade in Endangered Species of Wild Fauna and Flora.

NMFS, therefore, recognizes the taxonomic change and is making technical revisions to 50 CFR 223.102(e) to reflect the most recently accepted scientific name based on the best available scientific information about the listed species. Once the changes to 50 CFR 224.102(3) take effect, the taxonomic change will be incorporated into all new NMFS publications pertaining to the species. This species will continue to be listed as threatened and is subject to the same protections as existed prior to these changes. No other aspect of the entry for this species in 50 CFR 223.102(e) will change as a result of this rule.

Required Determinations

The Assistant Administrator for Fisheries finds that good cause exists to waive the requirement for prior notice and opportunity for public comment, pursuant to 5 U.S.C. 553(b)(B). Such procedures would be unnecessary as the taxonomic change made in this rule is technical and reflects decisions already taken in the scientific community. This rule does not change the listing status of the giant manta ray under the ESA, and therefore does not alter the legal protections afforded to the species or any other requirements arising from its listing under the ESA or add any new requirements.

This action is not subject to review under Executive Order (E.O.) 12866. Because a general notice of proposed rulemaking is not required, the analytical requirements of the Regulatory Flexibility Act, 5 U.S.C. 601, *et seq.,* are inapplicable.

This final rule does not contain policies with federalism implications under E.O. 13132. Policies that have federalism implications refers to regulations, legislative comments or proposed legislation, and other policy statements or actions that have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. This final rule does not have federalism implications; therefore, the agency did not follow the additional consultation procedures outlined in E.O. 13132.

This rule does not contain any collections of information that require approval by the Office of Management and Budget under the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*). This rule will not impose recordkeeping or reporting requirements on State or local governments, individuals, businesses, or organizations.

E.O. 12898 requires that Federal actions address environmental justice in the decision-making process. In particular, the environmental effects of the actions should not have a disproportionate effect on minority and low-income communities. This rule is not expected to have a disproportionate effect on minority populations or low-income populations.

This final rule makes a taxonomic change relative to a previous listing determination under the ESA to reflect the most recently accepted scientific name based on the best available scientific information about the species' taxonomy and nomenclature. NMFS has concluded that the National Environmental Policy Act (NEPA) does not apply to ESA listing actions, and we conclude that NEPA does not apply to this correction to the identification of the listed species to reflect the best available scientific information (see NOAA Administrative Order 216–6A and the Companion Manual for NOAA Administrative Order 216–6A, regarding Policy and Procedures for Compliance with the National Environmental Policy Act and Related Authorities).

References Cited

A complete list of references is available on our website at: *https://www.fisheries.noaa.gov/action/final-rule-list-giant-manta-ray-threatened-under-endangered-species-act.*

List of Subjects in 50 CFR Part 223

Endangered and threatened species.

Dated: November 16, 2023.

Samuel D. Rauch, III,

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

For the reasons set out in the preamble, NMFS amends 50 CFR part 223 as follows:

PART 223—THREATENED MARINE AND ANADROMOUS SPECIES

■ 1. The authority citation for part 223 is revised to read as follows:

Authority: 16 U.S.C. 1531 1543; subpart B, § 223.201–202 also issued under 16 U.S.C. 1361 *et seq.;* 16 U.S.C. 5503(d) for § 223.206(d)(9).

■ 2. In § 223.102, amend the table in paragraph (e), under the heading ''Fishes'' by revising the entry for ''Ray, giant manta'' to read as follows:

§ 223.102 Enumeration of threatened marine and anadromous species.

* * * * *

(e) * * *

Species [1]			Citation(s) for listing determination(s)	Critical habitat	ESA rules
Common name	Scientific name	Description of listed entity			
*	*	*	*	*	*
FISHES					
*	*	*	*	*	*
Ray, giant manta	*Mobula birostris*	Entire species	83 FR 2916, Jan. 22, 2018.	NA	NA

Species [1]			Citation(s) for listing determination(s)	Critical habitat	ESA rules
Common name	Scientific name	Description of listed entity			
*	*	*	*	*	*

[FR Doc. 2023–25822 Filed 11–21–23; 8:45 am]
BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 622

[Docket No. 231101–0256; RTID 0648–XD532]

Fisheries of the Caribbean, Gulf of Mexico, and South Atlantic; Re-Opening of Commercial Fishery for Golden Tilefish in the South Atlantic

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

ACTION: Temporary rule; re-opening.

SUMMARY: NMFS announces the re-opening of the commercial sector for golden tilefish in the exclusive economic zone (EEZ) of the South Atlantic. The 2023 commercial annual catch limits (ACLs) for the hook-and-line and longline components have recently increased through a separate rule. Therefore, NMFS re-opens the hook-and-line and longline components of the commercial sector for golden tilefish in the South Atlantic EEZ to allow the commercial ACL to be caught while increasing the corresponding benefit to the Nation with respect to providing food production.

DATES: This temporary rule is effective from December 7, 2023, through December 31, 2023.

FOR FURTHER INFORMATION CONTACT: Mary Vara, NMFS Southeast Regional Office, telephone: 727–824–5305, email: *mary.vara@noaa.gov.*

SUPPLEMENTARY INFORMATION: The snapper-grouper fishery of the South Atlantic includes golden tilefish and is managed under the Fishery Management Plan for the Snapper-Grouper Fishery of the South Atlantic Region (FMP). The FMP was prepared by the South Atlantic Fishery Management Council (Council) and NMFS. The FMP is implemented by NMFS under the authority of the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act) by regulations at 50 CFR part 622. All weights described in this temporary rule are in gutted weight.

The commercial sector for golden tilefish is composed of the hook-and-line and longline components, each with individual catch limits. Under the commercial accountability measures (AMs) for golden tilefish at 50 CFR 622.193(a)(1)(i) and (ii), NMFS is required to close each commercial component for golden tilefish when the applicable commercial quota specified under 50 CFR 622.190(a)(2)(ii) or (iii) is reached or is projected to be reached through a notification in the **Federal Register**. Earlier in the 2023 fishing year, NMFS determined separately that the commercial component quotas for golden tilefish in the South Atlantic were reached, and closed the hook-and-line component on October 31 (88 FR 74066, October 30, 2023) and closed the longline component on April 7 (88 FR 20079, April 5, 2023) for the rest of 2023 as required by the commercial AMs [50 CFR 622.193(a)(1)(i) and (ii)].

Also earlier in the 2023 fishing year, NMFS determined that the golden tilefish recreational sector reached its ACL, and NMFS closed the sector as required by the recreational AMs for the rest of 2023 (50 CFR 622.193(a)(2)(i); 88 FR 45369, July 17, 2023).

On November 7, 2023, NMFS published the final rule to implement Amendment 52 to the FMP, and that final rule is effective on December 7, 2023 (88 FR 76696). Among other management measures, Amendment 52 and the final rule increased the total ACL for golden tilefish in the South Atlantic EEZ. For the 2023 fishing year, the total ACL is 435,000 lb (197,313 kg).

The total ACL is divided between the commercial and recreational sectors, and the commercial ACL for golden tilefish is allocated 25 percent to the hook-and-line component and 75 percent to the longline component. The final rule to implement Amendment 52 increased the component ACLs, which are equivalent to the component quotas, based on the higher commercial ACL. In the 2023 fishing year, the hook-and-line component quota is 105,161 lb (47,700 kg) and the longline component quota is 315,484 lb (143,101 kg).

The final rule for Amendment 52 also increased the recreational ACL for golden tilefish to 2,559 fish for the 2023 fishing year. However, the most recent recreational landings data of South Atlantic golden tilefish indicate that the recently increased recreational ACL for 2023 has already been reached. Therefore, NMFS will not reopen the recreational harvest of golden tilefish in the South Atlantic during the 2023 fishing year.

In accordance with 50 CFR 622.8(c), NMFS re-opens the commercial hook-and-line and longline components for golden tilefish on December 7, 2023. The commercial components will remain open through the rest of the 2023 fishing year ending on December 31, 2023, to allow for the commercial ACL to be reached. NMFS has determined that this re-opening will allow for an additional opportunity to commercially harvest the increased hook-and-line and longline component quotas for golden tilefish in 2023 while also increasing the corresponding benefit to the Nation with respect to providing food production.

Classification

NMFS issues this action pursuant to section 305(d) of the Magnuson-Stevens Act. This action is required by 50 CFR 622.8(c), issued pursuant to section 304(b), and is exempt from review under Executive Order 12866.

Pursuant to 5 U.S.C. 553(b)(B), there is good cause to waive prior notice and an opportunity for public comment on this action, as notice and comment is unnecessary and contrary to the public interest. Such procedures are unnecessary and contrary to public interest because the regulations associated with the increased harvest levels and reopening of golden tilefish commercial components have already been subject to notice and public comment, and all that remains is to notify the public of the commercial reopening.

For the reasons stated earlier, the Assistant Administrator for Fisheries also finds good cause to waive the 30-day delay in the effectiveness of this action under 5 U.S.C. 553(d)(3).

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

Dated: November 17, 2023.

Kelly Denit,

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

[FR Doc. 2023–25821 Filed 11–17–23; 4:15 pm]
BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 660

[Docket No. 231115–0269]

RIN 0648–BM29

Fisheries Off West Coast States; West Coast Groundfish Electronic Monitoring Program; Service Provider Revisions

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

ACTION: Final rule.

SUMMARY: This final rule revises regulations governing the use of electronic monitoring (EM) in the Pacific Coast groundfish trawl fishery. This rulemaking modifies deadlines in Federal regulations for EM service providers to process EM data and submit vessel logbooks to NMFS. This action is intended to support the overarching goal of continually monitoring the Groundfish Trawl Rationalization Program for compliance with existing regulations in an economical and flexible manner while meeting the goals and objectives of the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act; MSA), the Pacific Coast Groundfish Fishery Management Plan, and other applicable laws. This rulemaking also makes minor administrative changes to EM and other groundfish regulations to clarify the regulations, correct terminology, correct web addresses, and remove obsolete administrative requirements. Some aspects of this action remove duplicative requirements for mail notifications or mail-based record-keeping and reporting, which are also undertaken electronically. During the COVID–19 pandemic, many administrative notifications and reporting requirements were moved to electronic methods; this action revises the regulations to be consistent with current practice.

DATES: Effective December 22, 2023.

ADDRESSES: This rule is accessible via the Office of the Federal Register website at *https://www.federalregister.gov/.* Background information and analytical documents (Analysis) are available at the NMFS West Coast Region website at *https://www.fisheries.noaa.gov/region/west-coast* and at the Pacific Fishery Management Council's website at *https://www.pcouncil.org.*

Electronic Access

This final rule is accessible at the Office of the Federal Register website at *https://www.federalregister.gov.* Background information and analytical documents (Analysis) are available at the NMFS West Coast Region website at: *https://www.fisheries.noaa.gov/region/west-coast-groundfish.html* and at the Pacific Fishery Management Council's website at *https://www.pcouncil.org.*

FOR FURTHER INFORMATION CONTACT: Melissa Hooper, phone: 206–526–4357, or email: *melissa.hooper@noaa.gov.*

SUPPLEMENTARY INFORMATION:

Authority for Action

NMFS and the Pacific Fishery Management Council (Council) manage the groundfish fisheries in the exclusive economic zone seaward of California, Oregon, and Washington under the Pacific Coast Groundfish Fishery Management Plan (FMP). The Council prepared the FMP under the authority of the MSA (16 U.S.C. 1801 *et seq.*). Regulations governing U.S. fisheries and implementing the FMP appear at 50 CFR part 660.

Background

This action revises regulations governing the Pacific Coast groundfish trawl fishery. The groundfish trawl fishery is managed under a catch share program called the Trawl Rationalization Program, which was implemented through Amendment 20 to the FMP in January 2011. The Program consists of an individual fishing quota (IFQ) program for the shorebased trawl fleet (including whiting and non-whiting sectors), and cooperatives for the at-sea mothership (MS) and catcher/processor (C/P) trawl fleets (whiting only). As part of the Program, Amendment 20 implemented requirements for 100 percent monitoring at-sea and dockside in order to ensure accountability for all landings and discards of allocated species. Catcher processors and motherships are required to carry two observers at all times, depending on the length of the vessel, and catcher vessels are required to carry one observer, including while in port until all fish are offloaded. In addition, first receivers, which are processors that are licensed to receive IFQ landings, are required to have catch monitors to monitor 100 percent of IFQ offloads. Vessel owners and first receivers are responsible for obtaining and funding catch share observers and catch monitors as a necessary condition of their participation in the program.

Amendment 20 also authorized the use of EM as an alternative to human observers to meet the at-sea monitoring requirement, but deferred to a future regulatory amendment to specify the details of any EM program. EM uses cameras and associated sensors to passively record and monitor fishing activities. The video can be reviewed by an analyst onshore at a later time to collect catch and effort information. EM has the potential to reduce monitoring costs because it does not require deploying a person on the vessel and the logistical and travel expenses that generates. Note that the proposed rule for this action (88 FR 48180; July 26, 2023) stated that Amendment 18 to the FMP authorized the use of EM in the groundfish fishery. While Amendment 18 did authorize the use of EM in general in the fishery, Amendment 20 created the requirement for 100 percent coverage in the trawl fishery and authorized the use of EM to meet that specific requirement, which is being modified by this final rule.

The Council developed and implemented an EM program for shorebased whiting, bottom trawl, and fixed gear vessels, and at-sea whiting catcher vessels in the Trawl Program through two regulatory amendments in 2019 (84 FR 31146; June 28, 2019) and 2022 (87 FR 59705; October 3, 2022). Two additional rulemakings in 2020 (85 FR 74613; November 23, 2020) and 2021 (86 FR 55525; October 6, 2021) delayed the beginning of the EM program to provide time to refine its requirements and prepare for implementation. Vessels will be able to use EM under the regulatory program in place of observers beginning January 1, 2024. A more detailed discussion of the development of the EM program, including the use of exempted fishing permits (EFPs) in an experimental fishery, is described in the proposed rule for this action and in the prior regulatory amendments and is not repeated here.

In preparation for the January 1 start of the program, the Council developed modifications to reporting deadlines and clarifications to the regulations for EM service providers to improve the efficiency and cost effectiveness of the program, which were published in a proposed rule July 26, 2023 (88 FR 48180). Further details on the development of this action can be found in the proposed rule and are not repeated here. Public comments were accepted on the proposed rule from July 26 through August 25, 2023. No public comments were received.

Through this final rule, NMFS is approving and implementing the Council's proposed revisions to the EM

regulations. NMFS has determined that the regulations are consistent with the goals and objectives of the Pacific Coast Groundfish FMP and the requirements of the MSA and other applicable law. This determination is based on NMFS' review of the administrative record, including the Council's record. After considering the required statutory factors and the goals and objectives of the Pacific Coast Groundfish FMP, NMFS has determined that the Council's recommended measures further the EM program's goals and objectives to provide for an alternative method of meeting the monitoring requirements of the Trawl Rationalization Program that reduces the costs and operational burden of these requirements, while ensuring the best scientific information available for conservation and management. Through this rule, NMFS is also approving some minor clarifications to other groundfish regulations.

Final Measures

This section summarizes the measures contained in this final rule. To implement these measures NMFS revises the regulations in §§ 660.18, 660.25, 660.60, 660.140, 660.150, 660.160, and 660.603 to improve the effectiveness of the groundfish EM program and to correct and clarify other groundfish regulations.

1. EM Program Revisions

Discard Logbook Processing Deadline

Through this final rule, NMFS is extending the deadline for EM service providers to process and submit logbook data to NMFS from 2 business days to 7 business days (§ 660.603(m)(5)). In the EM program, vessel operators will record discards in their logbooks that will be used to debit discards of IFQ species from their vessel accounts. Vessel operators are required to submit copies of their logbooks to their contracted EM service provider within 24 hours of the end of an EM trip. EM service providers must then enter, quality check, and submit data from the logbooks to NMFS. NMFS uses the logbook data to initially debit the vessel's account for discards of IFQ species. Once video from the trip is reviewed, the logbook discard estimates may be replaced in the vessel's account with an EM discard estimate if the difference between the two estimates falls outside established performance standards.

The 2-day deadline implemented in the original 2019 EM rule was based on logbook processing timelines achieved in the experimental EM fishery, which has been ongoing since 2015. Since that time, however, increased participation in the EFP has increased the volume of logbooks that must be processed and contributed to an increase in processing times. During the busiest times of the year, the EFP's video review provider, the Pacific States Marine Fisheries Commission (PSMFC), has reported that it can take up to 7 days after a trip to process the logbook. As EM participation levels are expected to remain constant or even grow in 2024 and beyond, the Council became concerned that the 2-day processing deadline was unrealistic for EM service providers to meet during the busiest times of the year. An EM service provider could hire additional staff to ensure it could handle the increased workload, but that would likely increase the costs of the EM program and could make it a less cost-effective alternative to observers, inconsistent with the goals of the EM program as stated in the original EM regulatory amendment (84 FR 31146). Therefore, the Council recommended, and NMFS approves, extending the deadline for EM service providers to process logbooks after an EM trip, to provide operational flexibility to EM service providers and to improve the cost effectiveness of the EM program, consistent with the goals of the EM program and the Pacific Coast Groundfish FMP. Extending the logbook processing deadline also furthers the objectives of the EM program to reduce the logistical burden and adverse economic impacts of the 100 percent at-sea monitoring requirements on these vessels and their communities, consistent with National Standard 8 of the MSA.

Extending the logbook processing deadline would delay the time for vessel accounts to be updated with initial discard estimates from 3 days after a trip (1 day for the EM provider to receive the logbook and 2 days to process it) to 8 days after a trip (1 day to receive the logbook and 7 days to process it), which could increase the risk of a vessel going into deficit if it continues fishing without accurate balances for IFQ quota pounds. However, vessel operators would retain copies of their logbooks that they could use to monitor their IFQ balances until accounts are updated with the logbook data. A processing timeline of approximately 1 week is also consistent with the timeline that human observer discard data posts to vessel accounts. Therefore, extending the logbook processing deadline maintains sufficient timeliness of information on discards of IFQ species for management decisions, while minimizing the costs of data collection requirements, consistent with National Standards 2 and 7 of the MSA.

EM Data Processing Deadlines

Through this final rule, NMFS is extending the deadline for EM service providers to process EM data and submit reports to vessel operators and NMFS from 3 weeks to 60 days after receipt of the hard drive (§§ 660.603(m)(4)–(5)). Following an EM trip, vessel operators are required to submit the hard drive containing the video imagery and sensor data to their contracted EM service provider for processing (generally within 72 hours of trip end). The EM service provider is responsible for reviewing and quality checking the imagery and sensor data and reporting its findings to NMFS. NMFS uses the summary data reported by the EM service provider to validate and, where appropriate, replace logbook discard estimates in vessel accounts, and to monitor compliance by vessel operators with the regulations. The EM service provider also provides feedback to the vessel operator on performance of the EM system and the crew from the trip based on review of the video.

As with other EM program requirements, the 3-week deadline for EM data processing and reporting was based on the data processing timelines observed in the experimental EM fishery. As participation levels have increased, processing times have increased and raised concerns that EM service providers may not be able to meet the original 3-week deadline in regulation during peak fishing seasons. EM service providers could hire additional staff to ensure that they could meet the 3-week processing deadline during peak fishing times, but this would likely increase the cost of EM and could reduce the cost effectiveness of the program as an alternative to human observers. Maintaining a year-round staff level that could meet the 3-week deadline at peak fishing times would also result in an overcapacity of reviewers at slower times of year. On the other hand, it is not a position that can easily be filled on a temporary or seasonal basis. Video reviewers require specialized training and experience in species identification, fishing operations, and regulations to interpret what they see on video and many EM service providers try to recruit former fisheries observers to ensure the best data quality. In addition, PSMFC noted during development of this action that they already struggle to recruit qualified reviewers in the current competitive employment market and seasonal

positions would be even less appealing to job seekers.

In light of these concerns, the Council considered two alternate deadlines for EM data processing of 60 days and 90 days, based on timelines observed in the experimental fishery since 2015 and feedback from EM service providers. In general, extending the deadline for processing and reporting of EM data would delay the availability of this information to NMFS and vessel operators. NMFS relies on reports from EM service providers to validate logbook-reported discards that were used to debit vessel accounts in the interim and ensure accurate IFQ account balances. Vessel operators in turn use updated vessel account balances to determine if they have sufficient quota pounds to cover additional fishing trips. Vessel operators are responsible for ensuring they have sufficient quota to cover any landings and discards of IFQ species and may not fish if their account is in deficit. Vessel operators may purchase additional quota to cover any deficit, including for a brief period after the end of the fishing year, and resume fishing when their account is in good standing, or carryover a deficit (up to 10 percent) to the following year if they cease fishing. Therefore, timely updates of vessel account balances are important for ensuring that fishermen have the most accurate information for their fishing operations and to prevent deficits. Less timely updates to vessel accounts could mean more fishing trips taken on provisional information and increased risk of unexpected deficits.

On an individual level, vessel owners could mitigate their risk of incurring a deficit by keeping a larger balance for IFQ species that they are concerned about, or by taking more time between trips. A vessel owner could weigh the trade-off between the likelihood of a deficit, the cost of carrying a larger balance (in terms of the cost of quota that must be purchased or lost revenue from a quota sale forgone), the lost revenue from postponing a trip to wait for EM data to be finalized, and determine the best option for their own business. A vessel owner could also reduce the risk of a surprise deficit by ensuring their captain's logbook discard estimates meet the performance standards and will not be replaced by EM data. A vessel owner could also choose not to participate in the EM program and instead opt for a human observer if they want timelier final discard information. Thus, even with an extended deadline, vessel operators have a suite of options to maximize fishing activity while avoiding exceeding available quota.

NMFS and the Council also rely on accurate vessel account balances to control fishing mortality in the trawl fishery to prevent overages of the overall trawl sector allocations and Annual Catch Limits (ACLs). However, extending the EM data processing deadline is unlikely to increase the risk of an overage for most species because most groundfish IFQ species are under-attained. The species at greatest risk would be those with small allocations or high attainment, such as yelloweye rockfish or sablefish north of 40°10′N latitude, respectively. Vessels try to avoid catching species with small allocations altogether because of their correspondingly small individual allocations. Even if one vessel were to exceed its individual allocation, it is unlikely many other vessels would and so uncaught pounds of the species could be found elsewhere in the trawl fishery or other sectors to cover the overage without exceeding the ACL. In addition, since the implementation of total accountability for all discards in the Trawl Program, the trawl fishery has become highly selective, with discards accounting for a small portion of total catch. Therefore, increased variability in discard estimates from EM vessels, which is an even smaller portion of total trawl discards, would be unlikely to pose a problem at the sector or ACL level.

NMFS and vessel operators also use the feedback from the video review to ensure that EM systems are meeting performance standards and that vessel crews are complying with catch handling instructions, EM system care responsibilities, and other regulations. While hard drives are waiting to be reviewed, EM vessels are still taking new fishing trips and a delay in review of the EM data could mean that compliance or performance issues are not identified and corrected in a timely manner, leading to reduced data quality. However, the EM program regulations include a number of safeguards to reduce the likelihood that an EM system malfunction or compliance issue will occur or, if it does occur, go undetected to the extent that it would substantively impact overall data quality.

For example, most vessels in the EM program participated in the experimental EM fishery and their crews are experienced in the catch handling, EM system care responsibilities, and other program requirements. In addition, all captains are required to attend an orientation session hosted by NMFS on EM program requirements and must undergo a briefing with their EM provider's staff on the EM system and proper catch handling onboard their vessel before obtaining their EM Authorization. Vessel operators are also required to run a test before each trip to ensure that the EM system is working properly and, if an issue affecting EM data collection (referred to as a ''critical'' malfunction) is identified, may not fish until it is resolved. These measures reduce the likelihood of a critical malfunction, crew error, or other issue occurring that will impact data collection and affect discard estimates.

There are other measures in place to disincentivize intentional tampering with the EM system to hide illegal discard events or other compliance issues. If a critical malfunction occurs at sea, such as the system losing power or a critical camera view going out, the vessel must stop fishing and attempt to resolve the issue. If they cannot resolve the issue, they must end their trip and return to port. This creates a strong incentive to maintain the EM system in good working order and against intentional tampering, even if there is a delay in detection from delayed video processing.

Finally, violation of any of the EM program's requirements, intentional or otherwise, could result in monetary fines through enforcement action and even expulsion from the EM program, whether detected 1 month or 3 months after the trip. In this way, a participant would be unlikely to jeopardize the cost savings and other benefits they derive from using EM by not complying with the EM program requirements even under an extended EM data processing deadline.

The Council weighed all these trade-offs between data timeliness and cost, and determined that a 60-day deadline for processing and reporting of EM data was the right balance between the need for timely data for management and cost effectiveness of EM. The Council considered but rejected a 90-day deadline, because it would be too long of a delay in availability of data and in updating vessel accounts. NMFS approves the Council's recommendation for extending the deadline for EM service providers to process EM data after an EM trip to provide operational flexibility to EM service providers and to improve the cost effectiveness of the EM program, consistent with the goals of the EM program, the Pacific Coast Groundfish FMP, and the MSA. Extending the EM data processing deadline also furthers the objectives of the EM program to reduce the logistical burden and adverse economic impacts of the 100-percent at-sea monitoring

requirements on these vessels and their communities, consistent with National Standard 8 of the MSA. As discussed above, extending the EM processing deadline maintains sufficient timeliness of information on discards of IFQ species for management decisions, while minimizing the costs of data collection requirements, consistent with National Standards 2 and 7 of the MSA.

Revise EM Discard Data Method Language

NMFS is clarifying and simplifying the current EM regulations by removing the paragraph at § 660.603(m)(1) that reads: ''The EM service provider must process vessels' EM data and logbooks according to a prescribed coverage level or sampling scheme, as specified by NMFS in consultation with the Council, and determine an estimate of discards for each trip using standardized estimation methods specified by NMFS. NMFS will maintain manuals for EM and logbook data processing protocols on its website.'' This information is already stated in the introductory paragraph at § 660.603(m) and at § 660.603(m)(5). The Council recommended a change to the language at § 660.603(m)(1) because it was concerned that the existing language implies a requirement for all EM service providers to process EM data using the same methods and methods prescribed by NMFS, which was not the intent of the EM program. Rather, the regulations establish the responsibilities of the EM service provider (to process the EM data and report findings to NMFS) and the standards they must meet (the purpose of the EM program as defined § 660.600(b)), but leave flexibility for EM service providers to design different methods to conduct the data processing and reporting in the way that best suits their business. EM service providers must detail their methods in their permit application which allows NMFS to review them and ensure they meet the program standards. Paragraphs §§ 660.603(m) and 660.603(m)(5) accurately reflect this intent. Removing paragraph § 660.603(m)(1) prevents any confusion with the requirement and has no substantive effect on the operation of the EM program. Therefore, NMFS has approved this administrative change to improve the clarity and effectiveness of the EM regulations, consistent with the Pacific Coast Groundfish FMP and the MSA.

2. Administrative Revisions

This final rule makes some minor administrative, non-substantive revisions to the Pacific Coast groundfish fishery regulations to correct terminology, correct web addresses, and remove some obsolete administrative requirements. Pursuant to Secretarial authority under MSA section 305(d), this part of the action is necessary to carry out the Pacific Coast Groundfish FMP and implementing regulations at 50 CFR 660.

NMFS revised the regulations throughout part 660 to correct misspellings and update web addresses and terminology. In many places in the regulations governing the Pacific Coast groundfish fisheries, the term 'cooperative' is abbreviated to 'coop', rather than 'co-op'. This final rule corrects the abbreviation throughout this Part. This final rule also corrects obsolete web addresses and outdated references to the NMFS 'Northwest Region', which, as of 2013, is now the West Coast Region.

NMFS revised the regulations governing the limited entry trawl fishery at §§ 660.140, 660.150, and 660.160 to remove the requirement for NMFS to mail paper reminders to fishery participants to renew their quota share permits, vessel accounts, and first receiver site licenses. During the COVID–19 global pandemic, NMFS transitioned these reminders to an electronic format. This final rule revises the regulations to be consistent with current practice.

In this final rule, NMFS revised regulations §§ 660.18(d)(1), 660.140, 660.150, and 660.160 governing the issuance of various trawl fishery permits to remove the requirement for NMFS to issue an Initial Agency Determination (IAD) for both approvals and disapprovals of applications. The purpose of an IAD is to notify the applicant of the agency's decision, its rationale, and the applicant's appeal rights. Since an applicant has no reason to appeal an approval of their application, it is unnecessary to issue an IAD for a permit approval. Rather, the permit itself services as notification of the application approval. In addition, the permit decisions for which NMFS is revising the IAD requirement involve little agency discretion that would require explanation in an IAD. Unlike initial qualification decisions in which approval of an application may also involve calculation of an allocation that an approved applicant may wish to dispute, for the permit decisions addressed in this rule NMFS must issue a permit to any applicant that meets the eligibility criteria. Removing the requirement for NMFS to issue an IAD for approvals of these types of permits reduces paperwork for both NMFS and the applicants. IADs would still be issued for all permit denials.

Through this final rule, NMFS also revised the regulations at § 660.113(c)(4) and (d)(4) to remove the requirement for MS and C/P cooperatives to submit cease-fishing reports to NMFS at the end of their fishing seasons. Cease-fishing reports were used by NMFS to safely reapportion uncaught allocation between the MS and C/P sectors to be used by the sector still fishing without putting the other sector at risk of an overage. Amendment 21–4 to the FMP (42 FR 68799, December 17, 2019) removed the allocations of non-whiting groundfish species made as part of Amendment 21 to the FMP (75 FR 60867, October 1, 2010) and instead created set-asides for these stocks in the at-sea sectors (the MS and C/P cooperatives). Without non-whiting groundfish allocations, cease-fishing reports are obsolete and should have been removed with other reapportionment procedures by Amendment 21–4. This rule corrects that error.

Classification

NMFS is issuing this rule pursuant to section 304(b)(1)(A) and 305(d) of the Magnuson-Stevens Act, which provides specific authority and procedure for implementing this action. See 16 U.S.C. 1854(b)(1)(A), 1855(d). The majority of this rulemaking is promulgated pursuant to section 304(b)(1)(A); the Council recommended this action at its March 2023 meeting. This rulemaking also includes minor regulatory changes promulgated pursuant to section 305(d). This action is necessary to improve comprehensibility of the regulations by updating and revising outdated regulations.

The NMFS Assistant Administrator has determined this final rule is consistent with the FMP, other provisions of the Magnuson-Stevens Act, and other applicable law.

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

The Chief Counsel for Regulation of the Department of Commerce certified to the Chief Counsel for Advocacy of the Small Business Administration during the proposed rule stage that this action would not have a significant economic impact on a substantial number of small entities. The factual basis for the certification was published in the proposed rule and is not repeated here. No comments were received regarding this certification. As a result, a regulatory flexibility analysis was not required and none was prepared.

This final rule revises existing requirements for the collection of information approved under the

Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*). The proposed rule would extend EM service provider submission deadlines for: (1) Vessel operator feedback: 60 days from the date of receipt of EM data for processing from the vessel operator; (2) EM summary and data compliance reports: 60 days from the date of receipt of EM data for processing from the vessel operator; and (3) Logbook data: submit logbook data to NMFS within 7 days of receipt from vessel operators.

Extending the submission deadlines is not expected to increase the public reporting burden for the information collection. The current collection of information requirements would continue to apply under the existing OMB Control Number 0648–0785: West Coast Region Groundfish Trawl Fishery Electronic Monitoring Program.

List of Subjects in 50 CFR Part 660

Fisheries, Fishing, and Indian Fisheries.

Dated: November 16, 2023.

Samuel D. Rauch, III,

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

For the reasons set out in the preamble, NMFS amends 50 CFR part 660 as follows:

PART 660—FISHERIES OFF WEST COAST STATES

■ 1. The authority citation for part 660 continues to read as follows:

Authority: 16 U.S.C. 1801 *et seq.;* 16 U.S.C. 773 *et seq.;* and 16 U.S.C. 7001 *et seq.*

■ 2. Amend part 660 by:

■ a. Removing the word ''coop'' and adding in its place the word ''co-op'' wherever it appears; and

■ b. Removing the word ''Coop'' and adding in its place the word ''Co-op'' wherever it appears.

■ 3. Amend § 660.18 by revising paragraph (d)(1) to read as follows:

§ 660.18 Observer and catch monitor provider permits and endorsements.

* * * * *

(d) * * *

(1) *Initial administrative determination.* For all complete applications, NMFS will issue an IAD if it disapproves the application. An approved application will result in issuance of the permit. If disapproved, the IAD will provide the reasons for this determination. If the applicant does not appeal the IAD within 30 calendar days, the IAD becomes the final decision of the Regional Administrator acting on behalf of the Secretary of Commerce.

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■ 4. Amend § 660.25 by:

■ a. Revising paragraph (b)(3)(iv)(C)(*2*) and (b)(4)(ix); and

■ b. Removing the phrase ''National Marine Fisheries Service, Northwest Region'' and adding in its place the phrase ''NMFS West Coast Region'' in paragraph (g)(3)(ii).

The revisions read as follows:

§ 660.25 Permits.

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(b) * * *

(3) * * *

(iv) * * *

(C) * * *

(*2*) *Application and issuance process for an ownership limitation exemption.* The SFD will make the qualifying criteria and application instructions available online at *https://www.fisheries.noaa.gov/region/west-coast.* A vessel owner who believes that they may qualify for the ownership limitation exemption must submit evidence with their application showing how their vessel has met the qualifying criteria described at paragraph (b)(3)(iv)(C)(*1*) of this section. The vessel owner must also submit a Sablefish Permit Ownership Limitation Exemption Identification of Ownership Interest form that includes disclosure of percentage of ownership in the vessel and disclosure of individual shareholders in any entity. Paragraph (i) of this section sets out the relevant evidentiary standards and burden of proof. Applications may be submitted at any time to NMFS at: NMFS West Coast Region, Sustainable Fisheries Division, ATTN: Fisheries Permit Office—Sablefish Ownership Limitation Exemption, 7600 Sand Point Way NE, Seattle, WA 98115. After receipt of a complete application, the SFD will issue an IAD in writing to the applicant determining whether the applicant qualifies for the exemption. If an applicant chooses to file an appeal of the IAD, the applicant must follow the appeals process outlined at paragraph (g) of this section and, for the timing of the appeals, at paragraph (g)(4)(ii) of this section.

* * * * *

(4) * * *

(ix) *Application forms available.* Application forms for a change in vessel registration, permit owner, or vessel owner are available at: NMFS West Coast Region, Sustainable Fisheries Division, ATTN: Fisheries Permit Office, 7600 Sand Point Way NE, Seattle, WA 98115; or *https://www.fisheries.noaa.gov/region/west-coast.* Contents of the application, and required supporting documentation, are also specified in the application form. Only complete applications will be processed.

* * * * *

■ 5. Amend § 660.60 by revising paragraph (d)(2) to read as follows:

§ 660.60 Specifications and management measures.

* * * * *

(d) * * *

(2) Automatic actions are effective when actual notice is sent by NMFS identifying the effective time and date. Actual notice to fishers and processors will be by email, internet (*https://www.fisheries.noaa.gov/region/west-coast*), phone, letter, or press release. Allocation reapportionments will be followed by publication in the **Federal Register**, in which public comment will be sought for a reasonable period of time thereafter.

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§ 660.113 [Amended]

■ 6. Amend § 660.113 by removing and reserving paragraphs (c)(4) and (d)(4).

■ 7. Amend § 660.140 by:

■ a. Revising paragraphs (d)(2)(iii)(A) and (d)(3)(i)(B);

■ b. Removing ''*http://www.nwr.noaa.gov/Groundfish-Halibut/Groundfish-Permits/index.cfm*'' and adding ''*https://www.fisheries.noaa.gov/region/west-coast*'' in its place in paragraph (d)(8)(v)(B);

■ c. Removing the phrase ''NMFS, Northwest Region'' and adding in its place the phrase ''NMFS West Coast Region'' in paragraph (d)(8)(vii)(B); and

■ d. Revising paragraphs (e)(2)(ii), (e)(3)(i)(B), (f)(3) introductory text, (f)(4), and (f)(6)(i).

The revisions read as follows:

§ 660.140 Shorebased IFQ Program.

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(d) * * *

(2) * * *

(iii) * * *

(A) *Initial administrative determination.* For all complete applications, NMFS will issue an IAD if it disapproves the application. If approved, the QS permit serves as the IAD. If disapproved, the IAD will provide the reasons for this determination. If the applicant does not appeal the IAD within 30 calendar days, the IAD becomes the final decision of the Regional Administrator acting on behalf of the Secretary of Commerce.

* * * * *

(3) * * *

(i) * * *

(B) Notification to renew QS permits will be sent by SFD by September 15 each year to the QS permit owner's most recent email address in the SFD record. The QS permit owner shall provide SFD with notice of any email address change within 15 days of the change.

* * * * *

(e) * * *

(2) * * *

(ii) *Registration.* A vessel account must be registered with the NMFS SFD Permits Office. A vessel account may be established at any time during the year. An eligible vessel owner must submit a request in writing to NMFS to establish a vessel account. The request must include the vessel name; USCG vessel registration number (as given on USCG Form 1270) or state registration number, if no USCG documentation; all vessel owner names (as given on USCG Form 1270, or on state registration, as applicable); and business contact information, including: Address, phone number, fax number, and email. Requests for a vessel account must also include the following information: A complete economic data collection form as required under § 660.113(b), (c) and (d), and a complete Trawl Identification of Ownership Interest Form as required under paragraph (e)(4)(ii) of this section. The request for a vessel account will be considered incomplete until the required information is submitted. Any change specified at paragraph (e)(3)(ii) of this section, including a change in the legal name of the vessel owner(s), will require the new owner to register with NMFS for a vessel account. A participant must have access to a computer with internet access and must set up online access to their vessel account to participate. NMFS will provide vessel account owners instructions to set up online access to their vessel account. NMFS will use the vessel account to send messages to vessel owners in the Shorebased IFQ Program; it is important for vessel owners to monitor their online vessel account and all associated messages.

* * * * *

(3) * * *

(i) * * *

(B) Notification to renew vessel accounts will be issued by SFD by September 15 each year to the vessel account owner's most recent email address in the SFD record. The vessel account owner shall provide SFD with notice of any email address change within 15 days of the change.

* * * * *

(f) * * *

(3) *Application process.* Persons interested in being licensed as an IFQ first receiver for a specific physical location must submit a complete application for a first receiver site license through the web form submission available at *https://www.noaa.gov/fisheries.* First receiver site license holders may request a paper application by contacting SFD. NMFS will only consider complete applications for approval. A complete application includes:

* * * * *

(4) *Initial administrative determination.* For all complete applications, NMFS will issue an IAD if the application is disapproved. The IAD will provide the reasons for this determination. NMFS will not reissue a first receiver site license until the required cost recovery program fees, as specified at § 660.115, have been paid. The IAD, appeals, and final decision process for the cost recovery program is specified at § 660.115(d)(3)(ii).

* * * * *

(6) * * *

(i) First receiver site license applications will be accessible through an online application on or about February 1 each year.

* * * * *

■ 8. Amend § 660.150 by:

■ a. Revising paragraph (d)(2).

■ b. Removing ''*http://www.nwr.noaa.gov/Groundfish-Halibut/Groundfish-Permits/index.cfm*'' adding ''*https://www.fisheries.noaa.gov/region/west-coast*'' in its place in paragraph (g)(6)(iv)(B); and

■ c. Removing the phrase ''NMFS, Northwest Region'' and adding in its place the phrase ''NMFS West Coast Region'' in paragraph (g)(6)(vi)(B).

The revision reads as follows:

§ 660.150 Mothership (MS) Co-op Program.

* * * * *

(d) * * *

(2) *Initial administrative determination.* For all complete applications, NMFS will issue an IAD if the application is disapproved. An approved application will result in issuance of the permit. If disapproved, the IAD will provide the reasons for this determination. The IAD for a MS co-op permit follows the same requirement as specified for limited entry permits at § 660.25(g)(4)(ii); if the applicant does not appeal the IAD within the 30 calendar days, the IAD becomes the final decision of the Regional Administrator acting on behalf of the Secretary of Commerce.

* * * * *

■ 9. Amend § 660.160 by:

■ a. Removing ''NMFS NWR'' and adding ''NMFS WCR'' in its place in paragraph (d)(1)(iii);

■ b. Removing ''*http://www.nwr.noaa.gov*'' and adding *https://www.fisheries.noaa.gov/region/west-coast* in its place in paragraph (d)(1)(iii); and

■ c. Revising paragraph (d)(2).

The revision reads as follows:

§ 660.160 Catcher/processor (C/P) Co-op Program.

* * * * *

(d) * * *

(2) *Initial administrative determination.* For all complete applications, NMFS will issue an IAD if the application is disapproved. An approved application will result in issuance of the permit. If disapproved, the IAD will provide the reasons for this determination. The IAD for a C/P co-op permit follows the same requirement as specified for limited entry permits at § 660.25(g)(4)(ii), if the applicant does not appeal the IAD within the 30 calendar days, the IAD becomes the final decision of the Regional Administrator acting on behalf of the Secretary of Commerce.

* * * * *

■ 10. Amend § 660.603 by removing and reserving paragraph (m)(1) and revising paragraphs (m)(4) introductory text and (m)(5).

The revisions read as follows:

§ 660.603 Electronic monitoring provider permits and responsibilities.

* * * * *

(m) * * *

(4) The EM service provider must communicate with vessel operators and NMFS to coordinate data service needs, resolve specific program issues, and provide feedback on program operations. No later than 60 days from the date of receipt of EM data for processing from the vessel operator, the EM service provider must provide feedback to vessel representatives, field services staff, and NMFS regarding:

* * * * *

(5) *Submission of data and reports.* On behalf of vessels with which it has a contract (see § 660.604(k)), the EM service provider must submit to NMFS logbook data, EM summary reports, including discard estimates, fishing activity information, and meta data (*e.g.,* image quality, reviewer name), and incident reports of compliance issues according to a NMFS-accepted EM Service Plan, which is required under paragraph (b)(1)(vii) of this section, and as described in the EM Program Manual or other written and oral instructions provided by the EM program, such that

the EM program achieves its purpose as defined at § 660.600(b). Logbook data must be submitted to NMFS within 7 business days of receipt from the vessel operator. EM summary reports must be submitted within 60 days of the date the EM data was received by the EM service provider from the vessel operator. If NMFS determines that the information does not meet these standards, NMFS may require the EM service provider to correct and resubmit the datasets and reports.

* * * * *

[FR Doc. 2023–25703 Filed 11–21–23; 8:45 am]

BILLING CODE 3510–22–P

Notices

Federal Register
Vol. 88, No. 224
Wednesday, November 22, 2023

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

DEPARTMENT OF AGRICULTURE

Forest Service

Proposed New Recreation Fee Site

AGENCY: Forest Service, Agriculture (USDA).

ACTION: Notice.

SUMMARY: The San Bernardino National Forest is proposing to establish a new recreation fee site. Recreation fee revenues collected at the new recreation fee site would be used for operation, maintenance, and improvement of the site. An analysis of nearby recreation fee sites with similar amenities shows the recreation fee that would be charged at the new recreation fee site is reasonable and typical of similar recreation fee sites in the area.

DATES: If approved, the new recreation fee would be implemented no earlier than six months following the publication of this notice in the **Federal Register**.

ADDRESSES: San Bernardino National Forest, 602 South Tippecanoe Avenue, San Bernardino, California 92408.

FOR FURTHER INFORMATION CONTACT: Jonar Rodrigo, Recreation Fee Program Manager—Southern Zone, 909–382–2622 or *jonar.rodrigo@usda.gov*.

SUPPLEMENTARY INFORMATION: The Federal Lands Recreation Enhancement Act (16 U.S.C. 6803(b)) requires the Forest Service to publish a six-month advance notice in the **Federal Register** of establishment of new recreation fee sites. In accordance with Forest Service Handbook 2309.13, chapter 30, the Forest Service will publish the proposed new recreation fee site in local newspapers and other local publications for public comment. Most of the new recreation fee revenues would be spent where they are collected to enhance the visitor experience at the new recreation fee site.

A standard amenity recreation fee of $5 per day per vehicle would be charged at Big Pine Flat Off-Highway Vehicle Staging Area. The Adventure Pass and the America the Beautiful—the National Parks and Federal Recreational Lands Pass would be honored at this standard amenity recreation fee site.

Expenditures from recreation fee revenues collected at the new recreation fee site would enhance recreation opportunities, improve customer service, and address maintenance needs. Once public involvement is complete, the new fee will be reviewed by a Recreation Resource Advisory Committee prior to a final decision and implementation.

Dated: November 17, 2023.

Jacqueline Emanuel,

Associate Deputy Chief, National Forest System.

[FR Doc. 2023–25874 Filed 11–21–23; 8:45 am]

BILLING CODE 3411–15–P

DEPARTMENT OF AGRICULTURE

Forest Service

Proposed New Recreation Fee Sites

AGENCY: Forest Service, Agriculture (USDA).

ACTION: Notice.

SUMMARY: The National Forests in North Carolina are proposing to establish several new recreation fee sites. Recreation fee revenues collected at the new recreation fee sites would be used for operation, maintenance, and improvement of the sites. An analysis of nearby recreation fee sites with similar amenities shows the recreation fees that would be charged at the new recreation fee sites are reasonable and typical of similar recreation fee sites in the area.

DATES: If approved, the new recreation fees would be implemented no earlier than six months following the publication of this notice in the **Federal Register**.

ADDRESSES: Recreation Fee Proposals, National Forests in North Carolina, 160A Zillicoa Street, Asheville, NC 28801.

FOR FURTHER INFORMATION CONTACT: Logan Free, Recreation Fee Coordinator, 828–257–4256 or *SM.FS.NFsNCfees@usda.gov.*

SUPPLEMENTARY INFORMATION: The Federal Lands Recreation Enhancement Act (16 U.S.C. 6803(b)) requires the Forest Service to publish a six-month advance notice in the **Federal Register** of establishment of new recreation fee sites. In accordance with Forest Service Handbook 2309.13, chapter 30, the Forest Service will publish the proposed new recreation fee sites in local newspapers and other local publications for public comment. Most of the new recreation fee revenues would be spent where they are collected to enhance the visitor experience at the new recreation fee sites.

An expanded amenity recreation fee of $50 per night for groups up to 50 people would be charged for the Yates Place Camp Group Campground. A standard amenity recreation fee of $5 per day per vehicle would be charged at Cedar Point Day and Flanners Beach developed recreation sites. The America the Beautiful—the National Parks and Federal Recreational Lands Pass would be honored at these standard amenity recreation fee sites. A special recreation permit fee of $5 per rider per day or a $30 annual pass is proposed for the Jackrabbit, Wood Run, and Pisgah Complex Trail Systems.

Expenditures from recreation fee revenues collected at the new recreation fee sites would enhance recreation opportunities, improve customer service, and address maintenance needs. Once public involvement is complete, the new recreation fees will be reviewed by a Recreation Resource Advisory Committee prior to a final decision and implementation. Reservations for group campgrounds could be made online at *www.recreation.gov* or by calling 877–444–6777. Reservations would cost $8.00 per reservation.

Dated: November 17, 2023.

Jacqueline Emanuel,

Associate Deputy Chief, National Forest System.

[FR Doc. 2023–25870 Filed 11–21–23; 8:45 am]

BILLING CODE 3411–15–P

COMMISSION ON CIVIL RIGHTS

Notice of Public Meeting of the Washington Advisory Committee Advisory Committee; Cancellation

AGENCY: Commission on Civil Rights.

ACTION: Notice; cancellation of virtual business meeting.

The Commission on Civil Rights published a notice in the **Federal Register** concerning a virtual business meeting of the Washington Advisory Committee. The meeting scheduled for Tuesday, December 5, 2023, at 11 a.m. Pacific time is cancelled. The notice is in the **Federal Register** of Monday, August 14, 2023, in FR Doc. 2023–17298 in the first, second, and third columns of page 55008.

FOR FURTHER INFORMATION CONTACT: Brooke Peery, *bpeery@usccr.gov,* (202) 701–1376.

Dated: November 17, 2023.

David Mussatt,

Supervisory Chief, Regional Programs Unit.

[FR Doc. 2023–25842 Filed 11–21–23; 8:45 am]

BILLING CODE P

COMMISSION ON CIVIL RIGHTS

Notice of Public Meeting of the Tennessee Advisory Committee

AGENCY: Commission on Civil Rights.

ACTION: Announcement of meeting.

SUMMARY: Notice is hereby given, pursuant to the provisions of the rules and regulations of the U.S. Commission on Civil Rights (Commission), and the Federal Advisory Committee Act (FACA) that a meeting of the Tennessee Advisory Committee to the Commission will convene by Zoom on Wednesday, November 29, 2023, at 3:30 p.m. (CT). The purpose of the meeting is to discuss their draft report on Voting Rights in the state.

DATES: The meeting will take place on Wednesday, November 29, 2023, at 3:30 p.m. (CST).

Registration Link (Audio/Visual): *https://www.zoomgov.com/j/1609784727?pwd=bkhjVWlYa2c4Y0ZmZkx1Uk9SOEJodz09*

Telephone (Audio Only): Dial (833) 568–8864 USA Toll Free; Access Code: 160 978 4727

FOR FURTHER INFORMATION CONTACT: Victoria Moreno at *vmoreno@usccr.gov* or by phone at 434–515–0204.

SUPPLEMENTARY INFORMATION: This meeting is available to the public through the Zoom link above. If joining only via phone, callers can expect to incur charges for calls they initiate over wireless lines, and the Commission will not refund any incurred charges. Individuals who are deaf, deafblind and hard of hearing may also follow the proceedings by first calling the Federal Relay Service at 1–800–877–8339 and providing the Service with the call-in number found through registering at the web link provided above for the meeting.

Members of the public are entitled to make comments during the open period at the end of the meeting. Members of the public may also submit written comments; the comments must be received in the Regional Programs Unit within 30 days following the respective meeting. Written comments may be emailed to Victoria Moreno at *vmoreno@usccr.gov.* All written comments received will be available to the public.

Persons who desire additional information may contact the Regional Programs Unit at (202) 809–9618. Records and documents discussed during the meeting will be available for public viewing as they become available at the *www.facadatabase.gov.* Persons interested in the work of this advisory committee are advised to go to the Commission's website, *www.usccr.gov,* or to contact the Regional Programs Unit at the above phone number or email address.

Agenda: Wednesday, November 29, 2023, at 1:30 p.m. (CT)

1. Welcome & Roll Call
2. Chair's Comments
3. Discussion on Report
4. Next Steps
5. Public Comment
6. Adjourn

Dated: November 17, 2023.

David Mussatt,

Supervisory Chief, Regional Programs Unit.

[FR Doc. 2023–25845 Filed 11–21–23; 8:45 am]

BILLING CODE P

COMMISSION ON CIVIL RIGHTS

Notice of Public Meeting of the Nebraska Advisory Committee to the U.S. Commission on Civil Rights

AGENCY: Commission on Civil Rights.

ACTION: Announcement of meeting.

SUMMARY: Notice is hereby given, pursuant to the provisions of the rules and regulations of the U.S. Commission on Civil Rights (Commission) and the Federal Advisory Committee Act that the Nebraska Advisory Committee (Committee) to the U.S. Commission on Civil Rights will hold a planning meeting via web conference. The purpose of the meeting will be to discuss their project on to the Effects of the COVID–19 Pandemic on K–12 Education in the state.

DATES: Tuesday, December 12, 2023 at 12:00 p.m. Central Time.

ADDRESSES: The meeting will be held via Zoom.

December 12th Planning Meeting: Registration Link (Audio/Visual): https://www.zoomgov.com/j/1609471833?pwd=VXpXMExxMTd0cGtKZFpUYUpNUmFZUT09.

Join by Phone (Audio Only): 1–833–435–1820 USA Toll Free; Meeting ID: 160 947 1833.

FOR FURTHER INFORMATION CONTACT: Victoria Moreno, DFO, at *vmoreno@usccr.gov* or by phone at 434–515–0204.

SUPPLEMENTARY INFORMATION: Members of the public may listen to the discussions through the above call-in numbers (audio only) or online registration links (audio/visual). An open comment period at each meeting will be provided to allow members of the public to make a statement as time allows. Callers can expect to incur regular charges for calls they initiate over wireless lines, according to their wireless plan. The Commission will not refund any incurred charges. Callers will incur no charge for calls they initiate over land-line connections to the toll-free telephone number. Individuals who are deaf, deafblind, and/or hard of hearing may also follow the proceedings by first calling the Federal Relay Service at 1–800–877–8339 and providing the Service with the conference call number and meeting ID number.

Members of the public are entitled to submit written comments; the comments must be received in the regional office within 30 days following the meetings. Written comments may be emailed to Victoria at *vmoreno@usccr.gov.*

Records generated from this meeting may be inspected and reproduced at the Regional Programs Unit Office, as they become available, both before and after the meetings. Records of the meetings will be available via *www.facadatabase.gov* under the Commission on Civil Rights, Nebraska Advisory Committee link. Persons interested in the work of this Committee are directed to the Commission's website, *http://www.usccr.gov,* or may contact the Regional Programs Unit at the above email or street address.

Agenda

I. Welcome and Roll Call
II. Chair's Comments
III. Committee Business
IV. Public Comment
V. Adjournment

Dated: November 17, 2023.

David Mussatt,

Supervisory Chief, Regional Programs Unit.

[FR Doc. 2023–25843 Filed 11–21–23; 8:45 am]

BILLING CODE P

DEPARTMENT OF COMMERCE

Foreign-Trade Zones Board

[B–59–2023]

Foreign-Trade Zone (FTZ) 84, Notification of Proposed Production Activity; KMP USA LLC; (Automotive Parts); Katy, Texas

KMP USA LLC submitted a notification of proposed production activity to the FTZ Board (the Board) for its facility in Katy, Texas within FTZ 84. The notification conforming to the requirements of the Board's regulations (15 CFR 400.22) was received on November 13, 2023.

Pursuant to 15 CFR 400.14(b), FTZ production activity would be limited to the specific foreign-status material(s)/component(s) and specific finished product(s) described in the submitted notification (summarized below) and subsequently authorized by the Board. The benefits that may stem from conducting production activity under FTZ procedures are explained in the background section of the Board's website—accessible via *www.trade.gov/ftz.*

The proposed finished products include: camshaft bushing kits; camshaft kits; connecting rods (con rod) and main bearings kits; con rod bearings kits; con rod bolt kits; crankshaft kits; crankshaft thrust washers kits; cylinder head assemblies; cylinder head bolt kits; cylinder liner and seal kits; engine filter kits; engine overhaul gasket kits; engine long block assemblies; engine oil pump kits; engine overhaul kits; engine piston and liner kits; engine sensor kits; engine short block assemblies; engine valve collet kits; engine valve kits; engine valve seal kits; engine valvetrain kits; excavator bucket pin and bushing kits; expansion plug kits; fuel injector seal kits; fuel line kits; fuel solenoid kits; hydraulic cylinder seal kits; engine brake gasket kits; engine valve guide kits; main bearing kits; piston kits; piston kit and connecting rod assemblies; piston pin and retainer kits; piston ring sets; spindle repair kits; transmission oil pump kits; turbocharger gasket kits; V-belt sets; water pump kits; and, water pump repair kits (duty rate ranges from duty-free to 5.8%).

The proposed foreign-status materials and components include: balancer shafts (cast iron); ball bearings (steel); bolts, studs or screws (steel); copper and aluminum bushings for balance shaft, camshafts (piece or set), connecting rods, crankshafts, equipment arm or bucket links, front cover or accessory drives, hydraulic cylinder rod ends and, spindles; camshafts (cast iron and steel); steel circlips; clutch alignment tools (plastic); clutch assemblies (aluminum and steel); clutch plates (aluminum, fiber and, steel); clutch release levers (copper and steel); clutch tension springs (copper and steel); coil solenoids (cast iron and steel); connecting rods (steel); half, pair or, set of connecting rod bearings (standard, undersize or oversize) (copper and aluminum); connecting rod end slipper bearing kits (copper, aluminum); pressure plate and cover assemblies (aluminum and steel); crankshafts (cast iron and steel); cylinder blocks (cast iron); bare or assembled cylinder heads (cast iron and steel); cylinder head injector sleeves (brass, copper and, steel); engine block cylinder liners (cast iron and steel); engine mounted air compressor cylinder liners (cast iron and steel); cylinder liner seals (rubber and plastic); cylinder liner shims (brass and steel); dowel pins (steel); dowel pin alignment inserts, dowel rings (steel); air, fuel, oil and, water engine filters (plastic, aluminum and, steel); engine oil cooler cores (aluminum, cast iron, copper and, steel); engine oil pumps (aluminum, cast iron and, steel); engine overhaul gasket kit; engine piston: body, crown, pins, skirts and, rings (compression, oil control or set) (aluminum, cast iron and, steel); engine push rods (steel); engine pressure and temperature sensors (plastic and brass); engine intake or exhaust valves (steel); engine valve crossheads (cast iron); engine intake or exhaust valve guides (steel); engine valve lash caps (steel); engine valve lock half: collet or keepers (steel); engine valve rotators (steel); engine intake or exhaust valve seals (plastic and steel); engine intake or exhaust valve seats (steel); inner or lower engine intake or exhaust valve springs (steel); upper or lower engine valve spring retainers (steel); engine water pumps, impeller, shafts and spacers (aluminum, cast iron, plastic and, steel); exhaust manifold sleeves (steel); expansion plugs (steel); fuel lines (aluminum and steel); fuel priming pumps, mechanical engine transfer pumps (aluminum, cast iron, steel and, plastic); gaskets for accessory drives, blower end plates, brake and cam follower housings, cylinder heads, drain plugs, engine mounted compressors, exhaust manifold, flanges, front covers, fuel pumps, injector sleeves, oil cooler covers, oil coolers, oil pans, oil pick up tubes, oil pumps, pre-combustion chambers, rear covers, rear housing rope seals, turbocharger oil drains, turbochargers, valve covers, and water pumps made from paper, rubber, steel, copper and, graphite; gear (balancer, camshaft, crankshaft, idler pump drive) (steel); grease fittings (aluminum and steel); rubber hoses; hour meter gauges (aluminum, plastic, glass and, steel); hydraulic cylinder seals (back up rings, buffer rings, dust seals, packing, piston rings, rings) (rubber and plastic); hydraulic cylinder wear rings (plastic); aluminum and steel hose clips; liquid gasket makers (plastic); steel lockwire; standard, undersize or oversize main bearings (aluminum, copper); water pump mechanical seals (steel and plastic); steel needle roller bearings; steel and plastic nuts; front or rear crankshaft/cover oil seals (steel, rubber and, plastic); rubber and plastic O-rings; equipment arm, cylinder rod or bucket link steel pins; engine mounted air compressor piston assemblies (aluminum, cast iron and, steel); piston cooling nozzles (steel, plastic and, cast iron); pre-combustion chambers (steel); engine oil cooler housing pressure relief plungers (steel and plastic); socket, ball or adjuster rocker arm inserts (steel and plastic); rocker arm rollers, pins and, supports (cast iron, brass and steel); intake or exhaust rocker levers (cast iron and steel); rocker lever shafts (cast iron, steel); steel roller bearings; rubber and plastic seals; engine block and cylinder head steel spacer plates; camshaft follower tappets (steel, brass and, cast iron); thermostat engine coolant regulator (aluminum, brass and, steel); standard, undersize or oversize thrust bearings (aluminum, copper and steel); crankshaft thrust blocks (brass and steel); steel thrust plates; standard, undersize or oversize thrust washers (aluminum, copper and, steel); transmission oil pumps (aluminum, cast iron and, steel); turbochargers (aluminum, cast iron, steel and, plastic); universal joint assemblies (cast iron and steel); engine mounted air compressor unloader valve caps and bodies (aluminum and cast iron); single or set rubber V-belts; aluminum and steel valves (part of engine mounted air compressor); steel and brass washers; water temperature gauges (aluminum, plastic, glass and, steel); steel wear plates (part of engine mounted air compressor); steel wear sleeves; and, steel woodruff keys (duty rate ranges from duty-free to 9%). The request indicates that certain materials/components are subject to duties under section 301 of the Trade Act of 1974 (section 301), depending on the country of origin. The applicable section 301 decisions require subject merchandise to be admitted to FTZs in privileged foreign status (19 CFR 146.41).

Public comment is invited from interested parties. Submissions shall be addressed to the Board's Executive Secretary and sent to: *ftz@trade.gov.* The closing period for their receipt is January 2, 2024.

A copy of the notification will be available for public inspection in the ''Online FTZ Information System'' section of the Board's website.

For further information, contact Christopher Wedderburn at *Chris.Wedderburn@trade.gov.*

Dated: November 17, 2023.

Elizabeth Whiteman,

Executive Secretary.

[FR Doc. 2023–25834 Filed 11–21–23; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

Bureau of Industry and Security

In the Matter of: Samantha Coronado, Inmate Number: 83982–509, FMC Carswell, Federal Medical Center, P.O. Box 27137, Fort Worth, TX 76127; Order Denying Export Privileges

On June 23, 2022, in the U.S. District Court for the Southern District of Texas, Samantha Coronado (''Coronado'') was convicted of violating 18 U.S.C. 554(a). Specifically, Coronado was convicted of smuggling 730 rounds of CBC .50 caliber ammunition from the United States to Mexico. As a result of her conviction, the Court sentenced Coronado to 46 months of confinement, three years of supervised release and a $100 assessment.

Pursuant to section 1760(e) of the Export Control Reform Act (''ECRA''),[1] the export privileges of any person who has been convicted of certain offenses, including, but not limited to, 18 U.S.C. 554, may be denied for a period of up to ten (10) years from the date of his/her conviction. 50 U.S.C. 4819(e). In addition, any Bureau of Industry and Security (''BIS'') licenses or other authorizations issued under ECRA, in which the person had an interest at the time of the conviction, may be revoked. *Id.*

BIS received notice of Coronado's conviction for violating 18 U.S.C. 554. As provided in Section 766.25 of the Export Administration Regulations (''EAR'' or the ''Regulations''), BIS provided notice and opportunity for Coronado to make a written submission to BIS. 15 CFR 766.25.[2] BIS has not received a written submission from Coronado.

Based upon my review of the record and consultations with BIS's Office of Exporter Services, including its Director, and the facts available to BIS, I have decided to deny Coronado's export privileges under the Regulations for a period of seven years from the date of Coronado's conviction. The Office of Exporter Services has also decided to revoke any BIS-issued licenses in which Coronado had an interest at the time of her conviction.[3]

Accordingly, it is hereby *Ordered:*

First, from the date of this Order until June 23, 2029, Samantha Coronado, with a last known address of Inmate Number: 83982–509, FMC Carswell, Federal Medical Center, P.O. Box 27137, Fort Worth, TX 76127, and when acting for or on her behalf, her successors, assigns, employees, agents or representatives (''the Denied Person''), may not directly or indirectly participate in any way in any transaction involving any commodity, software or technology (hereinafter collectively referred to as ''item'') exported or to be exported from the United States that is subject to the Regulations, including, but not limited to:

A. Applying for, obtaining, or using any license, license exception, or export control document;

B. Carrying on negotiations concerning, or ordering, buying, receiving, using, selling, delivering, storing, disposing of, forwarding, transporting, financing, or otherwise servicing in any way, any transaction involving any item exported or to be exported from the United States that is subject to the Regulations, or engaging in any other activity subject to the Regulations; or

C. Benefitting in any way from any transaction involving any item exported or to be exported from the United States that is subject to the Regulations, or from any other activity subject to the Regulations.

Second, no person may, directly or indirectly, do any of the following:

A. Export, reexport, or transfer (in-country) to or on behalf of the Denied Person any item subject to the Regulations;

B. Take any action that facilitates the acquisition or attempted acquisition by the Denied Person of the ownership, possession, or control of any item subject to the Regulations that has been or will be exported from the United States, including financing or other support activities related to a transaction whereby the Denied Person acquires or attempts to acquire such ownership, possession or control;

C. Take any action to acquire from or to facilitate the acquisition or attempted acquisition from the Denied Person of any item subject to the Regulations that has been exported from the United States;

D. Obtain from the Denied Person in the United States any item subject to the Regulations with knowledge or reason to know that the item will be, or is intended to be, exported from the United States; or

E. Engage in any transaction to service any item subject to the Regulations that has been or will be exported from the United States and which is owned, possessed or controlled by the Denied Person, or service any item, of whatever origin, that is owned, possessed or controlled by the Denied Person if such service involves the use of any item subject to the Regulations that has been or will be exported from the United States. For purposes of this paragraph, servicing means installation, maintenance, repair, modification or testing.

Third, pursuant to section 1760(e) of ECRA and sections 766.23 and 766.25 of the Regulations, any other person, firm, corporation, or business organization related to Coronado by ownership, control, position of responsibility, affiliation, or other connection in the conduct of trade or business may also be made subject to the provisions of this Order in order to prevent evasion of this Order.

Fourth, in accordance with part 756 of the Regulations, Coronado may file an appeal of this Order with the Under Secretary of Commerce for Industry and Security. The appeal must be filed within 45 days from the date of this Order and must comply with the provisions of part 756 of the Regulations.

Fifth, a copy of this Order shall be delivered to Coronado and shall be published in the **Federal Register**.

Sixth, this Order is effective immediately and shall remain in effect until June 23, 2029.

John Sonderman,

Director, Office of Export Enforcement.

[FR Doc. 2023–25838 Filed 11–21–23; 8:45 am]

BILLING CODE 3510–DT–P

[1] ECRA was enacted on August 13, 2018, as part of the John S. McCain National Defense Authorization Act for Fiscal Year 2019, and as amended is codified at 50 U.S.C. 4801–4852.

[2] The Regulations are currently codified in the Code of Federal Regulations at 15 CFR parts 730–774 (2022).

[3] The Director, Office of Export Enforcement, is the authorizing official for issuance of denial orders pursuant to amendments to the Regulations (85 *FR* 73411, November 18, 2020).

DEPARTMENT OF COMMERCE

International Trade Administration

[A–533–840]

Certain Frozen Warmwater Shrimp From India: Rescission of Antidumping Duty Administrative Review; 2022–2023, in Part

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

SUMMARY: On April 11, 2023, the U.S. Department of Commerce (Commerce) initiated an administrative review of the antidumping duty (AD) order on certain frozen warmwater shrimp (shrimp) from India for the period of review (POR), February 1, 2022, through January 31, 2023, for 269 companies. Because all interested parties timely withdrew their requests for administrative review for certain companies, we are rescinding this administrative review with respect to those companies. For a list of the companies for which we are rescinding this review, *see* Appendix I to this notice. For a list of the companies for which the review is continuing, *see* Appendix II to this notice.

DATES: Applicable November 22, 2023.

FOR FURTHER INFORMATION CONTACT: Terre Keaton Stefanova, AD/CVD Operations, Office IX, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–1280.

SUPPLEMENTARY INFORMATION:

Background

On February 2, 2023, Commerce published in the **Federal Register** a notice of opportunity to request an administrative review of the AD order on shrimp from India for the POR, February 1, 2022, through January 31, 2023.[1] In February 2022, Commerce received timely requests, in accordance with section 751(a) of the Tariff Act of 1930, as amended (the Act), to conduct an administrative review of this AD order from the Ad Hoc Shrimp Trade Action Committee (the petitioner),[2] the American Shrimp Processors Association (ASPA),[3] and certain individual companies.[4] Based on these requests, on April 11, 2023, in accordance with section 751(a) of the Act, Commerce published in the **Federal Register** a notice of initiation listing 269 companies for which Commerce received timely requests for review.[5]

In July 2023, all interested parties timely withdrew their requests for an administrative review of certain companies.[6] These companies are listed in Appendix I.

Partial Rescission

Pursuant to 19 CFR 351.213(d)(1), Commerce will rescind an administrative review, in whole or in part, if a party who requested the review withdraws the request within 90 days of the date of publication of notice of initiation of the requested review. As noted above, certain parties withdrew their requests for review by the 90-day deadline. Accordingly, we are rescinding this administrative review with respect to the companies listed in Appendix I.

Assessment

Commerce will instruct U.S. Customs and Border Protection (CBP) to assess antidumping duties on all appropriate entries. Antidumping duties shall be assessed at rates equal to the cash deposit of estimated antidumping duties required at the time of entry, or withdrawal from warehouse, for consumption, in accordance with 19 CFR 351.212(c)(1)(i). Commerce intends to issue appropriate assessment instructions to CBP no earlier than 35 days after publication of this notice in the **Federal Register**.

Notification to Importers

This notice serves as a 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 Regarding Administrative Protective Orders

This notice also serves as a 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. Timely written notification of the return/destruction of APO materials or conversion to judicial protective order is hereby requested. Failure to comply with the regulations and terms of an APO is a violation which is subject to sanction.

Notification to Interested Parties

This notice is issued and published in accordance with section 751(a)(1) of the Act and 19 CFR 351.213(d)(4).

Dated: November 15, 2023.

James Maeder,

Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations.

Appendix I

Akshay Food Impex Private Limited
Alashore Marine Exports (P) Ltd.
Alpha Marine
Ananda Enterprises (India) Private Limited
Ananda Aqua Applications; Ananda Aqua Exports (P) Limited; Ananda Foods
Apex Frozen Foods Limited
Aquatica Frozen Foods Global Pvt. Ltd.
Arya Sea Foods Private Limited
Asvini Fisheries Ltd.; Asvini Fisheries Private Ltd.
Avanti Frozen Foods Private Limited
BMR Exports; BMR Exports Private Limited

[1] *See Antidumping or Countervailing Duty Order, Finding, or Suspended Investigation; Opportunity to Request Administrative Review,* 88 FR 7071 (February 2, 2023).

[2] *See* Petitioner's Letter, ''Request for Administrative Reviews,'' dated February 28, 2023.

[3] *See* ASPA's Letter, ''American Shrimp Processors Association's Request for Administrative Reviews,'' dated February 23, 2023.

[4] *See* Indian Producers' Letter, ''Request for Administrative Reviews for Indian Producers/Exporters,'' dated February 28, 2023; Magnum Sea Foods Limited's (Magnum's) and Magnum Estates Limited's (MEL's) Letter, ''Magnum's Request for Administrative Review,'' dated February 28, 2023; B-One Business House Pvt. Ltd.'s (B-One's) Letter, ''Request for Administrative Review of B-One,'' dated February 28, 2023; Megaa Moda Pvt. Ltd.'s Letter, ''Request for Administrative Review of Megaa Moda Private Limited,'' dated February 28, 2023; NK Marine Exports' Letter, ''Request for 18th Administrative Review,'' dated February 27, 2023; RSA Marines' Letter, ''Request for Administrative Review of RSA Marines,'' dated February 27, 2023; and Mindhola Foods' Letter, ''Request for Administrative Review of Mindhola Foods LLP,'' dated February 27, 2023.

[5] *See Initiation of Antidumping and Countervailing Duty Administrative Reviews,* 88 FR 21609 (April 11, 2023).

[6] *See* B-One's Letter, ''B-One Withdrawal of Request for Review of the Antidumping Duty Order for the period of February 01, 2022 to January 31, 2023,'' dated July 8, 2023; Magnum's and MEL's Letter, ''Magnum Sea Foods Limited (Magnum) and Magnum Estates Limited (MEL) Withdrawal of Request for Review of the Antidumping Duty Order for the period of February 01, 2022 to January 31, 2023,'' dated July 8, 2023; Devi Fisheries Limited's Letter, ''Withdrawal of our request for Administrative Review for the period 02/01/22–01/31/23,'' dated July 10, 2023; Nekkanti Sea Foods Limited's Letter, ''Withdrawal of our request for Administrative Review for the period 02/01/22–01/31/23,'' dated July 10, 2023; ASPA's Letter, ''American Shrimp Processors Association's Partial Withdrawal of Review Requests,'' dated July 10, 2023; Petitioner's Letter, ''Domestic Producers' Partial Withdrawal of Review Requests,'' dated July 10, 2023; Twelve Indian Producers' Letter, ''Withdrawal of Requests for Administrative Reviews for 12 Indian Producers/Exporters (02/01/22–01/31/23),'' dated July 10, 2023; and RSA Marines Letter, ''RSA Marines Withdrawal of Request for Review of the Antidumping Duty Order on Certain Frozen Warm-water Shrimp from India (A–533–840) for the period of February 01, 2022 to January 31, 2023,'' dated June 20, 2023.

BMR Industries Private Limited
B-One Business House Pvt. Ltd.
Castlerock Fisheries Ltd.
Choice Trading Corporation Pvt. Ltd.
Coastal Aqua Private Limited
Coastal Corporation Ltd.
Devi Fisheries Limited; Satya Seafoods Private Limited; Usha Seafoods; Devi Aquatech Private Limited
Devi Marine Food Exports Private Ltd.; Kader Exports Private Limited; Kader Investment and Trading Company Private Limited; Liberty Frozen Foods Private Limited; Liberty Oil Mills Limited; Premier Marine Products Private Limited; Universal Cold Storage Private Limited [7]
DSF Aquatech Private Limited
Falcon Marine Exports Limited; KR Enterprises
Five Star Marine Exports Private Limited
Geo Seafoods
Godavari Mega Aqua Food Park Private Limited
Growel Processors Private Limited
IFB Agro Industries Limited
ITC Ltd.
Jagadeesh Marine Exports
Jaya Lakshmi Sea Foods Pvt. Ltd.
The Kadalkanny Group; Diamond Seafoods Exports; Edhayam Frozen Foods Private Limited; Kadalkanny Frozen Foods; Theva & Company
Kalyan Aqua & Marine Exp. India Pvt. Ltd.
KNC Agro Limited; KNC AGRO PVT. LTD.
LNSK Green House Agro Products LLP
Magnum Export; Magnum Exports Pvt. Ltd.
Magnum Sea Foods Limited; Magnum Estates Limited; Magnum Estates Private; Magnum Estates Private Limited
Mangala Marine Exim India Pvt. Ltd.
Mangala Seafoods; Mangala Sea Foods
Milesh Marine Exports Private Limited
Monsun Foods Pvt. Ltd.
Mourya Aquex Pvt. Ltd.
Munnangi Seafoods (Pvt) Ltd.
Naga Hanuman Fish Packers
Neeli Aqua Private Limited
Nekkanti Mega Food Park Private Limited
Nekkanti Sea Foods Limited
Nezami Rekha Sea Foods Private Limited; Nezami Rekha Sea Food Private Limited
Nila Sea Foods Exports; Nila Sea Food Pvt. Ltd.
Pasupati Aquatics Private Limited
Penver Products (P) Ltd.
Razban Seafoods Ltd.
Royal Imports and Exports
Royale Marine Impex Pvt. Ltd.
S.A. Exports
Sagar Grandhi Exports Pvt. Ltd.
Sai Aquatechs Private Limited
Sai Marine Exports Pvt. Ltd.
Sandhya Aqua Exports Pvt. Ltd.; Sandhya Aqua Exports
Sandhya Marines Limited
Sea Foods Private Limited
Sharat Industries Ltd.
Shree Datt Aquaculture Farms Pvt. Ltd.
Southern Tropical Foods Pvt. Ltd.
Sprint Exports Pvt. Ltd.
Summit Marine Exports Private Limited
Sunrise Seafoods India Private Limited
Suryamitra Exim Pvt. Ltd.
V V Marine Products
Vasista Marine
Veerabhadra Exports Private Limited
Wellcome Fisheries Limited
Z.A. Sea Foods Pvt. Ltd.

Appendix II

Abad Fisheries; Abad Fisheries Pvt. Ltd.
Accelerated Freeze Drying Co., Ltd.
ADF Foods Ltd.
Albys Agro Private Limited
Al-Hassan Overseas Private Limited
Allana Frozen Foods Pvt. Ltd.
Allanasons Ltd.
Alps Ice & Cold Storage Private Limited
Amaravathi Aqua Exports Private Ltd.
Amarsagar Seafoods Private Limited
Amulya Seafoods
Anantha Seafoods Private Limited
Anjaneya Seafoods
Asvini Agro Exports
Ayshwarya Sea Food Private Limited
B R Traders
Baby Marine Eastern Exports
Baby Marine Exports
Baby Marine International
Baby Marine Sarass
Baby Marine Ventures
Balasore Marine Exports Private Limited
Basu International
BB Estates & Exports Private Limited
Bell Foods (Marine Division); Bell Exim Private Limited (Bell Foods (Marine Divison)); Bhatsons Aquatic Products Bhavani Seafoods
Bhavani Seafoods
Bhimraj Exports Private Limited
Bijaya Marine Products
Blue-Fin Frozen Foods Private Limited
Blue Water Foods & Exports P. Ltd.
Bluepark Seafoods Pvt. Ltd.
Britto Seafood Exports Pvt Ltd.; Britto Exports; Britto Exports Pvt Ltd.
C.P. Aquaculture (India) Pvt. Ltd.
Calcutta Seafoods Pvt. Ltd.; Bay Seafood Pvt. Ltd.; Elque & Co.
Canaan Marine Products
Capithan Exporting Co.
Cargomar Private Limited
Chakri Fisheries Private Limited
Chemmeens (Regd)
Cherukattu Industries (Marine Div); Cherukattu Industries
Choice Canning Company
Cochin Frozen Food Exports Pvt. Ltd.
Cofoods Processors Private Limited
Continental Fisheries India Private Limited
Coreline Exports
Corlim Marine Exports Private Limited
CPF (India) Private Limited
Crystal Sea Foods Private Limited
Danica Aqua Exports Private Limited
Datla Sea Foods
Deepak Nexgen Foods and Feeds Pvt. Ltd.
Delsea Exports Pvt. Ltd.
Devi Sea Foods Limited
Dwaraka Sea Foods
Empire Industries Limited
Entel Food Products Private Limited
Esmario Export Enterprises
Everblue Sea Foods Private Limited
Febin Marine Foods Private Limited; Febin Marine Foods
Fedora Sea Foods Private Limited
Food Products Pvt., Ltd.; Parayil Food Products Pvt., Ltd.
Forstar Frozen Foods Pvt. Ltd.
Fouress Food Products Private Limited
Frontline Exports Pvt. Ltd.
G A Randerian Ltd.; G A Randerian (P) Limited
Gadre Marine Exports; Gadre Marine Exports Pvt. Ltd.
Galaxy Maritech Exports P. Ltd.
Geo Aquatic Products (P) Ltd.
Grandtrust Overseas (P) Ltd.
Green Asia Impex Private Limited
GVR Exports Pvt. Ltd.
Hari Marine Private Limited
Haripriya Marine Exports Pvt. Ltd.
High Care Marine Foods Exports Private Limited
HIC ABF Special Foods Pvt. Ltd.
Highland Agro
Hiravati Exports Pvt. Ltd.
Hiravati International Pvt. Ltd.
Hiravati Marine Products Private Limited
HMG Industries Ltd.
HN Indigos Private Limited
HT Foods Private Limited
Hyson Exports Private Limited
Hyson Logistics and Marine Exports Private Limited
Indian Aquatic Products
Indo Aquatics
Indo Fisheries
Indo French Shellfish Company Private Limited
International Freezefish Exports
Jinny Marine Traders
Jude Foods India Private Limited
K.V. Marine Exports
Karunya Marine Exports Private Limited
Kaushalya Aqua Marine Product Exports Pvt. Ltd.
Kay Kay Exports; Kay Kay Foods
Kings Infra Ventures Limited
Kings Marine Products
Koluthara Exports Ltd.
Libran Foods
Lito Marine Exports Private Limited
Mangala Sea Products
Marine Harvest India
Megaa Moda Pvt. Ltd.
Milsha Agro Exports Pvt. Ltd.
Milsha Sea Products
Minaxi Fisheries Private Limited
Mindhola Foods LLP
Minh Phu Group
MMC Exports Limited
MTR Foods
Naik Frozen Foods Private Limited; Naik Frozen Foods
Naik Oceanic Exports Pvt. Ltd.; Rafiq Naik Exports Pvt. Ltd.
Naik Seafoods Ltd.
Naq Foods India Private Limited
NAS Fisheries Pvt. Ltd.
Nine Up Frozen Foods
N.K. Marine Exports LLP
Nutrient Marine Foods Limited
Oceanic Edibles International Limited
Orchid Marine Exports Private Limited
Paragon Sea Foods Pvt. Ltd.
Paramount Seafoods
Pesca Marine Products Pvt., Ltd.
Poyilakada Fisheries Private Limited

[7] On December 23, 2022, Commerce determined that Kader Exports Private Limited is the successor-in-interest to the Liberty Group, which is comprised of the companies listed above. *See Certain Frozen Warmwater Shrimp from India: Notice of Final Results of Antidumping Duty Changed Circumstances Review,* 87 FR 78941 (December 23, 2022).

Pijikay International Exports P Ltd.
Pravesh Seafood Private Limited
Premier Exports International
Premier Marine Foods
Premier Seafoods Exim (P) Ltd.
Protech Organo Foods Private Limited
R V R Marine Products Private Limited
Raju Exports
Rajyalaksmi Marine Exports
Ram's Assorted Cold Storage Limited
Raunaq Ice & Cold Storage
RDR Exports
RF Exports Private Limited
Rising Tide
Riyarchita Agro Farming Private Limited
RSA Marines; Royal Oceans
Rupsha Fish Private Limited
S Chanchala Combines
Safera Food International
Sagar Samrat Seafoods
Sahada Exports
Sai Sea Foods
Salet Seafoods Pvt. Ltd.
Samaki Exports Private Limited
Sanchita Marine Products Private Limited
Sassoondock Matsyodyog Sahakari Society Ltd.
Sea Doris Marine Exports
Seagold Overseas Pvt. Ltd.
Seasaga Enterprises Private Limited; Seasaga Group
Shimpo Exports Private Limited
Shimpo Seafoods Private Limited
Shiva Frozen Food Exp. Pvt. Ltd.
Shroff Processed Food & Cold Storage P Ltd.
Sigma Seafoods
Silver Seafood
Sita Marine Exports
Sonia Fisheries
Sonia Marine Exports Private Limited
Sreeragam Exports Private Limited
Sri Sakkthi Cold Storage
Srikanth International
SSF Ltd.
St. Peter & Paul Sea Food Exports Pvt. Ltd.
Star Agro Marine Exports Private Limited
Star Organic Foods Private Limited
Stellar Marine Foods Private Limited
Sterling Foods
Sun Agro Exim
Supran Exim Private Limited
Suvarna Rekha Exports Private Limited
Suvarna Rekha Marines P Ltd.
TBR Exports Private Limited
Tej Aqua Feeds Private Limited
Teekay Marines Private Limited; Teekay Marine P. Ltd.
The Waterbase Limited
Torry Harris Seafoods Ltd.
Triveni Fisheries P Ltd.
U & Company Marine Exports
Ulka Sea Foods Private Limited
Uniloids Biosciences Private Limited
Uniroyal Marine Exports Ltd.
Unitriveni Overseas Private Limited; Unitriveni Overseas
Vaisakhi Bio-Marine Private Limited
Vasai Frozen Food Co.
Veronica Marine Exports Private Ltd.
Victoria Marine & Agro Exports Ltd.
Varma Marine
Vinner Marine
Vitality Aquaculture Pvt. Ltd.
VKM Foods Private Limited
VRC Marine Foods LLP
West Coast Fine Foods (India) Private Limited
West Coast Frozen Foods Private Limited
Zeal Aqua Limited

[FR Doc. 2023–25801 Filed 11–21–23; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–533–873]

Certain Cold-Drawn Mechanical Tubing of Carbon and Alloy Steel From India: Final Results of Antidumping Duty Administrative Review; 2021–2022

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

SUMMARY: The U.S. Department of Commerce (Commerce) determines that Goodluck India Limited (Goodluck) and Tube Products of India, Ltd., a unit of Tube Investments of India Limited (collectively, TII), made sales of subject merchandise in the United States at prices below normal value during the period of review (POR) June 1, 2021, through May 31, 2022.

DATES: Applicable November 22, 2023.

FOR FURTHER INFORMATION CONTACT: Alexis Cherry or Samantha Kinney, 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) 482–0607 or (202) 482–5305, respectively.

SUPPLEMENTARY INFORMATION:

Background

On July 7, 2023, Commerce published the preliminary results of the 2021–2022 administrative review of the antidumping duty order on certain cold-drawn mechanical tubing of carbon and alloy steel (cold-drawn mechanical tubing) from India, covering two producers/exporters, Goodluck and TII.[1] For the events that occurred since Commerce published the *Preliminary Results, see* the Issues and Decision Memorandum.[2] Commerce conducted this review in accordance with section 751(a)(1)(B) of the Tariff Act of 1930, as amended (the Act).

Scope of the Order [3]

The merchandise subject to the *Order* is cold-drawn mechanical tubing from India. The product is currently classified under the Harmonized Tariff Schedule of the United States (HTSUS) subheadings: 7304.31.3000, 7304.31.6050, 7304.51.1000, 7304.51.5005, 7304.51.5060, 7306.30.5015, 7306.30.5020, and 7306.50.5030. Subject merchandise may also enter under 7306.30.1000 and 7306.50.1000. The HTSUS subheadings above are provided for convenience and customs purposes only. The written description of the scope of the *Order* is dispositive. A full description of the scope of the *Order* is contained in the Issues and Decision Memorandum.

Analysis of Comments Received

All issues raised by parties in the case and rebuttal briefs are addressed in the Issues and Decision Memorandum. A list of the issues addressed in the Issues and Decision Memorandum is included in the appendix to this notice. The Issues and Decision Memorandum is a public document and is on file electronically via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at *https://access.trade.gov.* In addition, a complete version of the Issues and Decision Memorandum can be accessed directly at *https://access.trade/gov/public/FRNoticesListLayout.aspx.*

Changes Since the Preliminary Results

Based on our analysis of the comments received and our verification findings, Commerce made certain revisions to the margin calculations for Goodluck and TII. The Issues and Decision Memorandum contains descriptions of these revisions.

Final Results of Review

We determine that the following estimated weighted-average dumping margins exists for the period June 1, 2021, through May 31, 2022:

[1] *See Certain Cold-Drawn Mechanical Tubing of Carbon and Alloy Steel from India: Preliminary Results of Antidumping Duty Administrative Review; 2021–2022,* 88 FR 43295 (July 7, 2023) (*Preliminary Results*), and accompanying Preliminary Decision Memorandum.

[2] *See* Memorandum, ''Issues and Decision Memorandum for the Final Results of Antidumping Duty Administrative Review of Certain Cold-Drawn Mechanical Tubing of Carbon and Alloy Steel from India; 2021–2022,'' dated concurrently with, and hereby adopted by, this notice (Issues and Decision Memorandum).

[3] *See Certain Cold-Drawn Mechanical Tubing of Carbon and Alloy Steel from the People's Republic of China, the Federal Republic of Germany, India, Italy, the Republic of Korea, and Switzerland: Antidumping Duty Orders; and Amended Final Determinations of Sales at Less Than Fair Value for the People's Republic of China and Switzerland,* 83 FR 26962 (June 11, 2018) (*Order*).

Producer/exporter	Weighted-average dumping; margin (percent)
Goodluck India Limited[4]	0.61
Tube Products of India, Ltd., a unit of Tube Investments of India Limited	4.14

Disclosure

We intend to disclose the calculations performed within five days of the date of publication of this notice to parties in this proceeding, in accordance with 19 CFR 351.224(b).

Assessment Rates

Commerce has determined, and U.S. Customs and Border Protection (CBP) shall assess, antidumping duties on all appropriate entries in accordance with section 751(a)(2)(C) of the Act and 19 CFR 351.212(b). Commerce intends to issue assessment instructions to CBP no earlier than 35 days after the date of publication of the final results of this review in the **Federal Register**. If a timely summons is filed at the U.S. Court of International Trade, the assessment instructions will direct CBP not to liquidate relevant entries until the time for parties to file a request for a statutory injunction has expired (*i.e.,* within 90 days of publication).

Pursuant to 19 CFR 351.212(b)(1), where the respondent reported the entered value of its U.S. sales, we calculated importer-specific *ad valorem* duty assessment rates based on the ratio of the total amount of dumping calculated for the examined sales to the total entered value of the sales for which entered value was reported. Where the respondent did not report entered value, we calculated importer-specific per-unit duty assessment rates based on the ratio of the total amount of antidumping duties calculated for the examined sales to the total quantity of those sales. Where an importer-specific assessment rate is *de minimis* (*i.e.,* less than 0.5 percent), the entries by that importer will be liquidated without regard to antidumping duties. To determine whether an importer-specific per-unit duty assessment rate is *de minimis,* we calculated an estimated entered value.

Consistent with Commerce's clarification of its assessment practice, for entries of subject merchandise during the POR produced by Goodluck or TII for which they did not know the merchandise was destined for the United States, we will instruct CBP to liquidate unreviewed entries at the all-others rate if there is no rate for the intermediate company(ies) involved in the transaction.[5]

Cash Deposit Requirements

The following cash deposit requirements will be effective for all shipments of cold-drawn mechanical tubing from India 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 Goodluck and TII will be equal to the weighted-average dumping margin established for each company in the final results of the review; (2) for merchandise exported by producers or exporters not covered in this review but covered in a prior completed segment of the proceeding, the cash deposit rate will continue to be the company-specific rate published in the completed segment for the most recent period; (3) if the exporter is not a firm covered in this review or the original less-than-fair-value (LTFV) investigation, but the producer is, then the cash deposit rate will be the rate established in the completed segment for the most recent period for the producer of the merchandise; (4) the cash deposit rate for all other producers or exporters will continue to be 5.87 percent, the all-others rate established in the LTFV investigation in this proceeding.[6] These cash deposit requirements, when imposed, shall remain in effect until further notice.

Notification to Importers

This notice serves as a final reminder to importers of their responsibility under 19 CFR 351.402(f)(2) to file a certificate regarding the reimbursement of antidumping and/or countervailing duties prior to liquidation of the relevant entries during this POR. Failure to comply with this requirement could result in Commerce's presumption that reimbursement of antidumping and/or countervailing duties occurred and the subsequent assessment of double antidumping duties, and/or an increase in the amount of antidumping duties by the amount of the countervailing duties.

Administrative Protective Order

This notice also serves as a reminder to parties subject to an 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), which continues to govern business proprietary information in this segment of the proceeding. Timely written notification of the return or destruction of APO materials, or conversion to judicial protective order, is hereby requested. Failure to comply with the regulations and terms of an APO is a violation subject to sanction.

Notification to Interested Parties

We are issuing and publishing these results of administrative review in accordance with sections 751(a)(1) and 777(i) of the Act, and 19 CFR 351.221(b)(5).

Dated: November 16, 2023.

Abdelali Elouaradia,

Deputy Assistant Secretary for Enforcement and Compliance.

Appendix

List of Topics Discussed in the Issues and Decision Memorandum

[FR Doc. 2023–25840 Filed 11–21–23; 8:45 am]

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[4] Entries for Goodluck India Limited may have been made under the following company names: Goodluck India Limited; Good Luck Steel Tubes Limited; and Good Luck Industries.

[5] *See Antidumping and Countervailing Duty Proceedings: Assessment of Antidumping Duties,* 68 FR 23954 (May 6, 2003).

[6] *See Order,* 83 FR at 26962, 26965.

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XD552]

Marine Mammals; File No. 27514

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

ACTION: Notice; receipt of application.

SUMMARY: Notice is hereby given that Heather E. Liwanag, Ph.D., California Polytechnic State University, 1 Grand Avenue, San Luis Obispo, CA 93407–0401, has applied in due form for a permit to conduct research on northern elephant seals (*Mirounga angustirostris*) in California.

DATES: Written comments must be received on or before December 22, 2023.

ADDRESSES: The application and related documents are available for review by selecting ''Records Open for Public Comment'' from the ''Features'' box on the Applications and Permits for Protected Species (APPS) home page,

https://apps.nmfs.noaa.gov, and then selecting File No. 27514 from the list of available applications. These documents are also available upon written request via email to *NMFS.Pr1Comments@noaa.gov.*

Written comments on this application should be submitted via email to *NMFS.Pr1Comments@noaa.gov.* Please include File No. 27514 in the subject line of the email comment.

Those individuals requesting a public hearing should submit a written request via email to *NMFS.Pr1Comments@noaa.gov.* The request should set forth the specific reasons why a hearing on this application would be appropriate.

FOR FURTHER INFORMATION CONTACT: Jennifer Skidmore or Shasta McClenahan, Ph.D., (301) 427–8401.

SUPPLEMENTARY INFORMATION: The subject permit is requested under the authority of the Marine Mammal Protection Act of 1972, as amended (MMPA; 16 U.S.C. 1361 *et seq.*), the regulations governing the taking and importing of marine mammals (50 CFR part 216), and the Fur Seal Act of 1966, as amended (16 U.S.C. 1151 *et seq.*).

The applicant requests a 5 year permit to study northern elephant seals in California including Piedras Blancas, Gorda, Vandenberg Air Force Base, and the Channel Islands. Research would be conducted year-round on all age classes and both sexes, with increased frequency and effort during the breeding season (December–April). Research will include behavioral observations, acoustics recordings and playbacks, marking, unmanned aircraft systems, capture, measurements, instrumentation, ultrasound, and sampling (blood, scat, urine, swabs, fur, vibrissae) for health monitoring and research. Two unintentional mortality takes are requested per year not to exceed five over the duration of the permit. In addition, salvage, import, export, and receipt of pinniped parts (any species) is requested for scientific research. The following species may also be unintentionally harassed during research: California sea lions (*Zalophus californianus*), harbor seals (*Phoca vitulina*), and northern fur seals (*Callorhinus ursinus*). See the take table for complete numbers of animals requested by species, life stage, and procedure.

In compliance with the National Environmental Policy Act of 1969 (42 U.S.C. 4321 *et seq.*), an initial determination has been made that the activity proposed is categorically excluded from the requirement to prepare an environmental assessment or environmental impact statement.

Concurrent with the publication of this notice in the **Federal Register**, NMFS is forwarding copies of the application to the Marine Mammal Commission and its Committee of Scientific Advisors.

Dated: November 16, 2023.

Julia M. Harrison,

Chief, Permits and Conservation Division, Office of Protected Resources, National Marine Fisheries Service.

[FR Doc. 2023–25783 Filed 11–21–23; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

Agency Information Collection Activities; Submission to the Office of Management and Budget (OMB) for Review and Approval; Comment Request; Papahānaumokuākea Marine National Monument Permit Application and Reports for Permits

The Department of Commerce will submit the following information collection request to the Office of Management and Budget (OMB) for review and clearance in accordance with the Paperwork Reduction Act of 1995, on or after the date of publication of this notice. We invite the general public and other Federal agencies to comment on proposed and continuing information collections, which helps us assess the impact of our information collection requirements and minimize the public's reporting burden. Public comments were previously requested via the **Federal Register** on August 28, 2023 during a 60-day comment period. This notice allows for an additional 30 days for public comments.

Agency: National Oceanic & Atmospheric Administration (NOAA), Commerce.

Title: Papahānaumokuākea Marine National Monument Permit Application and Reports for Permits.

OMB Control Number: 0648–0548.

Form Number(s): None.

Type of Request: Regular submission, extension of a current information collection.

Number of Respondents: 411.

Average Hours per Response: Conservation and Management and Education (''general'' permits), 5 hours; Special Ocean Use permits, 10 hours; Native Hawaiian Practices permits, 8 hours; Recreation permits, 6 hours; permit modification requests and final reports, 10 hours; and annual reports, 5 hours.

Total Annual Burden Hours: 1,343.

Needs and Uses: This request is for an extension of a currently approved information collection. The National Oceanic and Atmospheric Administration (NOAA) Office of National Marine Sanctuaries (ONMS) is sponsoring the information collection as described herein. ONMS manages national marine sanctuaries pursuant to the purposes and policies of the National Marine Sanctuaries Act (NMSA, 16 U.S.C. 1431 *et seq.*). President Bush established the Papahānaumokuākea Marine National Monument (Monument) through Presidential Proclamation 8031 (Proclamation) dated June 15, 2006, (71 FR 36443, June 26, 2006) under the authority of the Antiquities Act (Act) (54 U.S.C. 320301). The Proclamation reserves all lands and interests in lands owned or controlled by the Government of the United States in the Northwestern Hawaiian Islands (NWHI), including emergent and submerged lands and waters, out to a distance of approximately 50 nautical miles (nmi) (93 km) from the islands. The boundaries of the Monument as described in Presidential Proclamation 8031 are 100 miles (160 km) wide and extend approximately 1200 miles (1931 km) around coral islands, seamounts, banks, and shoals. The area includes the Northwestern Hawaiian Islands Coral Reef Ecosystem Reserve, the Midway Atoll National Wildlife Refuge, the Hawaiian Islands National Wildlife Refuge, and the Battle of Midway National Memorial.

The Proclamation includes restrictions and prohibitions regarding activities in the Monument consistent with the authority provided by the Act. The Proclamation prohibits access to the Monument except when passing through the Monument without interruption or as allowed via permit. Vessels passing through the Monument without interruption are required to notify NOAA and the U.S. Fish and Wildlife Service upon entering into and leaving the Monument. Pursuant to the Proclamation, individuals wishing to access the Monument to conduct certain regulated activities must first apply for and be granted a permit. Applicants must also certify compliance with certain vessel monitoring system requirements.

The information submitted in permit applications will, in general, be used at the time the application is submitted to make a final decision on the application. Some of the information may also be used subsequent to the initial decision making to inform management actions or decision making. For example, a survey of a

project location by one permit applicant may be used by the agency in the future to respond to a vessel grounding in the same area in addition to facilitating the agency's decision on that application. Information submitted in a report will be used to periodically assess the permittee's compliance with permit terms and conditions and to assist in evaluating the appropriateness of the permitted activity.

Affected Public: Individuals, non-profit institutions; Federal, State, local, government, Native Hawaiian organizations; business or other for-profit organizations.

Frequency: On occasion. Permittees are required to submit a summary report due 30 days after the expiration of their permit; and an annual report due by December 31st for each year their permit is active.

Respondent's Obligation: Required to Obtain or Retain Benefits.

Legal Authority: 54 U.S.C. 320301 *et seq.;* 16 U.S.C. 1801 *et seq.;* 16 U.S.C. 742f, 16 U.S.C. 742l; 16 U.S.C. 1431 *et seq.*

This information collection request may be viewed at *www.reginfo.gov.* Follow the instructions to view the Department of Commerce collections currently under review by OMB.

Written comments and recommendations for the proposed information collection should be submitted within 30 days of the publication of this notice on the following website *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function and entering either the title of the collection or the OMB Control Number 0648–0548.

Sheleen Dumas,

Department PRA Clearance Officer, Office of the Under Secretary for Economic Affairs, Commerce Department.

[FR Doc. 2023–25848 Filed 11–21–23; 8:45 am]

BILLING CODE 3510–NK–P

DEPARTMENT OF DEFENSE

Department of the Army

Advisory Committee on Arlington National Cemetery Meeting Notice

AGENCY: Department of the Army, DoD.

ACTION: Notice of open committee meeting.

SUMMARY: The Department of the Army is publishing this notice to announce the following meeting of the Advisory Committee on Arlington National Cemetery (ACANC). This meeting is open to the public. For more information, please visit: *https://www.arlingtoncemetery.mil/About/Advisory-Committee-on-Arlington-National-Cemetery/ACANC-Meetings.*

DATES: The ACANC will meet on Thursday, December 7, 2023, from 1:00 p.m. to 4:00 p.m. Eastern Time in the Multipurpose Room of the Welcome Center at Arlington National Cemetery, Arlington, Virginia 22211.

FOR FURTHER INFORMATION CONTACT: Ms. Renea Yates, Designated Federal Official (DFO) for the ACANC, or Mr. Matthew Davis, Alternate Designated Federal Official (ADFO) for the ACANC, Arlington National Cemetery (ANC), Arlington, VA 22211; by email at *matthew.r.davis.civ@army.mil;* or by phone at 1–877–907–8585.

SUPPLEMENTARY INFORMATION: This meeting is being held under the provisions of the Federal Advisory Committee Act (FACA; 5 U.S.C. 10), the Government in the Sunshine Act of 1976 (5 U.S.C. 552b), and 41 CFR 102–3.150.

Purpose of the Meeting: The ACANC provides independent advice and recommendations to the Secretary of the Army independent advice and recommendations on matters related to ANC, including, but not limited to, cemetery administration, the erection of memorials at the cemetery, and master planning for the cemetery. The Secretary of the Army may act on the Committee's advice and recommendations.

Agenda: The Committee will receive a year-in-review briefing regarding ANC, review a road-designation proposal based on the congressional mandate to implement all Naming Commission recommendations, and review a commemorative works proposal for the Protestant and Catholic Chaplains Monuments in the context of Public Law 117–81, Section 584.

Public's Accessibility to the Meeting: Pursuant to FACA and 41 CFR 102–3.140 through 102–3.165, this meeting is open to the public.

Procedures for Attendance and Public Comment: To attend this meeting, contact Mr. Matthew Davis, the ADFO. (See the information listed in the **FOR FURTHER INFORMATION CONTACT** section; email is preferred.) Individuals will be asked to submit their full name, organization, email address, and phone number to attend. Public attendance will be via physical presence.

For additional information about public access procedures, contact Mr. Matthew Davis, the ADFO. (See the information listed in the **FOR FURTHER INFORMATION CONTACT** section; email is preferred.)

Written Comments and Statements: Pursuant to 5 U.S.C. 1009(a)(3), 41 CFR 102–3.105(j), and 41 CFR 102–3.140, the public or interested organizations may submit written comments or statements to the ACANC either in response to the stated agenda of the open meeting or regarding the ACANC's mission in general. Written comments or statements should be submitted to Mr. Matthew Davis, the ADFO. (See the information listed in the **FOR FURTHER INFORMATION CONTACT** section; email is preferred.) Each page of the comment or statement must include the author's name, title or affiliation, address, and daytime phone number. Written comments or statements being submitted in response to the agenda set forth in this notice must be received by the ADFO at least seven business days prior to the meeting to be considered by the ACANC. Written comments or statements received after this date may not be provided to the ACANC until its next meeting. The DFO will review all timely written comments or statements with the ACANC Chairperson and will ensure such comments or statements are provided to all ACANC members before the meeting.

Pursuant to 41 CFR 102–3.140d, the ACANC is not obligated to allow any member of the public to speak or otherwise address the ACANC during the meeting. Members of the public may be permitted to make verbal comments during these meetings and if allowed, verbal comments may only be made at the time and in the manner described below. If a member of the public is interested in making a verbal comment at the open meeting, the individual must submit a request to the ADFO with a brief statement of the subject matter to be addressed by the comment. (See the information listed in the **FOR FURTHER INFORMATION CONTACT** section; email is preferred.) The request must be submitted to the ADFO at least three business days before the meeting. The ADFO will log each request in the order received. In consultation with the Chairperson(s), the DFO will determine whether the subject matter of each comment is relevant to the ACANC mission and/or to the agenda of this public meeting. Members of the public who asked to make a verbal comment and whose comments are deemed relevant under the process described above will be invited to speak in the order in which the ADFO received their request. The appropriate Chairperson(s)

may allot a specific amount of time for verbal comments.

James W. Satterwhite, Jr.,

Army Federal Register Liaison Officer.

[FR Doc. 2023–25837 Filed 11–21–23; 8:45 am]

BILLING CODE 3711–02–P

DEPARTMENT OF DEFENSE

Department of the Army

[Docket ID: USA–2023–HQ–0011]

Submission for OMB Review; Comment Request

AGENCY: Department of the Army, Department of Defense (DoD).

ACTION: 30-Day information collection notice.

SUMMARY: The DoD has submitted to the Office of Management and Budget (OMB) for clearance the following proposal for collection of information under the provisions of the Paperwork Reduction Act.

DATES: Consideration will be given to all comments received by December 22, 2023.

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

FOR FURTHER INFORMATION CONTACT: Angela Duncan, 571–372–7574, *whs.mc-alex.esd.mbx.dd-dod-information-collections@mail.mil.*

SUPPLEMENTARY INFORMATION:

Title; Associated Form; and OMB Number: ArmyFit Program Azimuth Check Survey; OMB Control Number: 0702–AFIT.

Type of Request: New.

Number of Respondents: 500,000.

Responses per Respondent: 1.

Annual Responses: 500,000.

Average Burden per Response: 15 minutes.

Annual Burden Hours: 125,000.

Needs and Uses: This collection supports the mission of the Army Resiliency Directorate (ARD), HQDA G–1, to improve the readiness of the force and quality of life for the soldiers. ARD owns the Army Fitness Platform (ArmyFit). ArmyFit hosts the Global Assessment Tool (GAT), which is an assessment promoting self-development through its user feedback and enables the creation of a customized ArmyFit profile that directs individuals to tailored self-development and training resources for soldiers, their families, and Army civilians. The Family GAT is a self-appraisal survey for assessing an individual's fitness in dimensions of strength: physical, emotional, social, spiritual, and family. It is a tool for building resilience. The survey is taken by all Soldiers and offered to family members, Department of the Army Civilians, and contractors.

Affected Public: Individuals or households.

Frequency: On occasion.

Respondent's Obligation: Voluntary.

OMB Desk Officer: Ms. Jasmeet Seehra.

You may also submit comments and recommendations, identified by Docket ID number and title, by the following method:

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

Instructions: All submissions received must include the agency name, Docket ID number, and title for this **Federal Register** document. The general policy for comments and other submissions from members of the public is to make these submissions available for public viewing on the internet at *http://www.regulations.gov* as they are received without change, including any personal identifiers or contact information.

DoD Clearance Officer: Ms. Angela Duncan.

Requests for copies of the information collection proposal should be sent to Ms. Duncan at *whs.mc-alex.esd.mbx.dd-dod-information-collections@mail.mil.*

Dated: November 16, 2023.

Aaron T. Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2023–25793 Filed 11–21–23; 8:45 am]

BILLING CODE 6001–FR–P

DEPARTMENT OF DEFENSE

Office of the Secretary

[Docket ID: DoD–2023–OS–0115]

Proposed Collection; Comment Request

AGENCY: National Defense University (NDU), Chairman of the Joint Chiefs of Staff (CJCS), Department of Defense (DoD).

ACTION: 60-Day information collection notice.

SUMMARY: In compliance with the *Paperwork Reduction Act of 1995,* the NDU announces a proposed public information collection and seeks public comment on the provisions thereof. Comments are invited on: whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; the accuracy of the agency's estimate of the burden of the proposed information collection; ways to enhance the quality, utility, and clarity of the information to be collected; and ways to minimize the burden of the information collection on respondents, including through the use of automated collection techniques or other forms of information technology.

DATES: Consideration will be given to all comments received by January 22, 2024.

ADDRESSES: You may submit comments, identified by docket number and title, by any of the following methods:

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

Mail: Department of Defense, Office of the Assistant to the Secretary of Defense for Privacy, Civil Liberties, and Transparency, Regulatory Directorate, 4800 Mark Center Drive, Mailbox #24, Suite 08D09, Alexandria, VA 22350–1700.

Instructions: All submissions received must include the agency name, docket number and title for this **Federal Register** document. The general policy for comments and other submissions from members of the public is to make these submissions available for public viewing on the internet at *http://www.regulations.gov* as they are received without change, including any personal identifiers or contact information.

FOR FURTHER INFORMATION CONTACT: To request more information on this proposed information collection or to obtain a copy of the proposal and associated collection instruments, please write to National Defense University, 300 5th Avenue SW, Building 62, Washington, DC 20319, ATTN: LTC Ann Summers, or call (202) 685–3323.

SUPPLEMENTARY INFORMATION:

Title; Associated Form; and OMB Number: NDU Foreign Delegation Visit Request; OMB Control Number 0704–0600.

Needs and Uses: Foreign delegation visits help to conduct analysis for regional and DoD academic accreditations, create reports for University leadership to aid in the development of effective curricula, and facilitate academic completion requirements. The foreign visit request form is primarily used to collect

information on visiting delegations for protocol purposes and to ensure proper logistic support for the visiting delegation. The respondents in our collection are generally Foreign Nationals visiting the NDU to meet with NDU leadership. The collection instrument is a PDF document sent over email. Respondents access the PDF directly and return via email. Once the document is returned, the information is used to create a customized visit for the delegation and informs a read ahead document for NDU leadership. Information and electronic records are maintained in the NDU Enterprise Information System (NEIS), the NDU network. The NDU NEIS encompasses all hardware and software utilized to support the academic and business information hosted in university-owned systems.

Affected Public: Individuals or households.

Annual Burden Hours: 45.

Number of Respondents: 45.

Responses per Respondent: 1.

Annual Responses: 45.

Average Burden per Response: 1 hour.

Frequency: On occasion.

Dated: November 14, 2023.

Aaron T. Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2023–25812 Filed 11–21–23; 8:45 am]

BILLING CODE 6001–FR–P

DEPARTMENT OF DEFENSE

Office of the Secretary

[Docket ID: DoD–2023–HA–0116]

Proposed Collection; Comment Request

AGENCY: Office of the Assistant Secretary of Defense for Health Affairs (OASD(HA)), Department of Defense (DoD).

ACTION: 60-Day information collection notice.

SUMMARY: In compliance with the *Paperwork Reduction Act of 1995,* the Defense Health Agency (DHA) announces a proposed public information collection and seeks public comment on the provisions thereof. Comments are invited on: whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; the accuracy of the agency's estimate of the burden of the proposed information collection; ways to enhance the quality, utility, and clarity of the information to be collected; and ways to minimize the burden of the information collection on respondents, including through the use of automated collection techniques or other forms of information technology.

DATES: Consideration will be given to all comments received by January 22, 2024.

ADDRESSES: You may submit comments, identified by docket number and title, by any of the following methods:

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

Mail: Department of Defense, Office of the Assistant to the Secretary of Defense for Privacy, Civil Liberties, and Transparency, Regulatory Directorate, 4800 Mark Center Drive, Mailbox #24, Suite 08D09, Alexandria, VA 22350–1700.

Instructions: All submissions received must include the agency name, docket number and title for this **Federal Register** document. The general policy for comments and other submissions from members of the public is to make these submissions available for public viewing on the internet at *http://www.regulations.gov* as they are received without change, including any personal identifiers or contact information.

FOR FURTHER INFORMATION CONTACT: To request more information on this proposed information collection or to obtain a copy of the proposal and associated collection instruments, please write to Defense Health Agency, 7700 Arlington Blvd., Falls Church, VA 22042, Amanda Grifka, 703–681–1771.

SUPPLEMENTARY INFORMATION:

Title; Associated Form; and OMB Number: TRICARE Inpatient Satisfaction Survey (TRISS); OMB Control Number: 0720–TRSS.

Needs and Uses: The DHA administers the TRICARE TRISS survey to understand perceptions of inpatient care among Military Health System (MHS) users. The survey instrument adheres to the methodological and analytical protocols and questionnaire items mandated by the industry standard Hospital Consumer Assessment of Healthcare Providers and Systems protocol. Developed by the Centers for Medicare and Medicaid Services and the Agency for Healthcare Research and Quality, the program provides valid and reliable self-reported experience ratings of inpatient experiences.

As a result, the TRISS program allows objective and meaningful comparisons between hospitals, in areas that are important to consumers. Results are published online, and the public can view them at *https://www.medicare.gov/care-compare/.* But perhaps most significantly, the comparative scores and findings can be used by MHS leadership to improve care as well as by beneficiaries to make informed choices. TRISS is designed to provide actionable performance feedback to improve overall quality of health care. The main goals of the TRISS are to:

- Provide comparable data on the patient's perspective on care that allows objective and meaningful comparisons between hospitals on domains that are important to beneficiaries.
- Establish a uniform measure of user satisfaction with received healthcare services.
- Public reporting of the survey results is designed to create incentives for Military Treatment Facilities (MTFs) to improve their quality of care.

The study population consists of military personnel, their family members, and eligible retirees and their family members with a recent overnight hospitalization. The survey is administered to patients after a recent discharge from either a MTF or a civilian hospital to gather information about their experience of the care they received. Data are reported quarterly to track trends over time.

Affected Public: Individuals or households.

Annual Burden Hours: 12,720.

Number of Respondents: 63,600.

Responses per Respondent: 1.

Annual Responses: 63,600.

Average Burden per Response: 12 minutes.

Frequency: On occasion.

Dated: November 14, 2023.

Aaron T. Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2023–25811 Filed 11–21–23; 8:45 am]

BILLING CODE 6001–FR–P

DEPARTMENT OF DEFENSE

Office of the Secretary

[Docket ID: DoD–2023–OS–0114]

Proposed Collection; Comment Request

AGENCY: National Defense University (NDU), Chairman of the Joint Chiefs of Staff (CJCS), Department of Defense (DoD).

ACTION: 60-Day information collection notice.

SUMMARY: In compliance with the *Paperwork Reduction Act of 1995,* the NDU announces a proposed public information collection and seeks public comment on the provisions thereof.

Comments are invited on: whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; the accuracy of the agency's estimate of the burden of the proposed information collection; ways to enhance the quality, utility, and clarity of the information to be collected; and ways to minimize the burden of the information collection on respondents, including through the use of automated collection techniques or other forms of information technology.

DATES: Consideration will be given to all comments received by January 22, 2024.

ADDRESSES: You may submit comments, identified by docket number and title, by any of the following methods:

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

Mail: Department of Defense, Office of the Assistant to the Secretary of Defense for Privacy, Civil Liberties, and Transparency, Regulatory Directorate, 4800 Mark Center Drive, Mailbox #24, Suite 08D09, Alexandria, VA 22350–1700.

Instructions: All submissions received must include the agency name, docket number and title for this **Federal Register** document. The general policy for comments and other submissions from members of the public is to make these submissions available for public viewing on the internet at *http://www.regulations.gov* as they are received without change, including any personal identifiers or contact information.

FOR FURTHER INFORMATION CONTACT: To request more information on this proposed information collection or to obtain a copy of the proposal and associated collection instruments, please write to NDU, 300 5th Avenue SW, Building 62, Washington, DC 20319, ATTN: LTC Ann Summers, or call (202) 685–3323.

SUPPLEMENTARY INFORMATION:

Title; Associated Form; and OMB Number: Master's Degree Application Form for International Students; OMB Control Number: 0704–0599.

Needs and Uses: This form is used to collect the information required to admit international students to an NDU master's degree program. The respondents are prospective international students who wish to be admitted to an NDU master's degree program. They respond to this information collection in partial fulfillment of NDU application and admissions requirements. The completed collection instrument is processed by the NDU registrars and a committee of NDU faculty who review the application in consideration of admission to a master's degree program. The successful effect of this information collection is to satisfy NDU master's degree application requirements for international students so that an admissions decision can be made.

Affected Public: Individuals or households.

Annual Burden Hours: 30.

Number of Respondents: 120.

Responses per Respondent: 1.

Annual Responses: 120.

Average Burden per Response: 15 minutes.

Frequency: Annually.

Dated: November 14, 2023.

Aaron T. Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2023–25808 Filed 11–21–23; 8:45 am]

BILLING CODE 6001–FR–P

DEPARTMENT OF DEFENSE

Department of the Navy

[Docket ID: USN–2023–HQ–0022]

Proposed Collection; Comment Request

AGENCY: Department of the Navy (DON), Department of Defense (DoD).

ACTION: 60-Day information collection notice.

SUMMARY: In compliance with the *Paperwork Reduction Act of 1995,* the DON announces a proposed public information collection and seeks public comment on the provisions thereof. Comments are invited on: whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; the accuracy of the agency's estimate of the burden of the proposed information collection; ways to enhance the quality, utility, and clarity of the information to be collected; and ways to minimize the burden of the information collection on respondents, including through the use of automated collection techniques or other forms of information technology.

DATES: Consideration will be given to all comments received by January 22, 2024.

ADDRESSES: You may submit comments, identified by docket number and title, by any of the following methods:

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

Mail: Department of Defense, Office of the Assistant to the Secretary of Defense for Privacy, Civil Liberties, and Transparency, Regulatory Directorate, 4800 Mark Center Drive, Mailbox #24, Suite 08D09, Alexandria, VA 22350–1700.

Instructions: All submissions received must include the agency name, docket number and title for this **Federal Register** document. The general policy for comments and other submissions from members of the public is to make these submissions available for public viewing on the internet at *http://www.regulations.gov* as they are received without change, including any personal identifiers or contact information.

FOR FURTHER INFORMATION CONTACT: To request more information on this proposed information collection or to obtain a copy of the proposal and associated collection instruments, please write to Office of the DON Information Management Control Officer, 2000 Navy Pentagon, Rm. 4E563, Washington, DC 20350, ATTN: Ms. Sonya Martin, or call 703–614–7585.

SUPPLEMENTARY INFORMATION:

Title; Associated Form; and OMB Number: Naval Officers as Employees Survey; OMB Control Number: 0703–SDSU.

Needs and Uses: The proposed survey is sponsored by the Navy Chief of Information and originates out of the Navy's primary civilian public relations graduate education program at San Diego State University, where the Navy details public affairs officers annually in order to earn a master's degree. This study will explore the possible relationship between the Navy's digital communication subsidies, employee-organization relationships (EOR), and diversity, equity, inclusion, and belongingness (DEIB) in the officer ranks. Additionally, findings from this research may advance the Navy's understanding of how to use digital communication to improve DEIB and EOR in the officer corps. Only adults (those aged 18 years or older) are eligible to participate in the study. To get at this population, the researcher will study naval officers assigned to different types of units (*e.g.,* surface ships, aviation, submarines, special warfare, etc.) as they represent the key demographic desired for this study. Potential respondents will be recruited with the assistance of public affairs officers at type commands (TYCOMs) and fleets of these units. TYCOMs and fleets perform administrative, personnel, and operational training functions for a ''type'' of weapon system.

This study will employ a mixed-mode for collection of surveys, utilizing both an online survey hosted by Qualtrics and a paper-based survey method for when online completion of the survey is not ideal. Respondents will have an option to return the survey anonymously via mail. Data received from this survey will assist public relations researchers by gaining an understanding of EOR and DEIB in Naval officers from traditionally marginalized communities as well as advance employee-organization relationship theory.

Affected Public: Individuals or households.

Annual Burden Hours: 150.

Number of Respondents: 500.

Responses per Respondent: 1.

Annual Responses: 500.

Average Burden per Response: 18 minutes.

Frequency: Once.

Dated: November 14, 2023.

Aaron T. Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2023–25791 Filed 11–21–23; 8:45 am]

BILLING CODE 6001–FR–P

DEPARTMENT OF DEFENSE

Department of the Navy

[Docket ID: USN–2023–HQ–0019]

Proposed Collection; Comment Request

AGENCY: Department of the Navy (DON), Department of Defense (DoD).

ACTION: 60-Day information collection notice.

SUMMARY: In compliance with the *Paperwork Reduction Act of 1995,* the Navy Installations Command announces a proposed public information collection and seeks public comment on the provisions thereof. Comments are invited on: whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; the accuracy of the agency's estimate of the burden of the proposed information collection; ways to enhance the quality, utility, and clarity of the information to be collected; and ways to minimize the burden of the information collection on respondents, including through the use of automated collection techniques or other forms of information technology.

DATES: Consideration will be given to all comments received by January 22, 2024.

ADDRESSES: You may submit comments, identified by docket number and title, by any of the following methods:

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

Mail: Department of Defense, Office of the Assistant to the Secretary of Defense for Privacy, Civil Liberties, and Transparency, Regulatory Directorate, 4800 Mark Center Drive, Mailbox #24 Suite 08D09, Alexandria, VA 22350–1700.

Instructions: All submissions received must include the agency name, docket number and title for this FR document. The general policy for comments and other submissions from members of the public is to make these submissions available for public viewing on the internet at *http://www.regulations.gov* as they are received without change, including any personal identifiers or contact information.

FOR FURTHER INFORMATION CONTACT: To request more information on this proposed information collection or to obtain a copy of the proposal and associated collection instruments, please write to Office of the DON Information Management Control Officer, 2000 Navy Pentagon, Rm. 4E563, Washington, DC 20350, Ms. Barbara Figueroa or call 703–614–7885.

SUPPLEMENTARY INFORMATION:

Title; Associated Form; and OMB Number: Law Enforcement Officers Safety Act (LEOSA) Credential Program; SECNAV Form 5580/1; OMB Control Number: 0703–0067.

Needs and Uses: DON and the U.S. Marine Corps are requesting Office of Management and Budget (OMB) approval of the information collection to verify and validate eligibility of separated and retired DON law enforcement officers to ship, transport, possess or receive Government-issued or private firearms or ammunition. This will also verify and validate eligibility of separated, and retired DON law enforcement officers to receive DON endorsed law enforcement credentials, to include LEOSA credentials.

Affected Public: Individuals or households.

Annual Burden Hours: 450.

Number of Respondents: 900.

Responses per Respondent: 1.

Annual Responses: 900.

Average Burden per Response: 30 minutes.

Frequency: On occasion.

Dated: November 14, 2023.

Aaron T. Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2023–25790 Filed 11–21–23; 8:45 am]

BILLING CODE 6001–FR–P

DEPARTMENT OF DEFENSE

Department of the Navy

[Docket ID: USN–2023–HQ–0020]

Proposed Collection; Comment Request

AGENCY: Department of the Navy (DON), Department of Defense (DoD).

ACTION: 60-Day information collection notice.

SUMMARY: In compliance with the *Paperwork Reduction Act of 1995,* the Naval Health Research Center announces a proposed public information collection and seeks public comment on the provisions thereof. Comments are invited on: whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; the accuracy of the agency's estimate of the burden of the proposed information collection; ways to enhance the quality, utility, and clarity of the information to be collected; and ways to minimize the burden of the information collection on respondents, including through the use of automated collection techniques or other forms of information technology.

DATES: Consideration will be given to all comments received by January 22, 2024.

ADDRESSES: You may submit comments, identified by docket number and title, by any of the following methods:

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

Mail: Department of Defense, Office of the Assistant to the Secretary of Defense for Privacy, Civil Liberties, and Transparency, Regulatory Directorate, 4800 Mark Center Drive, Mailbox #24, Suite 08D09, Alexandria, VA 22350–1700.

Instructions: All submissions received must include the agency name, docket number and title for this **Federal Register** document. The general policy for comments and other submissions from members of the public is to make these submissions available for public viewing on the internet at *http://www.regulations.gov* as they are received without change, including any personal identifiers or contact information.

FOR FURTHER INFORMATION CONTACT: To request more information on this proposed information collection or to obtain a copy of the proposal and associated collection instruments, please write to Office of the DON Information Management Control Officer, 2000 Navy Pentagon, Rm. 4E563, Washington, DC 20350, ATTN: Ms. Sonya Martin, or call 703–614–7585.

SUPPLEMENTARY INFORMATION:

Title; Associated Form; and OMB Number: Challenges of Operational Environments Study; OMB Control Number: 0703–COPE.

Needs and Uses: The Challenges of Operational Environments Study is a longitudinal study that will assess stressors associated with different operational environments and their effect on mental and behavioral health. Because the operational environment of the Commands involved will change over time, the survey that is being submitted for approval has been designed to adapt similarly. The base survey will remain the same at every time point, while separate modules will be added according to a pre-determined phases (*i.e.,* maintenance period, sea trials, homeport shift, deployment, and post-deployment). Because the crew of the ships will change over time and participation is voluntary, some respondents may complete the survey at multiple time points, whereas others may complete it just once.

Affected Public: Individuals or households.

Annual Burden Hours: 4,167.

Number of Respondents: 5,000.

Responses per Respondent: 2.

Annual Responses: 10,000.

Average Burden per Response: 25 minutes.

Frequency: On occasion.

Dated: November 14, 2023.

Aaron T. Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2023–25794 Filed 11–21–23; 8:45 am]

BILLING CODE 3810–FR–P

DEPARTMENT OF DEFENSE

Department of the Navy

[Docket ID: USN–2023–HQ–0023]

Proposed Collection; Comment Request

AGENCY: Marine Junior Reserve Officer's Training Corps (MCJROTC), Department of Defense (DoD).

ACTION: 60-Day information collection notice.

SUMMARY: In compliance with the *Paperwork Reduction Act of 1995,* the MCJROTC announces a proposed public information collection and seeks public comment on the provisions thereof. Comments are invited on: whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; the accuracy of the agency's estimate of the burden of the proposed information collection; ways to enhance the quality, utility, and clarity of the information to be collected; and ways to minimize the burden of the information collection on respondents, including through the use of automated collection techniques or other forms of information technology.

DATES: Consideration will be given to all comments received by January 22, 2024.

ADDRESSES: You may submit comments, identified by docket number and title, by any of the following methods:

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

Mail: Department of Defense, Office of the Assistant to the Secretary of Defense for Privacy, Civil Liberties, and Transparency, Regulatory Directorate, 4800 Mark Center Drive, Mailbox #24, Suite 08D09, Alexandria, VA 22350–1700.

Instructions: All submissions received must include the agency name, docket number and title for this FR document. The general policy for comments and other submissions from members of the public is to make these submissions available for public viewing on the internet at *http://www.regulations.gov* as they are received without change, including any personal identifiers or contact information.

FOR FURTHER INFORMATION CONTACT: To request more information on this proposed information collection or to obtain a copy of the proposal and associated collection instruments, please write to Headquarters Marine Corps Records, Reports, Directives, and Forms Management section, 3000 Marine Corps, Pentagon Rm 2B253, Mr. Mark Kazzi, (571) 256–8883.

SUPPLEMENTARY INFORMATION:

Title; Associated Form; and OMB Number: Individual MCJROTC Instructor Evaluation Summary; NAVMC 10942; OMB Control Number: 0712–0004.

Needs and Uses: The information collection requirement is necessary to provide a written record of the overall performance of duty of MCJROTC instructors who are responsible for implementing the MCJROTC curriculum. The individual MCJROTC Instructor Evaluation Summary is completed by principles to evaluate the effectiveness of individual MCJROTC instructors. The form is further used as a performance related counseling tool and as a record of service performance to document performance and growth of individual MCJROTC instructors. Evaluating the performance of instructors is essential in ensuring that they provide quality training.

Affected Public: Individuals or households.

Annual Burden Hours: 509.

Number of Respondents: 1,018.

Responses per Respondent: 1.

Annual Responses: 1,108.

Average Burden per Response: 30 minutes.

Frequency: On occasion.

Dated: November 14, 2023.

Aaron T. Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2023–25809 Filed 11–21–23; 8:45 am]

BILLING CODE 6001–FR–P

DEPARTMENT OF DEFENSE

Department of the Navy

[Docket ID: USN–2023–HQ–0021]

Proposed Collection; Comment Request

AGENCY: Department of the Navy (DON), Department of Defense (DoD).

ACTION: 60-Day information collection notice.

SUMMARY: In compliance with the *Paperwork Reduction Act of 1995,* the Department of the Navy's Office of Military Awards announces a proposed public information collection and seeks public comment on the provisions thereof. Comments are invited on: whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; the accuracy of the agency's estimate of the burden of the proposed information collection; ways to enhance the quality, utility, and clarity of the information to be collected; and ways to minimize the burden of the information collection on respondents, including through the use of automated collection techniques or other forms of information technology.

DATES: Consideration will be given to all comments received by January 22, 2024.

ADDRESSES: You may submit comments, identified by docket number and title, by any of the following methods:

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

Mail: Department of Defense, Office of the Assistant to the Secretary of Defense for Privacy, Civil Liberties, and Transparency, Regulatory Directorate, 4800 Mark Center Drive, Mailbox #24, Suite 08D09, Alexandria, VA 22350–1700.

Instructions: All submissions received must include the agency name, docket number and title for this **Federal Register** document. The general policy for comments and other submissions from members of the public is to make these submissions available for public viewing on the internet at *http://www.regulations.gov* as they are received without change, including any personal identifiers or contact information.

FOR FURTHER INFORMATION CONTACT: To request more information on this proposed information collection or to obtain a copy of the proposal and associated collection instruments, please write to DON Information Management Control Office, 2000 Navy Pentagon, Washington, DC 20350, ATTN: Mrs. Sonya Martin or call 703–614–7585.

SUPPLEMENTARY INFORMATION:

Title; Associated Form; and OMB Number: Navy Personal Awards Form; OPNAV 1650/3; OMB Control Number: 0703–NPAF.

Needs and Uses: The purpose of DON military awards is to provide deserving members of the Naval Service recognition for qualifying acts of valor or non-combat heroism, for exceptionally meritorious achievement or service, and for arduous or otherwise special service. Nominations for Personal Military Decorations are submitted on the OPNAV 1650/3 for Service Members (active duty, retired, and veterans), Foreign Military, and Midshipmen. An award nomination package must include an Award Recommendation form, Summary of Action narrative justification, and a proposed citation. For all awards for heroism, combat or non-combat, notarized statements by at least two eyewitnesses must be included. Midshipmen in the Naval Reserve Officer Training (NROTC) are generally eligible for military awards only when serving under orders on active duty. As an exception to the general policy, when not on active duty NROTC midshipmen are eligible for Personal Military Decorations for acts of non-combat heroism on the same basis as inactive members of the Navy Reserve. If a decoration is approved, the referral Member of Congress (MoC) will be informed and the Navy or Marine Corps will make arrangements for an appropriate presentation ceremony. If the nomination, or request for upgrade, is disapproved, the MoC will be informed and provided the reason(s) for disapproval. The authority to complete this collection effort is given by SECNAVINST 1650.1J, DON Military Awards Policy; DoD Instruction 1348.33, DoD Military Decorations and Awards; and 10 U.S.C., Armed Forces.

Affected Public: Individuals or households.

Annual Burden Hours: 23.

Number of Respondents: 30.

Responses per Respondent: 1.

Annual Responses: 30.

Average Burden per Response: 45 minutes.

Frequency: On occasion.

Dated: November 14, 2023.

Aaron T. Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2023–25792 Filed 11–21–23; 8:45 am]

BILLING CODE 3810–FR–P

DEPARTMENT OF EDUCATION

[Docket No.: ED–2023–SCC–0197]

Agency Information Collection Activities; Submission to the Office of Management and Budget for Review and Approval; Comment Request; Early Childhood Longitudinal Study, Kindergarten Class of 2023–24 (ECLS–K:2024) Kindergarten and First-Grade National Data Collection and Transfer School Recruitment

AGENCY: National Center for Education Statistics (NCES), Department of Education (ED).

ACTION: Notice.

SUMMARY: In accordance with the Paperwork Reduction Act (PRA) of 1995, the Department is proposing a revision of a currently approved information collection request (ICR).

DATES: Interested persons are invited to submit comments on or before December 22, 2023.

ADDRESSES: Written comments and recommendations for proposed information collection requests should be submitted within 30 days of publication of this notice. Click on this link *www.reginfo.gov/public/do/PRAMain* to access the site. Find this information collection request (ICR) by selecting ''Department of Education'' under ''Currently Under Review,'' then check the ''Only Show ICR for Public Comment'' checkbox. *Reginfo.gov* provides two links to view documents related to this information collection request. Information collection forms and instructions may be found by clicking on the ''View Information Collection (IC) List'' link. Supporting statements and other supporting documentation may be found by clicking on the ''View Supporting Statement and Other Documents'' link.

FOR FURTHER INFORMATION CONTACT: For specific questions related to collection activities, please contact Carrie Clarady, (202) 245–6347.

SUPPLEMENTARY INFORMATION: The Department 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: Early Childhood Longitudinal Study, Kindergarten Class of 2023–24 (ECLS–K:2024) Kindergarten and First-Grade National Data Collection and Transfer School Recruitment.

OMB Control Number: 1850–0750.

Type of Review: Revision of a currently approved ICR.

Respondents/Affected Public: Individuals or households.

Total Estimated Number of Annual Responses: 157,586.

Total Estimated Number of Annual Burden Hours: 83,612.

Abstract: The Early Childhood Longitudinal Study (ECLS) program, conducted by the National Center for Education Statistics (NCES) within the Institute of Education Sciences (IES) of the U.S. Department of Education (ED), draws together information from multiple sources to provide rich, descriptive data on child development, early learning, and school progress. The ECLS program studies deliver national data on children's status at birth and at various points thereafter; children's transitions to nonparental care, early care and education programs, and school; and children's experiences and growth through the elementary grades. The Early Childhood Longitudinal Study, Kindergarten Class of 2023–24 (ECLS–K:2024) is the fourth cohort in the series of early childhood

longitudinal studies. The study will advance research in child development and early learning by providing a detailed and comprehensive source of current information on children's early learning and development, transitions into kindergarten and beyond, and progress through school. The ECLS–K:2024 will provide data about the population of children who will be kindergartners in the 2023–24 school year. The ECLS–K:2024 will focus on children's early school experiences continuing through the fifth grade, and will include collection of data from children, parents, teachers, and school administrators.

The request to conduct the first three national data collection rounds for the ECLS–K:2024 was approved on April 7, 2023 (OMB# 1850–0750 v.26). The ECLS–K:2024 fall kindergarten data collection will be conducted from August until December 2023, followed by the spring (March–July 2024) kindergarten round, and the spring (March–July 2025) first-grade round. Each of these rounds of data collection will involve advance school contacts, for example to conduct student sampling activities, collect teacher and school information, and locate families whose children may have moved schools. Future OMB packages will be submitted for the third-and fifth-grade field test (to be conducted in March–July 2026), as well as for the national spring (March–July 2027) third-grade round and the spring (March–July 2029) fifth-grade round.

This current revision request (accompanied by 30 days of public comment) is to update study respondent materials, web and paper surveys, and website designs that will be used in the kindergarten and first-grade data collection activities. Many of the revisions in this package were made based on analyses of the fall 2022 field test data (OMB# 1850–0750 v.25), which informed changes to the design of the surveys and child assessment. Other changes occurred after further discussion on operational procedures. Revisions to the study instruments (and to some extent, the respondent materials and websites) are largely limited to changes to the spring kindergarten materials; an additional revision request will be submitted to OMB for revisions to the spring first-grade materials as additional discussions on design and operational procedures continue. National data collection work completed to date will also inform these future revisions.

The requested changes do not affect the approved total cost to the federal government for conducting this study, but they do result in a small reduction to respondent burden.

Dated: November 17, 2023.

Stephanie Valentine,

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

[FR Doc. 2023–25799 Filed 11–21–23; 8:45 am]

BILLING CODE 4000–01–P

ELECTION ASSISTANCE COMMISSION

Help America Vote College Program Service Day Mini-Grant Program

AGENCY: Election Assistance Commission (EAC).

ACTION: Notice of funding opportunity.

SUMMARY: Through this Notice, EAC is announcing the fiscal year (FY) 2023 Help America Vote College Program (HAVCP) Service Day Mini-Grant Program (Mini-Grant) Notice of Funding Opportunity (NOFO).

DATES: Proposals must be submitted no later than 11:59 p.m. eastern time on Monday, December 18, 2023.

ADDRESSES: Proposals must be submitted to *HAVCP@eac.gov.*

FOR FURTHER INFORMATION CONTACT: Election Assistance Commission Office of Grants Management, Risa Garza, (202) 740–1483, or at *HAVCP@eac.gov.*

SUPPLEMENTARY INFORMATION:

A. Program Description

Assistance Listing Number: 90.400.

Funding Opportunity Number: EAC–23–002.

Funding Opportunity Title: Help America Vote College Program Service Day Mini-Grant Program.

1. Purpose of the Program. The Help America Vote College Program (HAVCP) was established in 2004, and through fiscal year 2009, distributed over $2.3 million to colleges and non-profits to recruit, train and support students serving as poll workers on Election Day. In 2023, the EAC introduced the HAVCP Service Day Mini-Grant (Mini-Grant) Program. The information in this NOFO is specific to the Service Day Mini-Grant Program. The Mini-Grant Program is designed to stimulate community action on college campuses and increase the visibility of the EAC's National Poll Worker Recruitment Day and Help America Vote Day. In 2023, the EAC will make an additional $1 million available for the Help America Vote College Program with $50,000 to $150,000 set aside for the Service Day Mini-Grant Program.

The purpose of this grant program is to: (1) Encourage students enrolled at institutions of higher education (including community colleges) to assist State and local governments in the administration of elections by serving as nonpartisan poll workers or assistants; (2) Encourage college students to become cognizant of the elections process and civic education, and to assist in the administration of elections in their community; and (3) Encourage state and local governments to use the services of the students participating in the program.

College Student means any individual enrolled either on a part-time or full-time basis in any undergraduate, graduate, or professional college accredited by an agency recognized by the U.S. Department of Education in the United States.

2. Statutory and Regulatory Authority. The U.S. Election Assistance Commission (EAC) anticipates the availability of $1 million dollars in discretionary grant funding, enacted in the 2023 Consolidated Appropriations Act (Pub. L. No: 117–328), to support the Help America Vote College Program (HAVCP) authorized in the Help America Vote Act of 2002 (HAVA), Public Law 107–252, Title V, Help America Vote College Program. Awards will be administered by the EAC.

3. Performance Measurement. HAVCP Service Day Mini-Grant Program awardees will be required to report on the total number of college student participants served through the funded Service Day activities. The number of students served could include college student participants interacting with staff/volunteers tabling, attending a presentation or roundtable, or engaging through digital (*i.e.,* social media, website), print (*i.e.,* college newspaper), and/or audio platforms (*i.e.,* radio show, podcast).

B. Federal Award Information

Service Day Program

Funding Instrument: Discretionary Mini-Grant.

Award Minimum: $3,000.

Award Maximum: $10,000.

Grant Period: 12 Months.

Anticipated Funding Available: $50,000-$150,000.

1. Funding Type. Funding will be provided in the form of a discretionary grant. EAC will authorize the Treasury Department to disburse funding identified in the agreement through the Payment Management System (PMS) to the applicant as an advance to be drawdown as expenses arise. Per 2 CFR 200, the timing and amount of advance

payments must be as close as is administratively feasible to the actual disbursements by the non-Federal entity for direct program or project costs and the proportionate share of any allowable indirect costs. The non-Federal entity must make timely payment to contractors in accordance with the contract provisions. Grantees will be able to request payments as often as practical for their program. Cash and in-kind match expenditures require the same documentation as Federal funds under 2 CFR 200. Grantees must request a drawdown of funds for incurred costs using the electronic Payment Management System (PMS). Prior to initial drawdown of funds, all Grantees must have secured online access to Payment Management System.

C. Eligibility Information

1. Eligible Applicants. EAC encourages applicants to forge robust partnerships to implement the grant and to sustain activities beyond the grant period of performance. The recommended partners for the HAVCP are institutions of higher education as defined in Section 101(a) of the Higher Education Act of 1965 (20 U.S.C. 1001); Nonprofit Organizations; Community and Technical Colleges and Systems; Historically Black Colleges and Universities (HBCUs); Hispanic-Serving Institutions (HSIs); Tribal Colleges and Universities (TCUs); State and Local Election Offices; and Other Minority Serving Institutions Program (MSIs) as designated by the Higher Education Act's Title III and V funding.

Priority Consideration. All selection criteria and application quality being equal, EAC will give priority consideration to projects from institutions and organizations that engage historically underrepresented groups, as defined by the Federal Government (See Appendix C), as poll workers. For the HAVCP Service Day Mini-Grant Program, the EAC will provide further priority consideration to applicants who have historically not been recipients of EAC funding. The EAC is interested in using the Mini-Grant opportunity to engage new organizations in supporting and improving the administration of elections. The HAVCP Service Day Mini-Grant Program will also provide priority consideration for organizations serving individuals or groups in an area of persistent poverty and/or historically disadvantaged community and for organizations serving individuals or groups in a rural area. The EAC is interested in using the Mini-Grant opportunity to engage organizations in locations where barriers to participation in the election process are frequently higher.

2. Cost Sharing or Matching. At the time of award, applicants must demonstrate either cash and/or in-kind contributions on-hand and/or commitments, or a combination thereof, to meet the required 10 percent match, based on the amount of Federal grant funds requested. Match must be met by the project end period.

EAC encourages applicants to leverage additional resources beyond the required match to supplement grant activities. Both matching and leveraged resources can come from a variety of sources, including, but not limited to the private sector (*e.g.,* businesses or industry associations); the philanthropic community (*e.g.,* foundations); and the non-profit sector (*e.g.,* community organizations or education and training institutions). Non-Federal, public-sector funds (*e.g.,* from States or local governments) may be used for matching funds, if necessary. Federal funds from other Federal agencies are not a permissible source of match, unless specifically authorized by the award pursuant to 2 CFR 200.306. Applicants may consult with EAC on sources of match to determine permissibility.

Grantees may recover indirect costs under this grant up to 10 percent of the total Federal share of the grant. If an applicant has an approved Federal indirect cost rate higher than 10 percent, the remainder of the indirect costs can be used as a matching contribution.

3. Other Requirements/Limitations. Applicants may not use any part of an award from the EAC to fund religious instruction, worship or proselytizing, voter registration, get out the vote (GOTV) drives, or other political activities that could be construed as lobbying. Project funds must be used for tasks and activities carried out without partisan bias and without promoting any political point of view regarding any election issue or candidates.

Applications that propose voter registration or GOTV efforts will be considered non-responsive and will not be eligible for funding under this announcement.

Any organization described in Section 501(c)(4) of the Internal Revenue Code of 1986, 26 U.S.C. 501(c)(4) that engages in lobbying activities is not eligible to apply.

The applicant nor its principals cannot be presently debarred, suspended, proposed for debarment, declared ineligible, or voluntarily excluded from participation in this transaction by any Federal department or agency. Federal regulations prohibit supplanting of funds, such as replacing routine and/or existing state or local expenditures with the use of Federal grant funds and/or using Federal grant funds for cost of activities that constitute general expenses required to carry out the overall responsibilities of state or local government.

D. Application and Submission Information

1. Address to Request Application Package. The FY 2023 HAVCP Application Kit, copies of necessary forms and samples, and the program regulations are available at *https://www.eac.gov/grants/help-america-vote-college-program.*

Application information is also available at *https://www.grants.gov/.*

2. Content and Form of Application Submission. The deadline for receipt of applications will be Monday, December 18, 2023. Please submit an email stating your intent to apply to *HAVCP@eac.gov.* This Notice of Intent is not required but helps EAC better plan the review of applications.

The fully completed HAVCP Service Day Mini-Grant Application Form must be submitted, as a word document or pdf, by email to *HAVCP@eac.gov* with the header ''HAVCP Service Day Mini-Grant Program Application—[ORGANIZATION NAME]'' before the application submission deadline. The electronic submission of your application must be made by an official representative of your institution who is authorized to request funding on behalf of the applicant organization.

3. Unique Entity Identifier and System for Award Management (SAM).

(a) At the time of application, each applicant must have an active registration in the System for Award Management (SAM) before submitting its application in accordance with 2 CFR part 25, Universal Identifier and System for Award Management. To register in SAM, entities will be required to obtain and create a Unique Entity Identifier (UEI). Instructions for obtaining the UEI are available at *https://sam.gov/content/entity-registration.*

(b) Each applicant must maintain an active SAM registration, with current, accurate, and complete information, at all times during which it has an active Federal award or an application under consideration by a Federal awarding agency.

(c) Each applicant must ensure they complete the Financial Assistance General Representations and Certifications in SAM.

(d) Applicants must provide a valid UEI in its application, unless

determined exempt under 2 CFR 25.110, Exceptions.

(e) The Agency will not make an award until the applicant has complied with all SAM requirements including providing the UEI. If an applicant has not fully complied with the requirements by the time the Agency is ready to make an award, the Agency may determine that the applicant is not qualified to receive a Federal award and use that determination as a basis for making a Federal award to another applicant.

4. Submission Dates and Times. The deadline for receipt of applications will be Monday, December 18, 2023. Please submit an email stating your intent to apply to *HAVCP@eac.gov.* This Notice of Intent is not required but helps EAC better plan the review of applications.

The fully completed HAVCP Service Day Mini-Grant Application Form must be submitted by email to *HAVCP@eac.gov* with the header ''HAVCP Service Day Mini-Grant Program Application—[ORGANIZATION NAME]'' before the application submission deadline. The electronic submission of your application must be made by an official representative of your institution who is authorized to request funding on behalf of the applicant organization.

Applications received after the deadline date and time are considered late applications and, absent extreme circumstances to be determined by the EAC, will not be reviewed. The EAC will notify each late applicant that the application will not be considered in the current competition. The EAC will only consider a request to submit an application after the deadline when the applicant can document that a technical issue with a government system prevented application submission prior to the application deadline. If an applicant misses a deadline due to unforeseen technical issues with a government system, the applicant may request a waiver to submit an application after the deadline to *HAVCP@eac.gov.* However, the waiver request will not be considered unless it includes a timestamp or other data point indicating the issue occurred prior to the application submission deadline.

5. Intergovernmental Review. Executive Order 12372, ''Intergovernmental Review of Federal Programs,'' is not required for this program.

6. Funding Restrictions. Applications must be for eligible purposes described in this Notice.

7. Other Submission Requirements. Applications must be submitted by email to *HAVCP@eac.gov* with the header ''HAVCP Service Day Mini-Grant Program Application—[ORGANIZATION NAME]'' by the deadline posted on *Grants.gov.* The electronic submission of your application must be made by an official representative of your institution who is authorized to request funding on behalf of the applicant organization. To request an accessible, hard copy of the application, please contact the EAC at *HAVCP@eac.gov.* EAC will not accept requests for a waiver of electronic submission requirements during the preview period. Such requests may only be submitted once the NOFO has been published on *Grants.gov.*

Interested applicants should submit an email to *HAVCP@eac.gov* stating your organization's intent to apply. This notice of intent is not required but helps us better plan the review of applications.

E. Application Review Information

1. Criteria. All complete and eligible applications will be evaluated and scored based on the criteria outlined in this section.

The review and selection process are intended to produce a diversified set of high-quality programs that represent the priorities described in this Notice. The determinations made by the EAC may be different from what the applicant self-determined upon submission of its application. The stages of the review and selection process follow:

The EAC will conduct an initial Compliance and Eligibility Review to determine if an application meets the eligibility requirements published in this Notice and advances to the next stage of the review process.

An application is compliant if the applicant:

- is an eligible organization,
- submitted an application by the submission deadline, and
- requested Federal funds in the range provided by the Notice.

Reviewing for eligibility is intended to ensure that only applications eligible for award are further reviewed. However, determinations of eligibility can take place at any point during the application review and selection process. Applicants that are determined to be ineligible will not receive an award.

2. Review and Selection Process. The EAC will assess the applications based on the Organizational Characteristics, Program Design/Strategy, and Budget selection criteria using the scoring rubric below. The EAC will also consider the priorities and strategic considerations detailed in this Notice. All staff reviewing applications will be screened for conflicts of interest. Final funding decisions will be made by the Election Assistance Commission.

HAVCP Scoring Criteria

Total Points Available: 30.

Each application is scored by three staff members. Average scores and priority points are used to present recommendations to the Election Assistance Commission Executive Director and Commissioners.

Organizational Characteristics (Possible Points: 20)

History of EAC Funding

Possible points	Criteria
10	Organization has not received past funding directly from EAC.
0	Organization has received past funding directly from EAC.

Area of Persistent Poverty and/or Historically Disadvantaged Community

Possible points	Criteria
5	Organization serves population(s) in an area of persistent poverty and/or historically disadvantaged community.
0	Organization does not serve population(s) in an area of persistent poverty and/or historically disadvantaged community.

Rural Area

Possible points	Criteria
5	Organization serves population(s) in a rural area.
0	Organization does not serve population(s) in a rural area.

Program Design and Strategy (Possible Points: 5)

Successful applications will address the following elements of Program Design and Strategy:

- A sound and relevant program that meets the unique needs of the communities served;
- A clear description of how the proposed activities will encourage college students to assist state and local governments in the administration of elections by serving as nonpartisan poll workers or assistants and encourage jurisdictions to utilize these efforts; and,
- The number of targeted college students, including how this number was calculated.

Possible points	Criteria
5	Application narrative clearly and completely addresses all requested components.
3	Application narrative clearly and completely addresses most of the requested components.
0	Application narrative is unclear and/or does not address critical application components.

Budget/Cost Effectiveness (Possible Points: 5)

Successful applications will address the following elements of Budget and cost effectiveness:

- Costs are clearly justified based on the proposed activities and project scope;
- Budget and budget narrative are accurate and complete (See Appendix C); and,
- Cost sharing is clearly and accurately identified.

Possible points	Criteria
5	Budget clearly and completely addresses all requested components.
3	Budget clearly and completely addresses most of the requested components.
0	Budget is unclear and/or does not address critical application components.

Priority Consideration. All selection criteria and application quality being equal, EAC will give priority consideration to projects from institutions and organizations that engage historically underrepresented groups, as defined by the Federal Government, as poll workers.

(a) The term ''equity'' means the consistent and systematic fair, just, and impartial treatment of all individuals, including individuals who belong to underserved communities that have been denied such treatment, such as Black, Latino, and Indigenous and Native American persons, Asian Americans and Pacific Islanders and other persons of color; members of religious minorities; lesbian, gay, bisexual, transgender, and queer (LGBTQ+) persons; persons with disabilities; persons who live in rural areas; and persons otherwise adversely affected by persistent poverty or inequality.

(b) The term ''underserved communities'' refers to populations sharing a particular characteristic, as well as geographic communities, that have been systematically denied a full opportunity to participate in aspects of economic, social, and civic life, as exemplified by the list in the preceding definition of ''equity.''

For the HAVCP Service Day Mini-Grant Program, the EAC will provide further priority consideration to applicants who have historically not been recipients of EAC funding. The EAC is interested in using the Mini-Grant opportunity to engage new organizations in supporting and improving the administration of elections. The HAVCP Service Day Mini-Grant Program will also provide priority consideration for organizations serving populations in an area of persistent poverty and/or historically disadvantaged community and for organizations located in a rural area. The EAC is interested in using the Mini-Grant opportunity to engage organizations serving locations where barriers to participation in the election process are frequently higher.

3. Applicant Clarification. The EAC may ask applicants for clarifying information during the Clarification Stage of the review process. An Operational and Financial Management Survey will also be requested at this time. The EAC staff will use this information to make funding recommendations. A request for clarification does not guarantee an award. Applicants may be recommended for funding even if they are not asked for clarifying information. An applicant's failure to respond to a request for clarification adequately and in a timely manner may result in the removal of its application from consideration.

4. Pre-Award Risk Assessment. The EAC staff will assess the risks posed by applicants to determine an applicant's ability to manage Federal funds. This assessment is in addition to the Compliance and Eligibility Review and the Application Review. Results from this assessment will inform funding decisions. If the EAC determines that an award will be made to an applicant with assessed risks, special conditions that correspond to the degree of assessed risk may be applied to the award. Additionally, if the EAC concludes that the reasons for applicants having poor risk assessment are not likely to be mitigated, those applications may not be selected for funding.

F. Federal Award Notices

Applicants will be notified in writing of the status of their application:

(a) Eligible and selected for funding;

(b) Eligible bur offered less than requested;

(c) Eligible but not selected for funding; or

(d) Ineligible for the award.

Applicants who are awarded funding will receive a Notice of Grant Award from the EAC with award terms and conditions as well as other grant documents. The Notice will inform grantees of the effective date for grant activities and disbursement.

1. Funding Type. Funding will be provided in the form of a discretionary grant. EAC will authorize the Treasury Department to disburse funding identified in the agreement through the Payment Management System (PMS) to the applicant as an advance to be drawdown as expenses arise. Per 2 CFR 200, the timing and amount of advance payments must be as close as is administratively feasible to the actual disbursements by the non-Federal entity for direct program or project costs and the proportionate share of any allowable indirect costs. The non-Federal entity must make timely payment to contractors in accordance with the contract provisions. Grantees will be able to request payments as often as practical for their program. Cash and in-kind match expenditures require the same documentation as Federal funds under 2 CFR 200. Grantees must request a drawdown of funds for incurred costs using the electronic Payment Management System (PMS). Prior to initial drawdown of funds, all Grantees must have secured online access to Payment Management System.

2. EAC Terms and Conditions. All awards made under this Notice will be subject to the EAC's General Terms and Conditions and the Program-Specific Terms and Conditions for the program (where applicable). These Terms and Conditions contain detailed, mandatory compliance and reporting requirements. The full Terms and Conditions may be viewed on the EAC website here: *https://www.eac.gov/grants/help-america-vote-college-program.*

3. Reporting. Recipients are required to provide one final Federal financial report (FFR) and one final progress report (PR) submitted by email to *HAVCP@eac.gov.* Final reports are cumulative over the entire award period and consistent with close-out requirements. The final reports are due 120 days after the performance period ends. All reports must be accurate, complete, and submitted on time.

The Federal financial report required will be the modified version of the Standard Form 425 (SF–425) used by the EAC for other Federal awards. The progress report required will consist of a short narrative, listing of the actual number of college students served, and images demonstrating the Service Day

activities undertaken with Federal and non-Federal matching funds.

Once the grant is awarded, recipients will be expected to have in place data collection and data management policies, processes, and practices that provide assurance that they are reporting high quality performance measure data. Failure to submit accurate, complete, and timely required reports may affect the recipient's ability to secure future EAC funding.

For general questions about this announcement, please contact the EAC Office of Grants Management at *HAVCP@eac.gov* or 202–734–0639. The program website also provides up to date contact information at *https://www.eac.gov/grants/help-america-vote-college-program.*

H. Other Information

1. Paperwork Reduction Act. In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. chapter 35), the information collection requirements associated with the programs, as covered in this Notice, have been approved by the Office of Management and Budget (OMB) under OMB Control Number 3265–0025. Public burden reporting for this collection of information is estimated to average 5 hours per response for individuals completing all parts of this form, including time for reviewing instructions, searching existing data sources, gathering, and maintaining the data needed, and completing and reviewing the collection of information. You are not required to answer these questions unless this number is displayed. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, U.S. Election Assistance Commission, 633 3rd Street NW, Suite 200, Washington, DC 20001.

2. Federal Funding Accountability and Transparency Act. All applicants, in accordance with 2 CFR part 25, must be registered in SAM and have a UEI number as stated in Section D.3. of this Notice. All recipients of Federal financial assistance are required to report information about first-tier sub-awards and executive total compensation in accordance with 2 CFR part 170, Reporting subaward and executive compensation information.

3. Issuance of Federal Awards. The Election Assistance Commission is not obligated to make any Federal awards as a result of this announcement.

4. EAC Terms and Conditions. All awards made under this Notice will be subject to the EAC's General Terms and Conditions and the Program-Specific Terms and Conditions for the program (where applicable). These Terms and Conditions contain detailed, mandatory compliance and reporting requirements.

5. Effects of Nondisclosure. The information requested is voluntary; however, to be a recipient of this grant program, disclosure of personal or sensitive information is required to receive Federal benefits.

6. Use of Material. To ensure that materials generated with HAVA funding are available to the public and readily accessible to recipients and non-recipients, the EAC reserves a royalty-free, nonexclusive, and irrevocable right to obtain, use, modify, reproduce, publish, or disseminate publications and materials produced under the award, including data, and to authorize others to do so (2 CFR 200.315).

7. Uniform Guidance. All awards made under this Notice will be subject to the Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards (Uniform Guidance), in 2 CFR part 200.

8. Federal Funding Accountability and Transparency Act. Grant recipients will be required to report at *www.FSRS.gov* on all subawards over $30,000 and may be required to report on executive compensation for recipients and subrecipients. Recipients must have the necessary systems in place to collect and report this information. See 2 CFR part 170 for more information and to determine how these requirements apply.

Camden Kelliher,

Deputy General Counsel, U.S. Election Assistance Commission.

[FR Doc. 2023–25817 Filed 11–21–23; 8:45 am]

BILLING CODE 4810–71–P

ELECTION ASSISTANCE COMMISSION

Help America Vote College Program

AGENCY: Election Assistance Commission.

ACTION: Notice of funding opportunity.

SUMMARY: Through this Notice, EAC is announcing the fiscal year (FY) 2023 Help America Vote College Program (HAVCP) Notice of Funding Opportunity (NOFO).

DATES: Proposals must be submitted no later than 11:59 p.m. eastern time on Monday, December 18, 2023.

ADDRESSES: Proposals must be submitted to *https://www.Grants.gov.*

FOR FURTHER INFORMATION CONTACT: Election Assistance Commission Office of Grants Management, Risa Garza, (202) 740–1483, or at *HAVCP@eac.gov.*

A. Program Description

Assistance Listing Number: 90.400.

Funding Opportunity Number: EAC–23–001.

Funding Opportunity Title: Help America Vote College Program Poll Worker Grant Program.

1. Purpose of the Program. The Help America Vote College Program (HAVCP) was established in 2004, and through fiscal year 2009, distributed over $2.3 million to colleges and non-profits to recruit, train and support students serving as poll workers on Election Day.

The purpose of this grant program is to: (1) Encourage students enrolled at institutions of higher education (including community colleges) to assist State and local governments in the administration of elections by serving as nonpartisan poll workers or assistants; (2) Encourage college students to become cognizant of the elections process and civic education, and to assist in the administration of elections in their community; and (3) Encourage state and local governments to use the services of the students participating in the program.

College Student means any individual enrolled either on a part-time or full-time basis in any undergraduate, graduate, or professional college accredited by an agency recognized by the U.S. Department of Education in the United States.

2. Statutory and Regulatory Authority. The U.S. Election Assistance Commission (EAC) anticipates the availability of $1 million dollars in discretionary grant funding, enacted in the 2023 Consolidated Appropriations Act (Pub. L. No: 117–328), to support the Help America Vote College Program (HAVCP) authorized in the Help America Vote Act of 2002 (HAVA), Public Law 107–252, Title V, Help America Vote College Program. Awards will be administered by the EAC.

3. Performance Measurements. Grant recipients will be required to report on one to three performance measures, one required universal measure and one to two optional measures selected by the applicant. Every recipient must report on the number of college students served. Selected performance measures should accurately reflect grant recipients' accomplishments, improve EAC's ability to report on the impact of its grant programs, and standardize measures across programs where appropriate.

Applicants must provide specific details about the procedures for tracking performance outcome measures and other participant data, such as demographic information and training

provided, and describe staffing, technology, computer applications, and other resources already available to accomplish this task. Applicants should also provide a specific plan for procuring the resources needed to meet this requirement if the resources are not already possessed by or accessible to the applicant.

Applicants are encouraged to align their goals with specific activities. Sample activities may include project administration and ramp-up; partnership engagement, outreach, and recruitment; enrollment and training; poll-worker placement; and follow-up with students to track outcomes.

For planning purposes, the applicant should identify key deliverables and the timeframe for achieving each deliverable, including any milestones to indicate the progression of activities. The applicant should also provide the name of the lead or supporting institution engaged in each activity or producing each deliverable, including any partner organizations.

B. Federal Award Information

Poll-Worker Program

Funding Instrument: Discretionary.

Award Minimum: $45,000.

Award Maximum: $100,000.

Grant Period: 2 Years.

Anticipated Funding Available: $850,000.

1. Funding Type. Funding will be provided in the form of a discretionary grant. EAC will authorize the Treasury Department to disburse funding identified in the agreement through the Payment Management System (PMS) to the applicant as an advance to be drawdown as expenses arise. Per 2 CFR 200, the timing and amount of advance payments must be as close as is administratively feasible to the actual disbursements by the non-federal entity for direct program or project costs and the proportionate share of any allowable indirect costs. The non-federal entity must make timely payment to contractors in accordance with the contract provisions. Grantees will be able to request payments as often as practical for their program. Cash and in-kind match expenditures require the same documentation as federal funds under 2 CFR 200. Grantees must request a drawdown of funds for incurred costs using the electronic Payment Management System (PMS). Prior to initial drawdown of funds, all Grantees must have secured online access to Payment Management System and EAC's grants management software.

C. Eligibility Information

1. Eligible Applicants. EAC encourages applicants to forge robust partnerships to implement the grant and to sustain activities beyond the grant period of performance. The recommended partners for the HAVCP are institutions of higher education as defined in section 101(a) of the Higher Education Act of 1965 (20 U.S.C. 1001); Nonprofit Organizations; Community and Technical Colleges and Systems; Historically Black Colleges and Universities (HBCUs); Hispanic-Serving Institutions (HSIs); Tribal Colleges and Universities (TCUs); State and Local Election Offices; and Other Minority Serving Institutions Program (MSIs) as designated by the Higher Education Act's Title III and V funding.

Priority Consideration. All selection criteria and application quality being equal, EAC will give priority consideration to projects from institutions and organizations that engage historically underrepresented groups, as defined by the federal government as poll workers.

2. Cost Sharing or Matching. At the time of award, applicants must demonstrate either cash and/or in-kind and on-hand and/or commitments, or a combination thereof, to meet the required 10 percent match, based on the amount of federal grant funds requested. Match must be met by the project end period.

EAC encourages applicants to leverage additional resources beyond the required match to supplement grant activities. Both matching and leveraged resources can come from a variety of sources, including, but not limited to the private sector (*e.g.,* businesses or industry associations); the philanthropic community (*e.g.,* foundations); and the non-profit sector (*e.g.,* community organizations or education and training institutions). Non-federal, public-sector funds (*e.g.,* from States or local governments) may be used for matching funds, if necessary. Federal funds from other federal agencies are not a permissible source of match, unless specifically authorized by the award pursuant to 2 CFR 200.306. Applicants may consult with EAC on sources of match to determine permissibility.

3. Other Requirements/Limitations. Applicants may not use any part of an award from the EAC to fund religious instruction, worship or proselytizing, voter registration, get out the vote (GOTV) drives, or other political activities that could be construed as lobbying. Project funds must be used for tasks and activities carried out without partisan bias and without promoting any political point of view regarding any election issue or candidates.

Applications that propose voter registration or GOTV efforts will be considered non-responsive and will not be eligible for funding under this announcement.

Grantees may recover indirect costs under this grant up to 10 percent of the total federal share of the grant. If an applicant has an approved federal indirect cost rate higher than 10 percent, the remainder of the indirect costs can be used as a matching contribution.

Any organization described in section 501(c)(4) of the Internal Revenue Code of 1986, 26 U.S.C. 501(c)(4) that engages in lobbying activities is not eligible to apply.

The applicant nor its principals cannot be presently debarred, suspended, proposed for debarment, declared ineligible, or voluntarily excluded from participation in this transaction by any federal department or agency. Federal regulations prohibit supplanting of funds, such as replacing routine and/or existing state or local expenditures with the use of federal grant funds and/or using federal grant funds for cost of activities that constitute general expenses required to carry out the overall responsibilities of state or local government.

D. Application and Submission Information

1. Address to Request Application Package. The FY 2023 HAVCP Application Kit, copies of necessary forms and samples, and the program regulations are available at *https://www.eac.gov/grants/help-america-vote-college-program.*

Application information is also available at *https://www.grants.gov/.*

2. Content and Form of Application Submission. The deadline for receipt of applications is 11:59 p.m. Eastern Time on Monday, December 18, 2023. Please submit an email stating your intent to apply to *HAVCP@eac.gov.* This notice of intent is not required but helps EAC better plan the review of applications.

Submit the following application components as uploads to the *Grants.gov* Attachments Form:

- HAVCP Application—Fillable form including Project Narrative and Budget Narrative
- Budget Worksheet
- Indirect Cost Rate Agreement (if applicable)

EAC urges applicants to create accounts and submit their *Grants.gov* submissions prior to the due date with sufficient time to correct any errors and resubmit by the submission deadline if a rejection notification is received.

To be considered timely, the full application must be submitted in *Grants.gov* by the application deadline. Failure to begin the SAM.gov or *Grants.gov* registration process in sufficient time (*i.e.,* waiting until the date identified in this solicitation) is not an acceptable reason for late submission. EAC uses *Grants.gov* to submit and receive applications. Applicants must ensure successful submission no later than 11:59 p.m. Eastern Time on Monday, December 18, 2023. *Grants.gov* will subsequently validate the application. The process can be complicated and time-consuming. You are strongly advised to initiate the process as soon as possible and to plan for time to resolve technical problems. Note that validation does not mean that your application has been accepted as complete or has been accepted for review by the agency. Rather, *Grants.gov* verifies only the submission of certain parts of an application.

3. Unique Entity Identifier and System for Award Management (SAM). (a) At the time of application, each applicant must have an active registration in the System for Award Management (SAM) before submitting its application in accordance with 2 CFR part 25, Universal Identifier and System for Award Management. To register in SAM, entities will be required to obtain and create a Unique Entity Identifier (UEI). Instructions for obtaining the UEI are available at *https://sam.gov/content/entity-registration.*

(b) Each applicant must maintain an active SAM registration, with current, accurate, and complete information, at all times during which it has an active federal award or an application under consideration by a federal awarding agency.

(c) Each applicant must ensure they complete the Financial Assistance General Representations and Certifications in SAM.

(d) Applicants must provide a valid UEI in its application, unless determined exempt under 2 CFR 25.110, Exceptions.

(e) The Agency will not make an award until the applicant has complied with all SAM requirements including providing the UEI. If an applicant has not fully complied with the requirements by the time the Agency is ready to make an award, the Agency may determine that the applicant is not qualified to receive a federal award and use that determination as a basis for making a federal award to another applicant.

4. Submission Dates and Times. The deadline for receipt of applications is 11:59 p.m. Eastern Time on Monday, December 18, 2023. Please submit an email stating your intent to apply to *HAVCP@eac.gov.* This notice of intent is not required but helps EAC better plan the review of applications.

See Section (2) *Content and Form of Application Submission* for detailed submission requirements.

5. Intergovernmental Review. Executive Order 12372, ''Intergovernmental Review of Federal Programs,'' is not required for this program.

6. Funding Restrictions. Applications must be for eligible purposes described in this Notice.

7. Other Submission Requirements. Applications must be submitted electronically at *Grants.gov*. To request an accessible, hard copy of the application, please contact the EAC at *HAVCP@eac.gov.*

Interested applicants should submit an email by *HAVCP@eac.gov* stating your organization's intent to apply. This notice of intent is not required but helps us better plan the review of applications.

E. Application Review Information

1. Criteria. All complete and eligible applications will be evaluated and scored based on the criteria outlined in this section.

The review and selection process are intended to produce a diversified set of high-quality programs that represent the priorities described in this Notice. The determinations made by the EAC may be different from what the applicant self-determined upon submission of its application. The stages of the review and selection process follow:

The EAC will conduct an initial Compliance and Eligibility Review to determine if an application meets the eligibility requirements published in this Notice and advances to the next stage of the review process.

An application is compliant if the applicant:

- is an eligible organization,
- submitted an application by the submission deadline, and
- requested federal funds in the range provided by the Notice.

Reviewing for eligibility is intended to ensure that only applications eligible for award are further reviewed. However, determinations of eligibility can take place at any point during the application review and selection process. Applicants that are determined to be ineligible will not receive an award.

2. Review and Selection Process. The EAC will assess the applications based on the Program Design/Strategy, Organizational Capability, and Budget selection criteria using the scoring rubric below. The EAC will also consider the priorities and strategic considerations detailed in this Notice. All staff reviewing applications will be screened for conflicts of interest. Final funding decisions will be made by the Election Assistance Commission.

HAVCP Scoring Criteria

Total Points Available: 100.

Each application is scored by three staff members. Average scores and priority points are used to present recommendations to the Election Assistance Commission Executive Director and Commissioners.

Program Design and Strategy (Possible Points: 50)

Successful applications will address the following elements of program design and strategy:

- A sound and relevant program that meets the unique needs of the communities served;
- A clear description of the tools used to measure program outcomes and how data will be collected and used to modify and improve strategies, products, and services;
- The applicant's approach and expertise in using innovative solutions to implement new or expand existing efforts to increase the number of college poll workers, including efforts focused on recruiting historically underrepresented individuals as poll workers;
- The extent to which the proposed program considers information found in EAC's Guidebook for Recruiting College Poll Workers; and
- The scope of the project, including the number of targeted college poll workers.

Possible points	Criteria
41–50	Clearly and completely addresses all 5 criteria.
31–40	Addresses 4 out of 5 criteria and/or missing some elements of clarity or completeness.
21–30	Addresses 3 out of 5 criteria and/or missing some elements of clarity or completeness.
11–20	Addresses 2 out of 5 criteria and/or is confusing or incomplete.
0–10	Meets 0–1 out of the 5 required criteria and missing significant descriptions and clarity.

Organizational Capacity (Possible Points: 35)

Successful applications will address the following elements of organizational capacity:

- Demonstrated relationships/partnerships with relevant state and local entities needed to make the project successful;
- Ability to manage a federal grant as evidenced by previous federal grants experience or similar size and complexity grant;
- Experience with managing volunteer recruitment efforts including experience working with historically underrepresented groups, as defined by the federal government, within the college student body, as appropriate for the proposed program model; and
- Experience of the organization and staff as evidenced by brief staff biographies and other past organizational programs.

Possible points	Criteria
25–35	Clearly and completely meets all 4 criteria.
17–24	Addresses 3 out of 4 criteria and/or some areas of experience are weak or missing information.
9–16	Addresses 2 out of 4 criteria and/or is confusing or incomplete. Lacking significant partnerships and experience.
0–8	Meets 0–1 out of the 4 required criteria and does not have the experience or partnerships necessary to manage a federal grant program.

Budget/Cost Effectiveness (Possible Points: 15)

Successful applications will address the following elements of budget and cost effectiveness:

- Costs are clearly justified based on the proposed activities and project scope;
- Budget and budget narrative are accurate and complete (See Appendix C); and
- Cost sharing is clearly and accurately identified.

Possible points	Criteria
11–15	Clearly and completely meets all 3 criteria.
6–10	Addresses 2 out of 3 criteria and/or contains some calculation errors.
0–5	Addresses 1 out of 3 criteria and/or is confusing or incomplete.

Priority Consideration. All selection criteria and application quality being equal, EAC will give priority consideration to projects from institutions and organizations that engage historically underrepresented groups, as defined by the federal government, as poll workers.

(a) The term ''equity'' means the consistent and systematic fair, just, and impartial treatment of all individuals, including individuals who belong to underserved communities that have been denied such treatment, such as Black, Latino, and Indigenous and Native American persons, Asian Americans and Pacific Islanders and other persons of color; members of religious minorities; lesbian, gay, bisexual, transgender, and queer (LGBTQ+) persons; persons with disabilities; persons who live in rural areas; and persons otherwise adversely affected by persistent poverty or inequality.

(b) The term ''underserved communities'' refers to populations sharing a particular characteristic, as well as geographic communities, that have been systematically denied a full opportunity to participate in aspects of economic, social, and civic life, as exemplified by the list in the preceding definition of ''equity.'' Source

3. Applicant Clarification. The EAC may ask applicants for clarifying information during the Clarification Stage of the review process. An Operational and Financial Management Survey will also be requested at this time. The EAC staff will use this information to make funding recommendations. A request for clarification does not guarantee an award. Applicants may be recommended for funding even if they are not asked for clarifying information. An applicant's failure to respond to a request for clarification adequately and in a timely manner may result in the removal of its application from consideration.

4. Pre-Award Risk Assessment. The EAC staff will assess the risks posed by applicants to determine an applicant's ability to manage federal funds. This assessment is in addition to the Compliance and Eligibility Review and the Application Review. Results from this assessment will inform funding decisions. If the EAC determines that an award will be made to an applicant with assessed risks, special conditions that correspond to the degree of assessed risk may be applied to the award. Additionally, if the EAC concludes that the reasons for applicants having poor risk assessment are not likely to be mitigated, those applications may not be selected for funding.

F. Federal Award Notices

Applicants will be notified in writing of the status of their application:

(a) Eligible and selected for funding;

(b) Eligible bur offered less than requested;

(c) Eligible but not selected for funding; or

(d) Ineligible for the award.

Applicants who are awarded funding will receive a Notice of Grant Award from the EAC with award terms and conditions as well as other grant documents. The Notice will inform grantees of the effective date for grant activities and disbursement.

1. Funding Type. Funding will be provided in the form of a discretionary grant. EAC will authorize the Treasury Department to disburse funding identified in the agreement through the Payment Management System (PMS) to the applicant as an advance to be drawdown as expenses arise. Per 2 CFR 200, the timing and amount of advance payments must be as close as is administratively feasible to the actual disbursements by the non-federal entity for direct program or project costs and the proportionate share of any allowable indirect costs. The non-federal entity must make timely payment to contractors in accordance with the contract provisions. Grantees will be able to request payments as often as practical for their program. Cash and in-kind match expenditures require the same documentation as federal funds under 2 CFR 200. Grantees must request a drawdown of funds for incurred costs using the electronic Payment Management System (PMS). Prior to initial drawdown of funds, all Grantees must have secured online access to Payment Management System and EAC's grants management software.

2. Administrative and National Policy Requirements. EAC Terms and Conditions. All awards made under this Notice will be subject to the EAC's General Terms and Conditions and the Program-Specific Terms and Conditions for the program (where applicable). These Terms and Conditions contain detailed, mandatory compliance and reporting requirements. The full Terms and Conditions may be viewed on the EAC website here: *https://www.eac.gov/grants/help-america-vote-college-program.*

3. Reporting. Recipients are required to provide federal financial reports (FFR) and progress reports (PR) semi-annually through EAC's web-based grants management system. All reports must be accurate, complete, and submitted on time.

In addition, at the end of the award period, recipients must submit final

financial and progress reports that are cumulative over the entire award period and consistent with close-out requirements. The final reports are due 120 days after the performance period ends.

Once the grant is awarded, recipients will be expected to have in place data collection and data management policies, processes, and practices that provide assurance they are reporting high quality performance measure data. Failure to submit accurate, complete, and timely required reports may affect the recipient's ability to secure future EAC funding.

G. Federal Awarding Agency Contact

For general questions about this announcement, please contact the EAC Office of Grants Management at *HAVCP@eac.gov* or 202–734–0639. The program website also provides up to date contact information at *https://www.eac.gov/grants/help-america-vote-college-program.*

H. Other Information

1. Paperwork Reduction Act. In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. chapter 35), the information collection requirements associated with the programs, as covered in this Notice, have been approved by the Office of Management and Budget (OMB) under OMB Control Number 3265–0025. Public burden reporting for this collection of information is estimated to average 17 hours per response for individuals completing all parts of this form, including time for reviewing instructions, searching existing data sources, gathering, and maintaining the data needed, and completing and reviewing the collection of information. You are not required to respond to these questions unless this number is displayed. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, U.S. Election Assistance Commission, 633 3rd Street NW, Suite 200, Washington, DC 20001.

2. Federal Funding Accountability and Transparency Act. All applicants, in accordance with 2 CFR part 25, must be registered in SAM and have a UEI number as stated in Section D.3. of this Notice. All recipients of federal financial assistance are required to report information about first-tier sub-awards and executive total compensation in accordance with 2 CFR part 170, Reporting subaward and executive compensation information.

3. Issuance of Federal Awards. The Election Assistance Commission is not obligated to make any federal awards as a result of this announcement.

4. EAC Terms and Conditions. All awards made under this Notice will be subject to the EAC's General Terms and Conditions and the Program-Specific Terms and Conditions for the program (where applicable). These Terms and Conditions contain detailed, mandatory compliance and reporting requirements.

5. Effects of Nondisclosure. The information requested is voluntary; however, to be a recipient of this grant program, disclosure of personal or sensitive information is required to receive federal benefits.

6. Use of Material. To ensure that materials generated with HAVA funding are available to the public and readily accessible to recipients and non-recipients, the EAC reserves a royalty-free, nonexclusive, and irrevocable right to obtain, use, modify, reproduce, publish, or disseminate publications and materials produced under the award, including data, and to authorize others to do so (2 CFR 200.315).

7. Uniform Guidance. All awards made under this Notice will be subject to the Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards (Uniform Guidance), in 2 CFR part 200.

8. Federal Funding Accountability and Transparency Act. Grant recipients will be required to report at *www.FSRS.gov* on all subawards over $30,000 and may be required to report on executive compensation for recipients and subrecipients. Recipients must have the necessary systems in place to collect and report this information. See 2 CFR part 170 for more information and to determine how these requirements apply.

Camden Kelliher,

Deputy General Counsel, U.S. Election Assistance Commission.

[FR Doc. 2023–25820 Filed 11–21–23; 8:45 am]

BILLING CODE 4810–71–P

DEPARTMENT OF ENERGY

[Case Number 2022–004; EERE–2022–BT–WAV–0010]

Energy Conservation Program: Decision and Order Granting a Waiver to Norlake, Inc., dba Refrigerated Solutions Group, From the Department of Energy Walk-In Coolers and Walk-In Freezers Test Procedure

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

ACTION: Notification of decision and order.

SUMMARY: The U.S. Department of Energy (''DOE'') gives notification of a Decision and Order (Case Number 2022–004) that grants to Norlake, Inc., dba Refrigerated Solutions Group (''RSG'') a waiver from specified portions of the DOE test procedure for determining the energy efficiency of specified walk-in cooler refrigeration systems. Under the Decision and Order, RSG is required to test and rate the specified basic models of its equipment in accordance with the alternate test procedure set forth in the Decision and Order.

DATES: The Decision and Order is effective on November 22, 2023. The Decision and Order will terminate upon the date on which use of the test procedure for walk-in coolers and walk-in freezers located at title 10 of the Code of Federal Regulations (''CFR''), part 431, subpart R, appendix C1 is required to determine compliance with energy conservation standards. At such time, RSG must use the relevant test procedure for this equipment for any testing to demonstrate compliance with the applicable standards, and any other representations of energy use.

FOR FURTHER INFORMATION CONTACT:

Ms. Julia Hegarty, U.S. Department of Energy, Office of Energy Efficiency and Renewable Energy, Building Technologies Office, Mailstop EE–5B, 1000 Independence Avenue SW, Washington, DC 20585–0121. Email: *AS_Waiver_Request@ee.doe.gov*.

Mr. Matthew Schneider, U.S. Department of Energy, Office of the General Counsel, GC–33, 1000 Independence Avenue SW, Washington, DC 20585–0121. Telephone: (240) 597–6265. Email: *matthew.schneider@hq.doe.gov*.

SUPPLEMENTARY INFORMATION: In accordance with 10 CFR 431.401(f)(2), DOE gives notification of the issuance of its Decision and Order as set forth below. The Decision and Order grants RSG a waiver from the applicable test procedure at 10 CFR part 431, subpart R, appendix C for the specified basic models for which RSG petitioned for waiver and provides that RSG must test and rate such equipment using the alternate test procedure specified in the Decision and Order. RSG's representations concerning the energy efficiency of the specified basic models must be based on testing according to the provisions and restrictions in the alternate test procedure set forth in the Decision and Order, and the representations must fairly disclose the test results. Distributors, retailers, and private labelers are held to the same requirements when making

representations regarding the energy efficiency of this equipment. (42 U.S.C. 6314(d))

Any manufacturer of a basic model employing a technology or characteristic for which a waiver was granted for another basic model and that results in the need for a waiver (as specified by DOE in a published decision and order in the **Federal Register**) must petition and be granted a waiver for that basic model. (10 CFR 431.401(j)) Manufacturers may also submit a request for interim waiver pursuant to the requirements of 10 CFR 431.401.

Case #2022–004

Decision and Order

I. Background and Authority

The Energy Policy and Conservation Act, as amended (''EPCA''),[1] authorizes the U.S. Department of Energy (''DOE'') to regulate the energy efficiency of a number of consumer products and certain industrial equipment. (42 U.S.C. 6291–6317) Title III, Part C [2] of EPCA established the Energy Conservation Program for Certain Industrial Equipment, which sets forth a variety of provisions designed to improve the energy efficiency for certain types of industrial equipment. This equipment includes walk-in coolers and walk-in freezers (collectively, ''walk-ins''), the focus of this document. (42 U.S.C. 6311(1)(G))

The energy conservation program under EPCA consists essentially of four parts: (1) testing, (2) labeling, (3) Federal energy conservation standards, and (4) certification and enforcement procedures. Relevant provisions of EPCA include definitions (42 U.S.C. 6311), energy conservation standards (42 U.S.C. 6313), test procedures (42 U.S.C. 6314), labeling provisions (42 U.S.C. 6315), and the authority to require information and reports from manufacturers (42 U.S.C. 6316; 42 U.S.C. 6299).

The Federal testing requirements consist of test procedures that manufacturers of covered equipment must use as the basis for: (1) certifying to DOE that their equipment complies with the applicable energy conservation standards adopted pursuant to EPCA (42 U.S.C. 6316(a); 42 U.S.C. 6295(s)), and (2) making representations about the efficiency of that equipment (42 U.S.C. 6314(d)). Similarly, DOE must use these test procedures to determine whether the equipment complies with relevant standards promulgated under EPCA. (42 U.S.C. 6316(a); 42 U.S.C. 6295(s))

Under 42 U.S.C. 6314, EPCA sets forth the criteria and procedures DOE is required to follow when prescribing or amending test procedures for covered equipment. EPCA requires that any test procedures prescribed or amended under this section must be reasonably designed to produce test results which reflect energy efficiency, energy use or estimated annual operating cost of covered equipment during a representative average use cycle and requires that test procedures not be unduly burdensome to conduct. (42 U.S.C. 6314(a)(2)) The test procedures for walk-in refrigeration systems are set forth at 10 CFR part 431, subpart R, appendix C, *Uniform Test Method for the Measurement of Net Capacity and AWEF of Walk-in Cooler and Walk-in Freezer Refrigeration Systems* (''appendix C'') and appendix C1, *Uniform Test Method for the Measurement of Net Capacity and AWEF2 of Walk-In Cooler and Walk-In Freezer Refrigeration Systems* (''appendix C1'').[3]

Any interested person may submit a petition for waiver from DOE's test procedure requirements. 10 CFR 431.401(a)(1). DOE will grant a waiver from the test procedure requirements if DOE determines either that the basic model for which the waiver was requested contains a design characteristic that prevents testing of the basic model according to the prescribed test procedures, or that the prescribed test procedures evaluate the basic model in a manner so unrepresentative of its true energy consumption characteristics as to provide materially inaccurate comparative data. 10 CFR 431.401(f)(2). In granting a waiver or interim waiver, DOE will not change the energy use or efficiency metric that the manufacturer must use to certify compliance with the applicable energy conservation standard and to make representations about the energy use or efficiency of the covered equipment. 10 CFR 431.401(a). DOE may grant the waiver subject to conditions, including adherence to alternate test procedures. 10 CFR 431.401(f).

As soon as practicable after the granting of any waiver, DOE will publish in the **Federal Register** a notice of proposed rulemaking to amend its regulations so as to eliminate any need for the continuation of such waiver. 10 CFR 431.401(*l*). As soon thereafter as practicable, DOE will publish in the **Federal Register** a final rule to that effect. *Id.* When DOE amends the test procedure to address the issues presented in a waiver, the waiver will automatically terminate on the date on which use of that test procedure is required to demonstrate compliance. 10 CFR 431.401(h)(3).

II. RSG's Petition for Waiver: Assertions and Determinations

On February 17, 2022, DOE received from RSG a petition for waiver and interim waiver from the DOE test procedure for walk-in refrigeration systems set forth at 10 CFR part 431, subpart R, appendix C. (RSG, No. 1, attachment 1, at pp. 1–3 [4]) Pursuant to 10 CFR 431.401(e)(i), DOE posted the petition on the DOE website. The petition did not identify any of the information contained therein as confidential business information.

DOE's currently applicable test procedure for walk-in refrigeration systems (*i.e.,* appendix C) incorporates by reference Air-Conditioning, Heating, and Refrigeration Institute (''AHRI'') Standard 1250–2009, *2009 Standard for Performance Rating of Walk-In Coolers and Freezers* (''AHRI 1250–2009''); AHRI Standard 420–2008, *Performance Rating of Forced-Circulation Free-Delivery Unit Coolers for Refrigeration* (''AHRI 420–2008''); and American Society of Heating, Refrigerating, and Air-Conditioning Engineers (''ASHRAE'') Standard 23.1–2010, *Methods of Testing for Rating the Performance of Positive Displacement Refrigerant Compressors and Condensing Units that Operate at Subcritical Temperatures of the Refrigerant* (''ASHRAE 23.1–2010''). AHRI 1250–2009 is the industry test standard for refrigeration systems for

[1] All references to EPCA in this document refer to the statute as amended through the Energy Act of 2020, Public Law 116–260 (Dec. 27, 2020), which reflect the last statutory amendments that impact Parts A and A–1 of EPCA.

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

[3] Appendix C is the test procedure currently required for walk-in refrigeration systems to demonstrate compliance with energy conservation standards. Use of appendix C1 will be required beginning on the compliance date of any amended energy conservation standards for walk-ins published after January 1, 2022. DOE has established separate test procedures for walk-in envelope components at 10 CFR part 431, subpart R, appendices A and B. Appendix A is used for testing the energy use of walk-in display panels, display doors, and non-display doors; appendix B is used for testing insulation R-value of non-display panels and non-display doors.

[4] A notation in this form provides a reference for information that is in the docket for this test procedure waiver (Docket No. EERE–2022–BT–WAV–0010) (available at *www.regulations.gov/document/EERE-2022-BT-WAV-0010*). This notation indicates that the statement preceding the reference is from document number 1 in the docket and appears at pages 1–3 of attachment 1 of that document. There are two attachments to document 1 of this docket. Attachment 1 is titled ''DOE Waiver 021722''. Attachment 2 is titled ''RSG DOE Single Package System Alternate Test Procedure 021522''.

walk-in coolers and freezers, including unit coolers and dedicated condensing units sold separately, as well as matched pairs. The procedure describes the method for measuring the refrigeration capacity and the electrical energy consumption for walk-in refrigeration systems. Using the refrigeration capacity and electrical energy consumption, AHRI 1250–2009 provides a calculation methodology to compute AWEF, the applicable energy-performance metric for refrigeration systems.

In its petition for waiver and interim waiver, RSG presented several ways in which the currently prescribed test procedure would evaluate the specified basic models in a manner so unrepresentative of their true energy consumption as to provide materially inaccurate comparative data. These issues are summarized below.

First, as presented in RSG's petition, the specified basic models of walk-in refrigeration systems are single-packaged dedicated systems that contain multiple refrigeration circuits that operate using a single power feed. (RSG, No. 1, attachment 1, at p. 1) RSG claimed that the specified basic models meet the definition of a single-packaged dedicated system. *Id.* DOE defines a single-packaged dedicated system as ''a single-package assembly that includes one or more compressors, a condenser, a means for forced circulation of refrigerated air, and elements by which heat is transferred from air to refrigerant, without any element external to the system imposing resistance to flow of the refrigerated air''. *See* 10 CFR 431.302. As described by RSG, each refrigeration circuit in the specified basic models is made up of a compressor, expansion, device, condenser, and evaporator. (RSG, No. 1, attachment 1, at p. 1) The separate refrigeration circuits may share condenser fans, evaporator fans and a control system. *Id.* In its request for waiver and interim waiver, RSG stated that neither appendix C nor AHRI 1250–2009 provide a method for testing a single-packaged dedicated system with multiple refrigeration circuits. *Id.*

Second, RSG stated that the current test procedure requires that the unit under test be set up using a 25-foot line-set. *Id.* Section 3.3 of appendix C provides the test method for matched systems, single-packaged dedicated systems, and unit coolers tested alone, which references AHRI 1250–2009. Section C5 (Methods of Testing for Walk-In Cooler and Freezer Systems that Have Matched Unit Coolers and Condensing Units) of AHRI 1250–2009 references test setup requirements that include the addition of a line-set that includes either one or two mass flow meters. Under section C5 of AHRI 1250–2009, the gross refrigeration capacity must be determined either by the dual instrumentation refrigerant enthalpy method (section C5.1.1 of AHRI 1250–2009, Method 1) or by the calibrated box method (section C5.1.2 of AHRI 1250–2009, Method 2). Both methods require installation of a refrigerant mass flow meter in the system's liquid line to determine the cooling capacity. Section C8.3 and Figure C1 of AHRI 1250–2009 specify the setup and measurements to be conducted for Method 1, for which 25-feet of additional refrigerant line is added to connect the condenser to the evaporator (unit cooler). Within this 25-foot line, two mass flow meters are incorporated, and the heat balance calculated from the two flow measurements must be within ±5 percent. Section C9.2 and Figure C2 of AHRI 1250–2009 specify the setup and measurements for Method 2, in which 26-feet of additional refrigerant line is added to connect the condenser to the unit cooler (as for Method 1), incorporating one mass flow meter. Air-side gross refrigeration capacity and refrigerant-side gross refrigeration capacity are determined and must be equal to within ±5 percent for the test to be considered valid. The 25 feet and 26 feet [5] of additional liquid line and suction line piping used to set up the test is termed a ''line-set''. In its petition for waiver and interim waiver, RSG stated that single-packaged dedicated systems are not intended to be remotely split via a line-set. (RSG, No. 1, attachment 1, at p. 1)

In its request for waiver and interim waiver, RSG noted that DOE has issued test procedure waivers for single-packaged dedicated refrigeration systems using air enthalpy test methods. (RSG, No. 1, attachment 1, at p. 2) DOE granted a waiver to Store It Cold for basic models of single-packaged dedicated systems on August 9, 2019. 84 FR 39286. Store It Cold petitioned for a waiver after determining that the dual instrumentation refrigerant enthalpy method specified in AHRI 1250–2009 was not providing consistent capacity measurements for its single-packaged dedicated systems. 84 FR 39286, 39287. The alternate test procedure associated with this prior waiver required that the specified single-packaged dedicated system basic models shall be tested using the Indoor Air Enthalpy Method and the Outdoor Air Enthalpy Method in accordance with ASHRAE 37–2009, *Methods of Testing for Rating Electrically Driven Unitary Air-Conditioning and Heat-Pump Equipment* (''ASHRAE 37''). 84 FR 39286, 39292. DOE also granted waivers to Air Innovations, CellarPro, Vinotemp, and Vinotheque for walk-in refrigeration systems used in wine cellar applications, for which some of the basic models included in these waivers were single-packaged dedicated systems.[6] The alternate test methods included in these waivers require the specified basic models to be tested in accordance with AHRI Standard 1250–2020 (*2020 Standard for Performance Rating of Walk-In Coolers and Freezers,* ''AHRI 1250–2020''), which references the air enthalpy methods in ASHRAE 37 for testing single-packaged dedicated systems.[7] Use of air enthalpy methods for testing a single-packaged dedicated system capture the impact of thermal loss and the infiltration of warm air into the evaporator portion of these systems, which increases the refrigerant load on the system. In its petition for waiver and interim waiver, RSG stated that its laboratory is not set up to conduct air enthalpy testing, and that it would require substantial time and expense to set up its laboratory to conduct air enthalpy testing. (RSG, No. 1, attachment 1, at p. 2) Additionally, RSG explained that it contacted third-party labs to inquire about testing single-packaged dedicated systems using the air enthalpy method, but these labs responded that they are not currently able to conduct air enthalpy testing. *Id.*

Third, in its request for waiver and interim waiver from the DOE test procedure, RSG stated that the current tolerance requirement of 0.5 °F for the on-coil temperature in section C3.3.3 of AHRI 1250–2009 is unrealistic. *Id.* RSG stated that indoor air temperature tolerances impact the on-coil temperatures, and that the test procedure currently prescribes a 1 °F indoor air temperature test condition tolerance.[8] *Id.* RSG therefore suggested

[5] AHRI 1250–2009 does not explain why Method 1 requires 25 feet of refrigeration line and Method 2 requires 26 feet of refrigeration line during test set up.

[6] See Waiver Decision and Orders for Air Innovations (86 FR 23702 (May 4, 2021)), CellarPro (86 FR 26496 (May 14, 2021)), Vinotheque (86 FR 26504 (May 14, 2021)), and Vinotemp (86 FR 36732 (Jul. 13, 2021)).

[7] Subsequent to DOE's grant of waiver to Store It Cold, AHRI published an updated version of AHRI 1250 (*i.e.,* AHRI 1250–2020) that provides testing provisions for single-packaged dedicated systems that incorporate by reference the approach used in ASHRAE 37 with some modification.

[8] Test condition tolerance is the maximum allowed deviation of the average of the measurements of a parameter made during a test period as compared with its target value. The

Continued

that the on-coil temperature tolerance should also be 1 °F. *Id.* RSG noted further that it can be difficult to repeatedly achieve an on-coil temperature tolerance of 0.5 °F when units are shut down, re-plumbed, and recharged for testing. *Id.*

RSG also requested an interim waiver from the existing DOE test procedure, explaining that if DOE were to deny its application for waiver and interim waiver, it would experience economic hardship in the form of lost sales and/or a significant delay in the distribution into commerce of the specified basic models. *Id.*

On July 22, 2022, DOE published a notification announcing its receipt of the petition for waiver and interim waiver and granted RSG an interim waiver. 87 FR 43808 (''Interim Waiver Order''). In the Interim Waiver Order, DOE initially determined that the alternate test procedure—with certain minor modifications as discussed in the Interim Waiver Order—appears to allow for the accurate measurement of the energy efficiency of the specified basic models, while alleviating the testing problems cited by RSG in its attempts to implement the DOE test procedure for these basic models. *Id.* at 87 FR 43814. The alternate test procedure established in the Interim Waiver Order is based on the calibrated box method (*i.e.,* Method 2 of AHRI 1250–2009) with modifications to the refrigerant enthalpy test provisions of this method. *Id.* at 87 FR 43813. Using the calibrated box method, the measured capacity includes the thermal loss through the evaporator of the single-packaged dedicated system under test. *Id.* The calibrated box method serves as the primary test method. A modified version of the single-packaged refrigerant enthalpy method is specified in the alternate test procedure for use as a secondary test method.[9] *Id.* Under the modified refrigerant enthalpy method, the refrigerant liquid line length is reduced from 25 feet (as prescribed in AHRI 1250–2009) to a maximum of 5 feet, allows for the capacity measurements of multiple refrigerant circuits, and adds a calculation to estimate the single-packaged thermal loss of the unit under test. *Id.* The capacity as measured by the primary and secondary test methods must be within 6 percent of one another for a valid test. *Id.* at 87 FR 43814.

The alternate test procedure established in the Interim Waiver Order differed from the alternate test procedure proposed by RSG with regard to the condenser air entering wet-bulb temperature test condition. *Id.* RSG proposed that the condenser air entering wet-bulb temperature test condition be 68 °F for single-packaged dedicated systems that do not use evaporative dedicated condensing units, for which all or part of the equipment is located in the outdoor room. *Id.* Whereas, the alternate test procedure established in the Interim Waiver Order specifies the condensing air entering wet-bulb temperature as 65 °F, which maintains consistency with the requirements in Table 8 of AHRI 1250–2020. *Id.*

In the Interim Waiver Order, DOE solicited comments from interested parties on all aspects of the petition and the specified alternate test procedure. 87 FR 43808, 43809. DOE did not receive any comments in response to the Interim Waiver Order.

On May 4, 2023, DOE published a test procedure final rule (''May 2023 Final Rule'') that established a new test procedure for walk-in coolers and walk-in freezers at appendix C1, in addition to specifying minor amendments to appendix C. 88 FR 28780, 28810. Appendix C1 includes test provisions for multi-circuit single-package dedicated systems that are substantively the same as the methodology granted in the Interim Waiver Order. Use of appendix C1 is not required until the compliance date of any amended energy conservation standards based on the test procedure in appendix C1. Until such time, use of appendix C is required to demonstrate compliance with current standards. As discussed in the May 2023 Final Rule, the amendments to appendix C did not include provisions for multi-circuit single-package dedicated systems.[10] As such, for the basic models subject to the Interim Waiver Order, the need for the waiver from appendix C will continue until such time as use of appendix C1 is required.

For the reasons explained here and in the Interim Waiver Order, absent a waiver the basic models identified by RSG in its petition cannot be tested and rated for energy consumption on a basis representative of their true energy consumption characteristics. Therefore, DOE has determined that the current test procedure for walk-in cooler refrigeration systems would evaluate the subject basic models in a manner so unrepresentative of its true energy consumption characteristics as to provide materially inaccurate comparative data. DOE has reviewed the recommended procedure suggested by RSG and concludes that, with minor modification to the condenser air entering wet bulb temperature as discussed previously, it will allow for the accurate measurement of the energy use of the equipment, while alleviating the testing problems associated with RSG's implementation of DOE's applicable walk-in test procedure for the specified basic models.

Thus, DOE is requiring that RSG test and rate specified walk-in basic models according to the alternate test procedure specified in this Decision and Order, which is identical to the alternate test procedure specified in the Interim Waiver Order.[11]

This Decision and Order is applicable only to the basic models listed and does not extend to any other basic models. DOE evaluates and grants waivers for only those basic models specifically set out in the petition, not future models that may be manufactured by the petitioner. RSG may request that DOE extend the scope of this waiver to include additional basic models that employ the same technology as those listed in this waiver. 10 CFR 431.401(g). RSG may also submit another petition for waiver from the test procedure for additional basic models that employ a different technology and meet the criteria for test procedure waivers. 10 CFR 431.401(a)(1).

DOE notes that it may modify or rescind the waiver at any time upon DOE's determination that the factual basis underlying the petition for waiver is incorrect, or upon a determination that the results from the alternate test procedure are unrepresentative of the basic models' true energy consumption characteristics. 10 CFR 431.401(k)(1). Likewise, RSG may request that DOE rescind or modify the waiver if the company discovers an error in the information provided to DOE as part of its petition, determines that the waiver is no longer needed, or for other

indoor air dry-bulb test condition tolerance is specified as 1 °F in Table 2 of AHRI 1250–2009.

[9] A secondary test method's results are used to ensure the capacity tolerance is met when compared to the capacity determined by a primary test method, but are not used for rating performance.

[10] DOE notes a typographical error in Table III.8 of the May 2023 Final Rule. 88 FR 28780, 28827. In that table, the interim waiver granted to RSG was indicated as being addressed by amendments to appendix C, with compliance beginning October 31, 2023. *Id.* The table should have indicated the RSG interim waiver as being addressed by appendix C1, with a compliance date corresponding to ''Compliance date of updated standards.''

[11] DOE notes that while the test provisions of this Decision and Order are identical to those presented in the Interim Waiver Order, the section numbering of the test provisions specified in this Decision and Order are slightly different than those sections specified in the Interim Waiver Order due to other section numbering changes made to appendix C by the May 2023 Final Rule.

appropriate reasons. 10 CFR 431.401(k)(2).

III. Order

After careful consideration of all the material that was submitted by RSG, in this matter, it is *ordered* that:

(1) RSG must test and rate the following Norlake- and Masterbilt-branded basic models with the test procedure set forth in paragraph (2).

Cooler basic models	Freezer basic models
CPB050PC–S–0	CPF050PC–S–0
CPB075PC–S–0	CPF075PC–S–0
CPB100PC–S–0	CPF100PC–S–0
	CPF150PC–S–4
	CPF200PC–S–4

(2) The alternate test procedure for the RSG basic models identified in paragraph (1) of this Order is the test procedure for walk-in refrigeration systems prescribed by DOE at 10 CFR part 431, subpart R, appendix C (''appendix C'') as amended by the May 2023 Final Rule, except that multiple-circuit single-packaged dedicated systems shall use: (1) either the calibrated box method or an indoor air enthalpy test as the primary test method, as detailed below; (2) the modified refrigerant enthalpy method as the secondary test method, as detailed below; (3) the net capacity from the primary and secondary test methods must agree within ± 6 percent, as detailed below; and (4) reported values for the overall system shall be the summation of the gross capacities obtained from the modified refrigerant enthalpy method conducted for each refrigeration circuit included in the unit under test, as detailed below. All other requirements of appendix C as amended by the May 2023 Final Rule and DOE's regulations remain applicable.

In appendix C:

Revise section 3.1.1 to read as follows:

3.1.1. In Table 1 of AHRI 1250–2009, Instrumentation Accuracy, refrigerant temperature measurements shall have a tolerance of ±0.5 °F for unit cooler in/out. Temperature measurements used to determine water vapor content of the air shall be accurate to within ±0.4 °F. All other temperature measurements shall be accurate to ±1.0 °F.

Revise section 3.1.4 to read as follows:

3.1.4. In Tables 2 through 14 of AHRI 1250–2009, the Test Condition Outdoor Wet Bulb Temperature requirement and its associated tolerance apply only to units with evaporative cooling and single-packaged dedicated systems.

Insert new section 3.1.8 as follows:

3.1.8 Tables 3, 4, 7 and 8 of AHRI 1250–2009 shall be modified to read as follows:

TABLE 3—FIXED CAPACITY MATCHED REFRIGERATOR SYSTEM, CONDENSING UNIT LOCATED INDOOR

Test description	Unit cooler air entering dry-bulb, °F	Unit cooler air entering relative humidity, (%)	Condenser air entering dry-bulb, (°F)	Condenser air entering wet-bulb, °F	Compressor capacity	Test objective
Off Cycle Fan Power.	35	<50	.....	.....	Compressor Off	Measure fan input wattage during compressor off cycle.
Refrigeration Capacity.	35	<50	90	75 [1] or 65 [2]	Compressor On	Determine Net Refrigeration Capacity of Unit Cooler, input power, and EER at Rating Condition.

[1] Required only for evaporative Dedicated Condensing Units

[2] Maximum allowable value for Single-Packaged Dedicated Systems that do not use evaporative Dedicated Condensing Units, where all or part of the equipment is located in the outdoor room.

TABLE 4—FIXED CAPACITY MATCHED REFRIGERATOR SYSTEM, CONDENSING UNIT LOCATED OUTDOOR

Test description	Unit cooler air entering dry-bulb, °F	Unit cooler air entering relative humidity, (%)	Condenser air entering dry-bulb, (°F)	Condenser air entering wet-bulb, °F	Compressor capacity	Test objective
Off Cycle Fan Power.	35	<50	.....	.....	Compressor Off	Measure fan input wattage during compressor off cycle.
Refrigeration Capacity A.	35	<50	95	75 [1] or 68 [2]	Compressor On	Determine Net Refrigeration Capacity of Unit Cooler, input power, and EER at Rating Condition.
Refrigeration Capacity B.	35	<50	59	54 [1] or 46 [2]	Compressor On	Determine Net Refrigeration Capacity of Unit Cooler, and system input power at moderate condition.
Refrigeration Capacity C.	35	<50	35	34 [1] or 29 [2]	Compressor On	Determine Net Refrigeration Capacity of Unit Cooler, and system input power at cold condition.

[1] Required only for evaporative Dedicated Condensing Units.

[2] Maximum allowable value for Single-Packaged Dedicated Systems that do not use evaporative Dedicated Condensing Units, where all or part of the equipment is located in the outdoor room.

TABLE 7—FIXED CAPACITY MATCHED FREEZER SYSTEM, CONDENSING UNIT LOCATED INDOOR

Test description	Unit cooler air entering dry-bulb, °F	Unit cooler air entering relative humidity, (%)	Condenser air entering dry-bulb, (°F)	Condenser air entering wet-bulb, °F	Compressor capacity	Test objective
Off Cycle Fan Power.	−10	<50	.....	.....	Compressor Off	Measure fan input wattage during compressor off cycle.
Refrigeration Capacity.	−10	<50	90	75 [1] or 65 [2]	Compressor On	Determine Net Refrigeration Capacity of Unit Cooler, input power, and EER at Rating Condition.
Defrost Frost Load.	−10	Various	90	75 [1] or 65 [2]	System Dependent	Test according to section C11 of AHRI 1250–2009.

[1] Required only for evaporative Dedicated Condensing Units.

[2] Maximum allowable value for Single-Packaged Dedicated Systems that do not use evaporative Dedicated Condensing Units, where all or part of the equipment is located in the outdoor room.

TABLE 8—FIXED CAPACITY MATCHED FREEZER SYSTEM, CONDENSING UNIT LOCATED OUTDOOR

Test description	Unit cooler air entering dry-bulb, °F	Unit cooler air entering relative humidity, (%)	Condenser air entering dry-bulb, (°F)	Condenser air entering wet-bulb, °F	Compressor capacity	Test objective
Off Cycle Fan Power.	−10	<50	.....	.....	Compressor Off	Measure fan input wattage during compressor off cycle.
Refrigeration Capacity A.	−10	<50	95	75 [1] or 68 [2]	Compressor On	Determine Net Refrigeration Capacity of Unit Cooler, input power, and EER at Rating Condition.
Refrigeration Capacity B.	−10	<50	59	54 [1] or 46 [2]	Compressor On	Determine Net Refrigeration Capacity of Unit Cooler, input power, and EER at Rating Condition.
Refrigeration Capacity C.	−10	<50	35	34 [1] or 29 [2]	Compressor On	Determine Net Refrigeration Capacity of Unit Cooler, input power, and EER at Rating Condition.
Defrost Frost Load.	−10	Various	95	75 [1] or 68 [2]	System Dependent	Test according to section C11 of AHRI 1250–2009.

[1] Required only for evaporative Dedicated Condensing Units.
[2] Maximum allowable value for Single-Packaged Dedicated Systems that do not use evaporative Dedicated Condensing Units, where all or part of the equipment is located in the outdoor room.

Remove section 3.2.5.

Add a new section 4, following section 3.5 *Hot Gas Defrost Refrigeration Systems*

4.0 Multiple-Circuit Single-Packaged Dedicated Systems

When conducting testing in accordance with AHRI 1250–2009 (incorporated by reference; see 10 CFR 431.303), the following modifications must be made.

4.1 Specific Modifications: Test Conditions and Tolerance

4.1.1 Replace section C3.1.2 of AHRI 1250–2009 with the following: Air wet-bulb and dry-bulb temperatures entering the Single-Packaged Dedicated System at its evaporator return and condenser air inlet shall be measured based on the airflow area at the point of measurement. One measuring station is required for each 2.0 ft^2 of the first 10.0 ft^2 of airflow area and one additional measuring station is required for each 4.0 ft^2 of airflow area above 10.0 ft^2. A minimum of two stations shall be used and the number of measuring stations shall be rounded up to the next whole number.

4.1.2 Replace section C3.1.5 of AHRI 1250–2009 with the following: If sampling tubes are used, each tube opening may be considered a temperature measuring station provided the openings are uniformly spaced along the tube, the airflow rates entering each port are relatively uniform (±15%) and the arrangement of tubes complies with the location requirements of section C3.1.2 of AHRI 1250–2009. Additionally, a one-time temperature traverse shall be made over the measurement surface, prior to the tests to assess the temperature variation and ensure it complies with the allowable deviation specified in section C3.1.4 of AHRI 1250–2009. (Refer to ANSI/ASHRAE Standard 41.1 for more information and diagrams). If sampling tubes are not used for single-packaged dedicated systems that do not use evaporative dedicated condensing units, a single air wet-bulb or RH sensor may be used. When used, this sensor shall be located at the geometric center of the largest condenser coil face and 6–12 inches from the condenser coil.

4.1.3 Replace section 3.1.6 of AHRI 1250–2009 with the following: Refrigerant temperatures entering and leaving the evaporator section of the Single-Packaged Dedicated System shall be measured by a temperature measuring instrument placed in a thermometer well and inserted into the refrigerant stream. These wells shall be filled with non-solidifying, thermal conducting liquid or paste to ensure the temperature sensing instrument is exposed to a representative temperature. The entering temperature of the refrigerant shall be measured within six pipe diameters upstream of the expansion device. If the refrigerant tube outer diameter is less than ½-inch, the refrigerant temperature may be measured using the average of two temperature measuring instruments with a minimum accuracy of ±0.5 °F placed on opposite sides of the refrigerant tube surface. In this case, the refrigerant tube shall be insulated with 1-inch-thick insulation from a point 6 inches upstream of the measurement location to a point 6 inches downstream of the measurement location. Also, the entering measurement location may be moved to a location 6 inches upstream of the expansion device.

4.2 Refrigerant Properties Measurement

4.2.1 Replace section C3.3.1 of AHRI 1250–2009 with the following: With the equipment operating at the desired test conditions, the temperature and pressure of the refrigerant leaving the unit cooler, entering the expansion device, and entering and leaving the compressor shall be measured. For cases where the calibrated box method or indoor air enthalpy method is also conducted, data used to calculate capacity according to the single-package refrigerant enthalpy method and the additional method shall be collected over the same intervals.

4.2.2 Replace section C3.3.3 of AHRI 1250–2009 with the following: For Single-Packaged Dedicated Systems tested using either the calibrated box method or the indoor air enthalpy method as the primary measurement and the single-package refrigerant enthalpy method as the secondary method, a preliminary test for Rating Condition A using the primary method is required prior to setting up the refrigerant enthalpy method measurements. In preparation for this preliminary test, temperature sensors shall be attached to the equipment's evaporator and condenser coils. The sensors shall be located at points that are not affected by vapor superheat or liquid subcooling. Placement near the midpoint of the coil, at a return bend, is recommended. The preliminary test shall be conducted with the requirement that the temperatures of the on-coil sensors be included with the regularly recorded data. After the preliminary test is completed, the refrigerant shall be removed from the equipment, and the refrigerant enthalpy measurement setup shall be completed. The equipment

shall be evacuated and recharged with refrigerant. The test shall then be repeated. Once steady-state operation is achieved, refrigerant shall be added or removed until, as compared to the average values from the preliminary test, the following conditions are achieved: (1) each on-coil temperature sensor indicates a reading that is within ±1.0 °F, (2) the temperatures of the refrigerant entering and leaving the compressor are within ±4 °F, and (3) the refrigerant temperature entering the expansion device is within ±1 °F. Once these conditions have been achieved over an interval of at least ten minutes, refrigerant charging equipment shall be removed, and the remaining tests shall be conducted.

4.2.3 When conducting the refrigerant enthalpy method for a Single-Packaged Dedicated System, the length of the added liquid line conducting refrigerant out of the system, to the flow meter, and back into the system shall be no more than 5 feet. No such modification to the suction line shall be made.

4.3 Methods for Testing for Walk-In Cooler and Freezer Systems That Have Matched Unit Coolers and Condensing Units

Disregard section C5 of AHRI 1250–2009 and instead test according to the following method:

4.3.1 The Refrigeration Capacity for Single-Packaged Dedicated Systems shall be determined using either the Calibrated Box method or the Indoor Air Enthalpy method as a primary test method and the Single-Package Refrigerant Enthalpy method as the secondary test method.

4.3.1.1 Single-Package Refrigerant Enthalpy method shall determine gross refrigeration capacity by measuring the enthalpy change and the mass flow rate of the refrigerant using a single set of measurements.

4.3.1.2 Calibrated Box method shall determine net refrigeration capacity by measuring the heat input to the calibrated box, including thermal transfer through the calibrated box walls.

4.3.2 Indoor Air Enthalpy method shall determine net refrigeration capacity of Single-Packaged Dedicated System and input power in accordance with ASHRAE 37–2009, Figure C4 of AHRI 1250–2020, and the following modifications.

4.3.2.1 Net refrigeration capacity is determined by measuring airflow rate and the dry-bub temperature and water vapor content of the air that enters and leaves the coil.

4.3.2.2 Air enthalpies shall be determined in accordance with ANSI/ASHRAE 41.6. Entering air is to be sufficiently dry as to not produce frost on the evaporator coil. Therefore, only sensible capacity measured by dry bulb change shall be used to calculate capacity.

4.3.3 Testing Sequence. The primary test method shall be used to measure the capacity for Rating Condition A prior to set-up of the Single-Package Refrigerant Enthalpy Measurement. After set-up of the Refrigerant Enthalpy method, the Net Capacity shall be measured using both the primary test method and the Refrigerant Enthalpy method. The Net Capacity measurement using the Refrigerant Enthalpy method shall be within 6 percent of the net capacity measurement using the primary method.

If a capacity balance within tolerance is not initially achieved, take steps to reduce the thermal losses of the Single-Packaged Dedicated System evaporator compartment by sealing air gaps and potentially adding more external insulation. If using the Calibrated Box method as the primary method, achieving a capacity balance may require conducting the calibration with calibrated box insulation material at the same average temperature as during capacity measurement, or using multiple calibrations conducted at different average insulation material temperatures and using these data to construct a correlation for the calibration coefficient, K_{cb}, as a function of average insulation temperature. The official performance measurements are based on the primary method testing without any air gap sealing and additional external insulation used to achieve the 6 percent energy balance in place.

4.3.4 The refrigerant enthalpy method Net Capacity shall be calculated from the Gross Capacity Measurement as follows.

$$\dot{q}_{ss,2} = \dot{Q}_{ref} - 3.412 \times \dot{E}F_{comp,on} - \dot{Q}_{sploss}$$

Where $\dot{Q}_{sploss}$ represents the Single-Packaged Dedicated System thermal losses through the walls of the evaporator side of the Single-Packaged Dedicated System to the condenser side and to the exterior ambient, and shall be calculated as follows.

$$\dot{Q}_{sploss} = UA_{cond} \times (T_{condside} - T_{evapside}) + UA_{amb} \times (T_{amb} - T_{evapside})$$

Where:

UA_{cond} and UA_{amb} are, for the condenser/evaporator partition and the evaporator compartment walls exposed to ambient air, respectively, the product of the overall heat transfer coefficient and surface area of the unit as manufactured, *i.e.,* without external insulation that might have been added during the test;

$T_{evapside}$ is the air temperature in the evaporator compartment;

$T_{condside}$ is the air temperature in the condenser compartment; and

T_{amb} is the air temperature outside the Single-Packaged Dedicated System.

The Net Capacity to be used in AWEF calculations shall be the net capacity measured using the primary method.

4.3.5 Upon the completion of the Rating Condition A steady state test, an off-cycle evaporator fan power test shall be conducted to measure the evaporator fan power consumption during a compressor-off period in accordance with section C10 of AHRI 1250–2009.

4.3.6 Upon the completion of the Rating Condition A steady state test for walk-in freezer systems, a mandatory defrost test shall be conducted to establish the energy input for a defrost cycle.

4.3.7 Upon the completion of the Rating Condition A steady state test, off-cycle evaporator fan power test, and defrost test (for walk-in freezer systems), the Rating Condition B and C steady state tests shall be conducted. Capacity balance as described in section C9.2 of AHRI 1250–2020 for Rating Condition A is not required for Rating Conditions B and C.

4.4 Test Chamber Requirements

Disregard section C6 of AHRI 1250–2009 and instead test according to the following method:

4.4.1 For single-packaged dedicated systems, test chamber requirements shall be as follows:

a. For the calibrated box method, follow ASHRAE 16–2016 Section 6.1 for calibrated type calorimeters excluding water and water energy inputs for the indoor-side compartment.

b. For the indoor air enthalpy method, follow ASHRAE 37–2009.

4.5 Single-Packaged Dedicated System Refrigerant Enthalpy Method

4.5.1 General Description. In this method, capacity is determined from the refrigerant enthalpy change and flow rate. Enthalpy changes are determined from measurements of entering and leaving pressures and temperatures of the refrigerant, and the flow rate is determined by a suitable flow meter in the liquid line. This method shall not be used for tests in which the refrigerant liquid leaving the flow meter is subcooled less than 3 °F or for tests in which any instantaneous measurement of the superheat of the vapor leaving the evaporator coil is less than 5 °F. Supplementary cooling may be artificially provided for the liquid line to ensure enough subcooling when

making measurements to establish the capacity balance for Rating Condition A, however, no official measurements used to calculate AWEF may be made while providing such supplementary cooling.

4.5.2 Measurements. Refer to Section 4.1 of this appendix and section C3 of AHRI 1250–2009 for requirements of air-side and refrigerant-side measurements.

4.5.3 Test Setup and Procedure. Refer to Section 4.4 of this appendix, section C7 of AHRI 1250–2009, and Figure C3 of this section for specific test setup. The length of the added liquid line shall be 5 feet, maximum.

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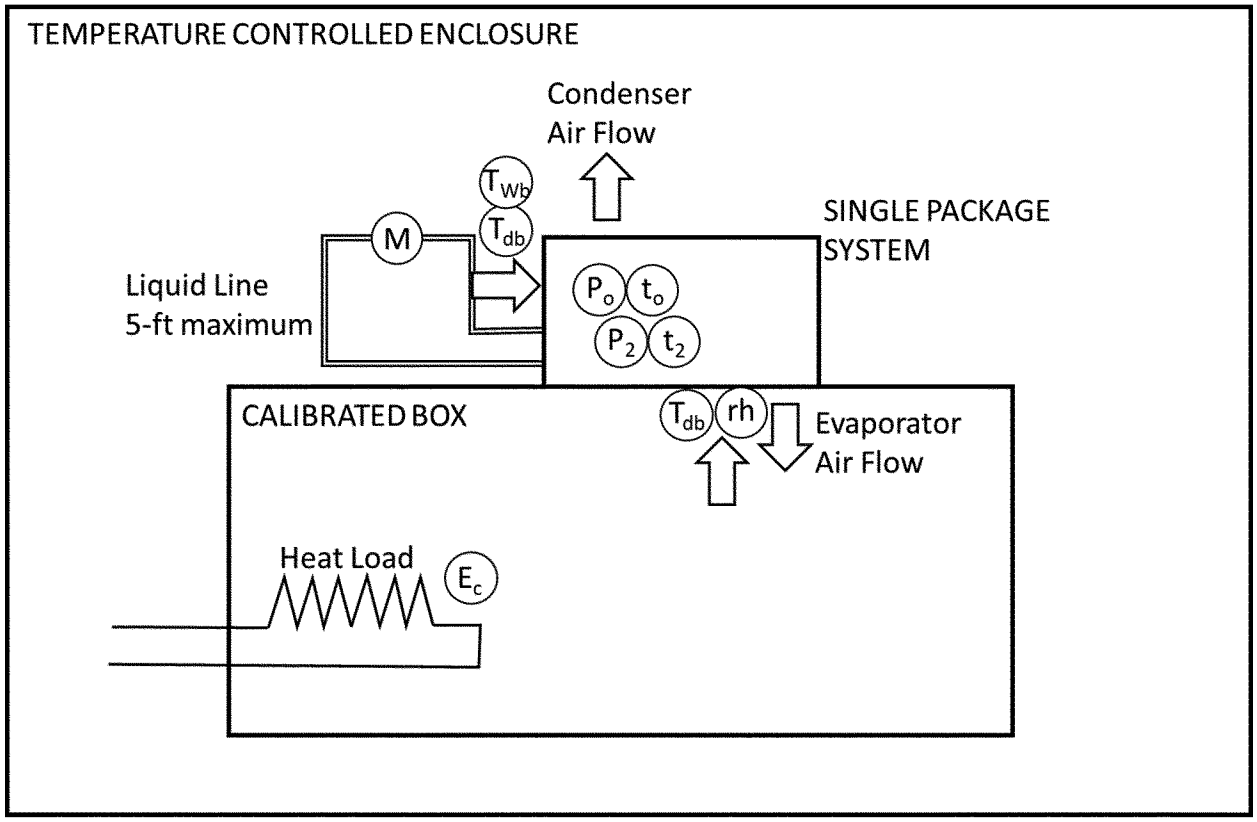

LEGEND	
M	Mass Flow Meter
T_{db} T_{Wb}	Air Temperature Measurement Station
rh	Air Relative Humidity Measurement
P	Refrigerant Pressure Measurement
t	Refrigerant Temperature Measurement Station
E_c	Heat Load Input Power

Figure C3: Calibrated Box and Single-package Refrigerant Enthalpy Method

4.5.4 Data to be Measured and Recorded. Refer to ''Refrigerant Enthalpy Method'' in Table C2 in section C7.2 of AHRI 1250–2009 for the required data that need to measured and recorded, except as follows.

4.5.4.1 Water vapor content of air entering the unit cooler (evaporator) and condensing unit may be measured using a wet bulb temperature measurement or a relative humidity sensor, but both are not required.

4.5.4.2 Wet bulb temperature of air leaving the unit cooler (evaporator) and condensing unit need not be measured.

4.5.4.3 Required refrigerant pressure measurement includes only subcooled liquid entering the expansion valve and superheated vapor exiting the unit cooler (evaporator).

4.5.4.4 Only one refrigerant mass flow measurement is required.

4.5.4.5 Measurement of Refrigerant oil flow rate and oil/refrigerant mass ratio are not required.

4.5.5 Refrigeration Capacity Calculation.

4.5.5.1 The refrigerant-side gross capacity is calculated by

$$\dot{Q}_{ref} = \dot{m}_{ref}(h_{out} - h_{in})$$

4.5.5.2 Measurement of Capacity for a Single-Packaged Dedicated System with Multiple Refrigeration Circuits.

For a Single-Packaged Dedicated System with multiple refrigeration circuits, apply the refrigerant enthalpy method separately for each circuit and sum the separately-measured gross refrigeration capacities.

4.6 Calibrated Box Test Procedure

4.6.1 Measurements. Refer to section 4.1 of this section and section C3 of AHRI 1250–2009 for requirements of air-side and refrigerant-side measurements.

4.6.2 Apparatus setup for Calibrated Box Calibration and Test. Refer to section 4.4 of this section, section C7 of AHRI 1250–2009, and Figure C4 of this section for specific test setup.

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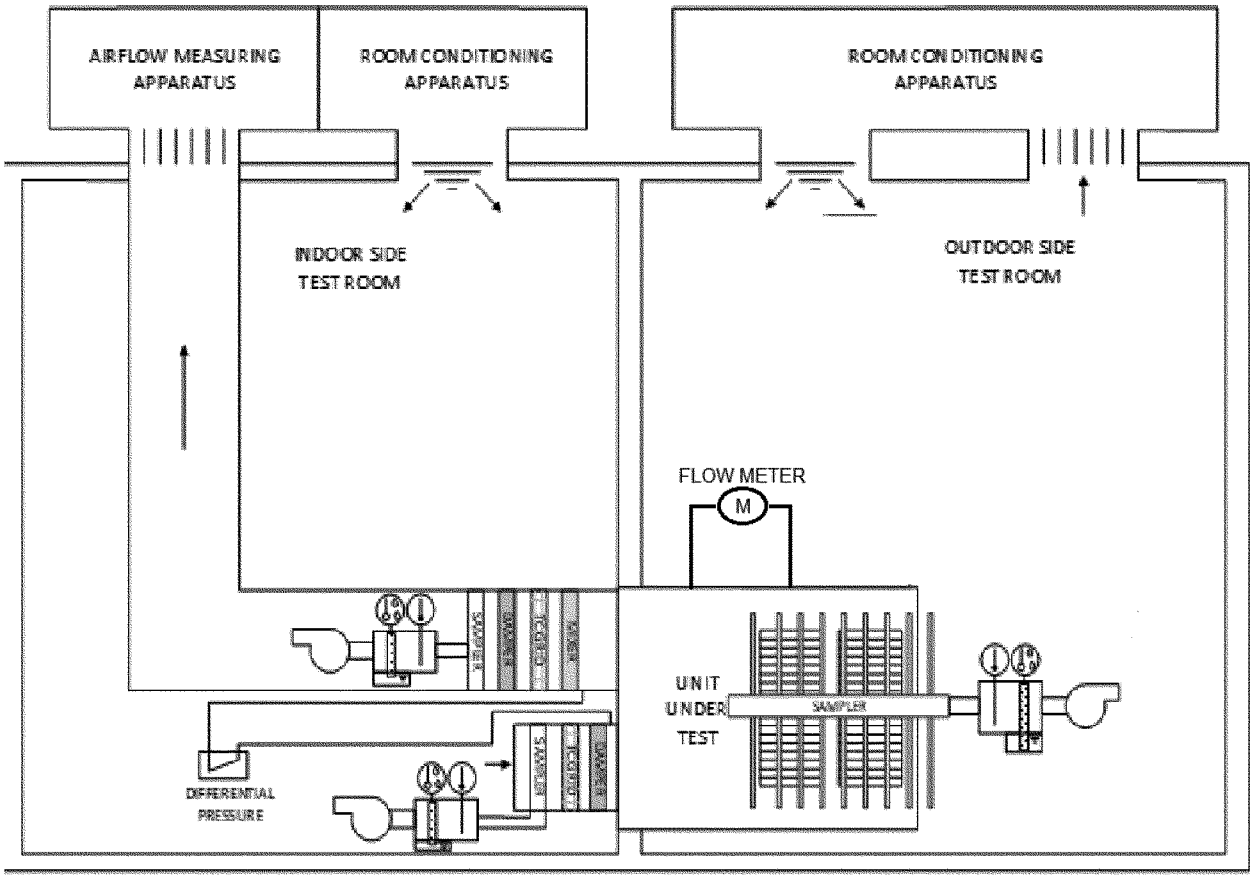

Figure C4: Indoor Air Enthalpy and Single-package Refrigerant Enthalpy Method

4.6.2.1 The calibrated box shall be installed in a temperature-controlled enclosure in which the temperature can be maintained at a constant level. When using the calibrated box method for Single-Packaged Dedicated Systems, the enclosure air temperature shall be maintained such that the condenser air entering conditions are as specified for the test.

4.6.2.2 The temperature-controlled enclosure shall be of a size that will provide clearances of not less than 18 in at all sides, top and bottom, except that clearance of any one surface may be reduced to not less than 5.5 inches.

4.6.2.3 The heat leakage of the calibrated box shall be noted in the test report.

4.6.2.4 Refrigerant lines within the calibrated box shall be well insulated to avoid appreciable heat loss or gain.

4.6.2.5 Instruments for measuring the temperature around the outside of the calibrated box to represent the enclosure temperature T_{en} shall be located at the center of each wall, ceiling, and floor.

Exception: in the case where a clearance around the outside of the calibrated box, as indicated above, is reduced to less than 18 inches, the number of temperature-measuring devices on the outside of that surface shall be increased to six, which shall be treated as a single temperature to be averaged with the temperature of each of the other five surfaces. There will be six rectangular sections of equal area, and each of these six sections will have a temperature-measuring instrument located at its center. If the refrigeration system is mounted at the location that would cover the center of the face on which it is mounted, up to four temperature measurements shall be used on that face to represent its temperature. Each sensor shall be aligned with the center of the face's nearest outer edge and centered on the distance between that edge and the single-packaged unit (this is illustrated in Figure C5 when using surface temperature sensors), and they shall be treated as a single temperature to be averaged with the temperature of each of the other five surfaces. However, any of these sensors shall be omitted if either (a) the distance between the outer

edge and the single-packaged unit is less than one foot or (b) if the sensor location would be within two feet of any of the foot-square surfaces discussed below representing a warm discharge air impingement area. In this case, the remaining sensors shall be used to represent the average temperature for the surface.

One of the following two approaches shall be used for the box external temperature measurement. Box calibration and system capacity measurement shall both be done using the same one of these approaches.

4.6.2.5.1 Air temperature sensors. Each temperature sensor shall be at a distance of 6 inches from the calibrated box. If the clearance from a surface of the box (allowed for one surface only) is less than 12 inches, the temperature measuring instruments shall be located midway between the outer wall of the calibrated box and the adjacent surface.

4.6.2.5.2 Surface temperature sensors. Surface temperature sensors shall be mounted on the calibrated box surfaces to represent the enclosure temperature, T_{en}.

Additional surface temperature sensors may be used to measure external hot spots during refrigeration system testing. If this is done, two temperature sensors shall be used to measure the average temperature of the calibrated box surface covered by the condensing section—they shall be centered on equal-area rectangles comprising the covered calibrated box surface whose common sides span the short dimension of this surface. Additional surface temperature sensors may be used to measure box surfaces on which warm condenser discharge air impinges. A pattern of square surfaces measuring one foot square shall be mapped out to represent the hot spot upon which the warm condenser air impinges. One temperature sensor shall be used to measure surface temperature at the center of each square (see Figure C5 of this section). A drawing showing this pattern and identifying the surface temperature sensors shall be provided in the test report. The average surface temperature of the overall calibrated box outer surface during testing shall be calculated as follows.

$$T_{en} = \frac{\sum_{i=1}^{6} A_i T_i + \sum_{j=1}^{2} A_j \left(T'_j - T_1\right) + \sum_{k=1}^{n} A_k \left(T''_k - T_1\right)}{\sum_{i=1}^{6} A_i}$$

Where:

A_i is the surface area of the i^{th} of the six calibrated box surfaces;

T_i is the average temperature measured for the i^{th} surface;

A_j is half of the surface area of the calibrated box covered by the condensing section;

T'_j is the j^{th} of the two temperature measurements underneath the condensing section;

T_1 is the average temperature of the four or fewer measurements representing the temperature of the face on which the single-packaged system is mounted, prior to adjustments associated with hot spots based on measurements T_j and/or T_k;

A_k is the area of the k^{th} of n 1-square-foot surfaces used to measure the condenser discharge impingement area hot spot; and,

T''_k is the k^{th} of the n temperature measurements of the condenser discharge impingement area hot spot.

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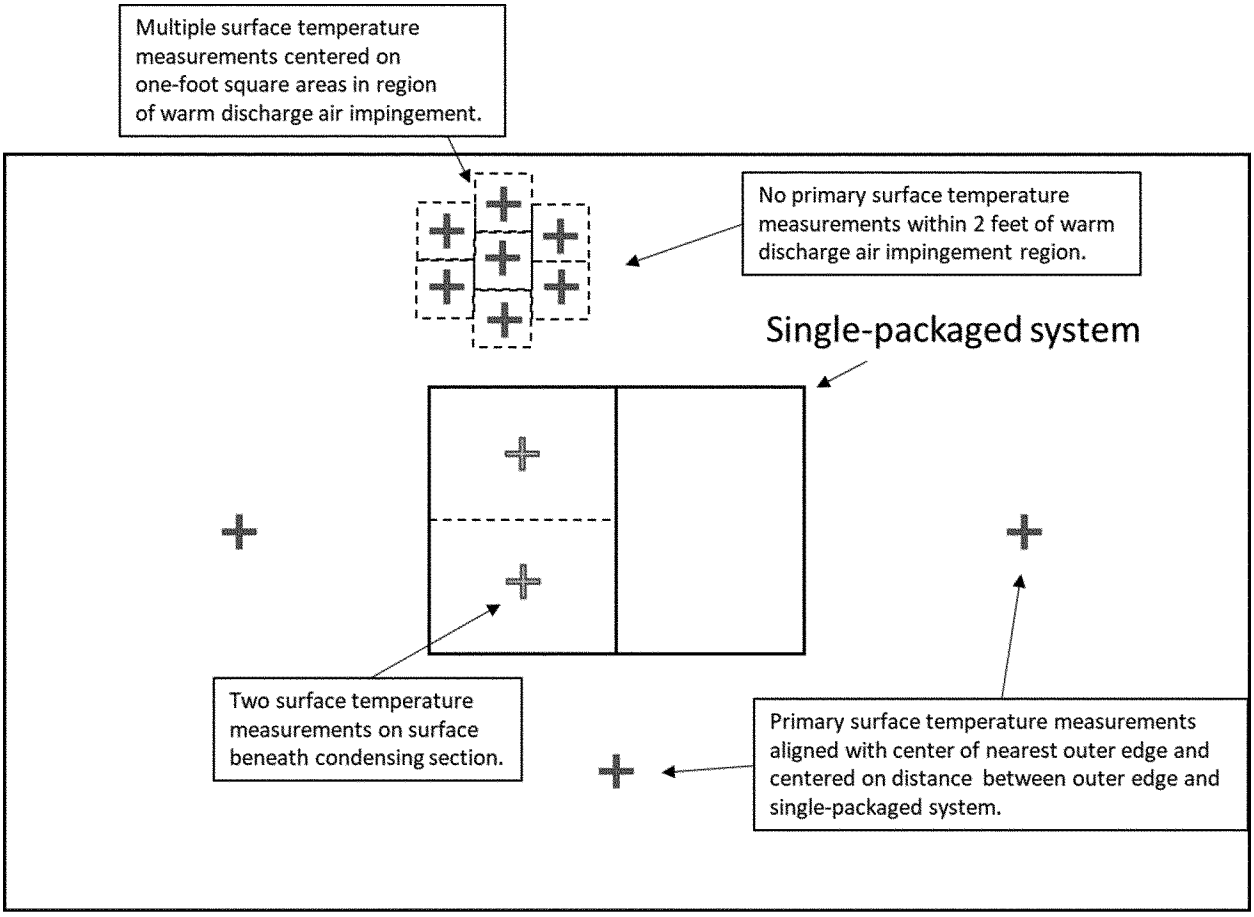

Figure C5: Illustration of Layout of Surface Temperature Sensors on Face of Calibrated Box on which Single-Packaged System is Mounted when Using Section 4.6.2.5.2 of 10 CFR Part 431 Subpart R, Appendix C.

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4.6.2.6 Heating means inside the calibrated box shall be shielded or installed in a manner to avoid radiation to the Single-Packaged Dedicated System, the temperature measuring instruments, and to the walls of the box. The heating means shall be constructed to avoid stratification of temperature, and suitable means shall be provided for distributing the temperature uniformly.

4.6.2.7 The average air dry-bulb temperature in the calibrated box during Single-Packaged Dedicated System tests and calibrated box heat leakage tests shall be the average of eight temperatures measured at the corners of the box at a distance of 2 inches to 4 inches from the walls. The instruments shall be shielded from any cold or warm surfaces except that they shall not be shielded from the adjacent walls of the box. The Single-Packaged Dedicated System under test shall be mounted such that the temperature instruments are not in the direct air stream from the discharge of the Single-Packaged Dedicated System.

4.6.3 Calibration of the Calibrated Box. Calibration of the Calibrated Box shall occur prior to installation of the Single-Packaged Dedicated System. This shall be done either (a) prior to cutting the opening needed to install the Single-Packaged Dedicated System, or (b) with an insulating panel with the same thickness and thermal resistance as the box wall installed in the opening intended for the Single-Packaged Dedicated System installation. Care shall be taken to avoid thermal shorts in the location of the opening either during calibration or during subsequent installation of the Single-Packaged Dedicated System. A calibration test shall be made for air movements comparable to those expected for Single-Packaged Dedicated System capacity measurement, *i.e.,* with air volume flow rate within 10 percent of the air volume flow rate of the Single-Packaged Dedicated System evaporator.

4.6.3.1 The heat input shall be adjusted to maintain an average box temperature not less than 25.0 °F above the test enclosure temperature.

4.6.3.2 The average dry-bulb temperature inside the calibrated box shall not vary more than 1.0 °F over the course of the calibration test.

4.6.3.3 A calibration test shall be the average of eleven consecutive hourly readings when the box has reached a steady-state temperature condition.

4.6.3.4 The box temperature shall be the average of all readings after a steady-state temperature condition has been reached.

4.6.3.5 The calibrated box has reached a steady-state temperature condition when:

4.6.3.5.1 The average box temperature is not less than 25 °F above the test enclosure temperature.

4.6.3.5.2 Temperature variations do not exceed 5.0 °F between temperature-measuring stations.

4.6.3.5.3 Temperatures do not vary by more than 2 °F at any one temperature-measuring station.

4.6.4 Data to be Measured and Recorded. Refer to Table C2 in section C7.2 of AHRI 1250–2020 for the required data that need to measured and recorded.

4.6.5 Refrigeration Capacity Calculation.

4.6.5.1 The heat leakage coefficient of the calibrated box is calculated by

$$K_{cb} = \frac{3.412 \times \dot{E}_c}{T_{en} - T_{cb}}$$

4.6.5.2 For each Dry Rating Condition, calculate the Net Capacity:

$\dot{q}_{ss} = K_{cb}\,(T_{en} - T_{cb}) + 3.412 \times \dot{E}_c$

(3) *Representations.* RSG may not make representations about the efficiency of a basic model listed in paragraph (1) of this Order for compliance, marketing, or other purposes unless that basic model has been tested in accordance with the provisions set forth in this alternate test procedure and such representations fairly disclose the results of such testing.

(4) This Order shall remain in effect until the date upon which use of appendix C1 is required to demonstrate compliance with any amended energy conservation standards based on the test procedure in appendix C1.

(5) This Order is issued on the condition that the statements and representations provided by RSG are valid. If RSG makes any modifications to the controls or configurations of any basic model subject to this Order, such modifications will render the waiver invalid with respect to that basic model, and RSG will either be required to use the current Federal test method or submit a new application for a test procedure waiver. DOE may rescind or modify this waiver at any time if it determines the factual basis underlying the petition for the waiver is incorrect, upon a determination that the results from the alternate test procedure are unrepresentative of a basic model's true energy consumption characteristics, or for other appropriate reasons. 10 CFR 431.401(k)(1). Likewise, RSG may request that DOE rescind or modify the waiver if RSG discovers an error in the information provided to DOE as part of its petition, determines that the waiver is no longer needed, or for other appropriate reasons. 10 CFR 431.401(k)(2).

(6) Issuance of this Order does not release RSG from the applicable requirements set forth at 10 CFR part 429.

DOE makes decisions on waivers and interim waivers for only those basic models specifically set out in the petition, not future models that may be manufactured by the petitioner. RSG may submit a new or amended petition for waiver and request for grant of interim waiver, as appropriate, for additional basic models of single-packaged dedicated systems with multiple refrigeration circuits. Alternatively, if appropriate, RSG may request that DOE extend the scope of a waiver or an interim waiver to include additional basic models employing the same technology as the basic models set forth in the original petition consistent with 10 CFR 431.401(g).

Signing Authority

This document of the Department of Energy was signed on November 17, 2023, by Jeffrey Marootian, Principal Deputy Assistant Secretary for Energy Efficiency and Renewable, pursuant to delegated authority from the Secretary of Energy. That document with the original signature and date is maintained by DOE. For administrative purposes only, and in compliance with requirements of the Office of the Federal Register, the undersigned DOE Federal Register Liaison Officer has been authorized to sign and submit the document in electronic format for publication, as an official document of the Department of Energy. This administrative process in no way alters the legal effect of this document upon publication in the **Federal Register**.

Signed in Washington, DC, on November 17, 2023.

Treena V. Garrett,

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

[FR Doc. 2023–25873 Filed 11–21–23; 8:45 am]

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DEPARTMENT OF ENERGY

[Case Number 2023–004; EERE–2023–BT–WAV–0016]

Energy Conservation Program: Notification of Petition for Waiver of United CoolAir Corporation From the Department of Energy Commercial Air Conditioners and Heat Pumps Test Procedure and Notification of Denial of Interim Waiver

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

ACTION: Notification of petition for waiver and denial of application for interim waiver; request for comments.

SUMMARY: This notification announces receipt of and publishes a petition for waiver and interim waiver from United CoolAir Corporation (''UCA''), which seeks a waiver for specified basic models of double-duct air conditioners and heat pumps from the U.S. Department of Energy (''DOE'') test procedure used for determining the efficiency of double-duct air conditioners and heat pumps. This notification also announces that DOE is declining to grant the request for an interim waiver for the reasons described in this notification. DOE solicits comments, data, and information concerning UCA's petition and its suggested alternate test procedure so as to inform DOE's final decision on UCA's waiver request.

DATES: Written comments and information are requested and will be accepted on or before December 22, 2023.

ADDRESSES: Interested persons are encouraged to submit comments using the Federal eRulemaking Portal at *www.regulations.gov* under docket number EERE–2023–BT–WAV–0016. Follow the instructions for submitting comments. Alternatively, interested persons may submit comments, identified by docket number EERE–2023–BT–WAV–0016, by any of the following methods:

(1) *Email: UnitedCoolAirACHP2023WAV0016@ee.doe.gov.* Include the case number [Case No. 2023–004] in the subject line of the message.

(2) *Postal Mail:* Appliance and Equipment Standards Program, U.S. Department of Energy, Building Technologies Office, Mailstop EE–5B, Petition for Waiver [Case No. 2023–004], 1000 Independence Avenue SW, Washington, DC 20585–0121. If possible, please submit all items on a compact disc (''CD''), in which case it is not necessary to include printed copies.

(3) *Hand Delivery/Courier:* Appliance and Equipment Standards Program, U.S. Department of Energy, Building Technologies Office, 950 L'Enfant Plaza SW, 6th Floor, Washington, DC 20024. Telephone: (202) 287–1445. If possible, please submit all items on a CD, in which case it is not necessary to include printed copies.

No telefacsimiles (''faxes'') will be accepted. For detailed instructions on submitting comments and additional information on this process, see the **SUPPLEMENTARY INFORMATION** section of this document.

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

The docket web page can be found at *www.regulations.gov/docket/EERE–2023–BT–WAV–0016.* The docket web page contains instructions on how to access all documents, including public comments, in the docket. See the **SUPPLEMENTARY INFORMATION** section for information on how to submit comments through *www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: FOR FURTHER INFORMATION CONTACT:

Ms. Julia Hegarty, U.S. Department of Energy, Office of Energy Efficiency and Renewable Energy, Building Technologies Office, Mailstop EE–5B, 1000 Independence Avenue SW, Washington, DC 20585–0121. Telephone: (240) 597–6737 Email: *AS_Waiver_Request@ee.doe.gov.*

Ms. Kathryn McIntosh, U.S. Department of Energy, Office of the General Counsel, Mail Stop GC–33, Forrestal Building, 1000 Independence Avenue SW, Washington, DC 20585–0103. Telephone: (202) 586–2002. Email: *Kathryn.McIntosh@hq.doe.gov.*

SUPPLEMENTARY INFORMATION: DOE is publishing UCA's petition for waiver in its entirety, pursuant to 10 CFR 431.401(b)(1)(iv). DOE invites all interested parties to submit in writing by December 22, 2023, comments and information on all aspects of the petition, including the alternate test procedure. Pursuant to 10 CFR 431.401(d), any person submitting written comments to DOE must also send a copy of such comments to the petitioner. The contact information for the petitioner is: John Hodges, *jhodges@hwglaw.com,* Harris, Wiltshire & Grannis LLP, 1919 M Street NW, Washington, DC 20036.

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

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

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

DOE processes submissions made through *www.regulations.gov* before posting. Normally, comments will be posted within a few days of being submitted. However, if large volumes of comments are being processed simultaneously, your comment may not be viewable for up to several weeks. Please keep the comment tracking number that *www.regulations.gov* provides after you have successfully uploaded your comment.

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

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

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

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

Confidential Business Information. According 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. Submit these documents via email. DOE will make its own determination about the confidential status of the information and treat it according to its determination.

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

Case Number 2023–004

Denial of Interim Waiver

I. Authority and Background

The Energy Policy and Conservation Act, as amended (''EPCA''),[1] authorizes the U.S. Department of Energy (''DOE'') to regulate the energy efficiency of several consumer products and certain industrial equipment. (42 U.S.C. 6291–6317) Title III, Part C of EPCA [2] established the Energy Conservation Program for Certain Industrial Equipment, which sets forth a variety of provisions designed to improve energy efficiency for certain types of industrial equipment. This equipment includes double-duct air conditioners and heat pumps, which are a subset of air-cooled commercial package air conditioning and heating equipment, the subject of this document. (42 U.S.C. 6311(1)(B)–(D))

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

The Federal testing requirements consist of test procedures that manufacturers of covered equipment must use as the basis for: (1) certifying to DOE that their equipment complies with the applicable energy conservation standards adopted pursuant to EPCA (42 U.S.C. 6316(b); 42 U.S.C. 6296), and (2) making representations about the efficiency of that equipment (42 U.S.C. 6314(d)). Similarly, DOE uses these test procedures to determine whether the equipment complies with relevant standards promulgated under EPCA.

Under 42 U.S.C. 6314, EPCA sets forth the criteria and procedures DOE is required to follow when prescribing or amending test procedures for covered equipment. EPCA requires that any test procedures prescribed or amended under this section must be reasonably designed to produce test results which reflect the energy efficiency, energy use, or estimated annual operating cost of covered equipment (or class thereof) during a representative average use cycle and requires that test procedures not be unduly burdensome to conduct. (42 U.S.C. 6314(a)(2)) The test procedure for air-cooled commercial package air conditioning and heating equipment, including double-duct air conditioners and heat pumps, is contained in the Code of Federal Regulations (''CFR'') at 10 CFR part 431, subpart F, appendix A, *Uniform Test Method for the Measurement of Energy Consumption of Air-Cooled Small (≥65,000 Btu/h), Large, and Very Large Commercial Package Air Conditioning and Heating Equipment* (''appendix A'').

Under 10 CFR 431.401, any interested person may submit a petition for waiver from DOE's test procedure requirements. DOE will grant a waiver from the test procedure requirements if DOE determines either that the basic model(s) for which the waiver was requested contains a design characteristic that prevents testing of the basic model according to the prescribed test procedures, or that the prescribed test procedures evaluate the basic model in a manner so unrepresentative of its true energy consumption characteristics as to provide materially inaccurate comparative data. 10 CFR 431.401(f)(2). A petitioner must include in its petition any alternate test procedures known to the petitioner to evaluate the performance of the equipment type in a manner representative of the energy consumption characteristics of the basic model. 10 CFR 431.401(b)(1)(iii). DOE may grant the waiver subject to conditions, which may include adherence to alternate test procedures specified by DOE. 10 CFR 431.401(f)(2).

As soon as practicable after the granting of any waiver, DOE will publish in the **Federal Register** a notice of proposed rulemaking to amend its regulations so as to eliminate any need for the continuation of such waiver. 10 CFR 431.401(l). As soon thereafter as practicable, DOE will publish in the **Federal Register** a final rule to that effect. *Id.*

The waiver process also provides that DOE will grant an interim waiver from the test procedure requirements if it appears likely that the petition for waiver will be granted and/or if DOE determines that it would be desirable for public policy reasons to grant immediate relief pending a determination on the petition for waiver. 10 CFR 431.401(e)(3). Within one year of issuance of an interim waiver, DOE will either: (i) publish in the **Federal Register** a determination on the petition for waiver; or (ii) publish in the **Federal Register** a new or amended test procedure that addresses the issues presented in the waiver. 10 CFR 431.401(h)(1).

If the interim waiver test procedure methodology is different than the decision and order test procedure methodology, certification reports to DOE required under 10 CFR 429.12 and any representations must be based on either of the two methodologies until 180–360 days after the publication date of the decision and order, as specified by DOE in the decision and order. Thereafter, certification reports and any representations must be based on the decision and order test procedure methodology, unless otherwise specified by DOE. Once a manufacturer uses the decision and order test procedure methodology in a certification report or any representation, all subsequent certification reports and any representations must be made using the decision and order test procedure methodology while the waiver is valid. 10 CFR 431.401(i)(1). When DOE amends the test procedure to address the issues presented in a waiver, the waiver or interim waiver will automatically terminate on the date on which use of that test procedure is required to demonstrate compliance. 10 CFR 431.401(h)(3).

II. UCA's Petition for Waiver and Interim Waiver

On November 19, 2018, DOE received from UCA a petition for waiver and interim waiver from the test procedure for commercial air conditioners and heat pumps set forth at 10 CFR part 431 subpart F.[3] (UCA, No. 1 at pp. 1–9) [4] The petition did not identify any of the

[1] All references to EPCA in this document refer to the statute as amended through the Energy Act of 2020, Public Law 116–260 (Dec. 27, 2020), which reflect the last statutory amendments that impact Parts A and A–1 of EPCA.

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

[3] The specific models for which the petition applies include UCA C-Series commercial indoor horizontal double-duct air conditioner models C***T***, H***T***, E***T***, B***T***, and BC***T***, with nominally rated capacities of 72000, 96000, 120000, 144000 and 180000 Btu/h; C13-Series commercial indoor horizontal double-duct air conditioner models C***H***, H***H***, E***H***, B***H***, and BC***H***, with nominally rated capacities of 72000, 96000 and 120000 Btu/h; VertiCool Classic commercial indoor vertical double-duct air conditioner models VA***T***, VAR***T***, VARC***T***, BVA***T***, BCVA***T***, and EVA***T***, with nominally rated capacities of 72000, 96000, 120000, 144000, 180000, 240000 and 300000 Btu/h; and VertiCool Aurora commercial indoor vertical double-duct air conditioner models VA***H***, VAR***H***, VARC***H***, BVA***H***, BCVA***H***, and EVA***H***, with nominally rated capacities of 72000, 96000, 120000, 144000, 180000, 240000 and 300000 Btu/h. These models were provided by UCA in the Appendix included in its November 19, 2018 petition. The petition is included at the end of this notice.

[4] A notation in this form provides a reference for information that is in the docket for this test procedure waiver. This notation indicates that the statement preceding the reference is document number 1 in the docket and appears at page 2 of that document.

information contained therein as confidential business information.

In its petition, UCA stated that the current DOE test procedure does not address the unique characteristics of UCA's double-duct technology. (UCA, No. 1 at p. 1) UCA noted that the basic models for which it is seeking a waiver use a double-duct configuration, which do not have an outdoor section and instead have ducting to an outside wall or window for the supply and discharge of outside air to and from the indoor condenser. (UCA, No. 1 at p. 3) UCA asserts in its waiver petition that the energy characteristics of these double-duct air conditioners [5] are different from equipment with an outdoor section. (*Id.* at p. 3) UCA additionally states that the Federal test procedure does not account for this technology, and that the standard AHRI 340/360–2007,[6] incorporated by reference at the time of petition, was developed to test products with both outdoor and indoor sections (and UCA noted the references to ''indoor section'' and ''outdoor section'' throughout that standard). UCA asserted that because double-duct units do not have an outdoor section, they cannot be tested by the DOE test procedure and a waiver is necessary. (*Id.* at pp. 4–5) Further, UCA expressed that double-duct air conditioners have higher condenser fan motor horsepower to move condenser air against significant air pressure (0.5–1.5 in H_2O) and smaller but deeper condenser coils, which creates a higher pressure drop than that of an outdoor condensing section, resulting in more energy consumption of the condenser fan motor, and claimed that both of these characteristics were not accounted for in the test procedure. (*Id.*)

UCA also requested an interim waiver from the existing DOE test procedure, asserting that the petition for waiver is likely to be granted because the DOE test procedure does not address the unique characteristics of the requested basic models. (*Id.* at p. 7) UCA stated that without the granting of an interim waiver, UCA would suffer economic hardship and be at a competitive disadvantage if it must wait to rate these basic models pending a determination on petition for waiver. (*Id.*) UCA also claimed that the petition was supported by sound public policy because the products offered property owners and developers the ability to install new efficient central air conditioning in old buildings. (*Id.*)

III. Requested Alternate Test Procedure

EPCA requires that manufacturers use DOE test procedures when making representations about the energy consumption and energy consumption costs of covered equipment. (42 U.S.C. 6314(d)) Consistency is important when making representations about the energy efficiency of covered equipment, including when demonstrating compliance with applicable DOE energy conservation standards. Pursuant to 10 CFR 431.401, and after consideration of public comments on the petition, DOE may establish in a subsequent Decision and Order an alternate test procedure for the basic models addressed by the Interim Waiver Order.

UCA seeks to use an alternate test procedure to test and rate specific double-duct commercial unitary air conditioners (''CUAC'') basic models. As an alternate test procedure, UCA proposed to test the specified basic models by ducting the condenser fan and imposing external static pressure (''ESP'') per the manufacturer's instructions. Then, UCA proposed to adjust the input power of the condenser fan motor by subtracting ''added'' condenser motor horsepower imposed by the additional ESP, as presented below:

$$\varphi_{fa} = \frac{q \times \Delta p}{\eta}$$

Where:

ϕ_{fa} is the fan power adjustment, in watts;
η is 0.3×10^3 by convention;
Δp is the measured ESP difference, in pascals; and
q is the nominal airflow rate, in litres per second.

(UCA, No. 1 at pp. 6–7)

This formula is drawn from section 4.1.3.2 of ANSI/ARI/ASHRAE ISO Standard 13256–1:1998 [7] and is used in that test standard to adjust for the motor horsepower expended in moving air through the indoor ducts. UCA proposed that this formula be used to adjust the condenser motor horsepower for double-duct units tested at non-zero condenser ESP to account only for the motor horsepower utilized in overcoming internal resistance of the unit. (*Id.*)

In the course of reviewing UCA's petition, DOE requested additional data from UCA to support their proposed alternate test procedure. UCA provided confidential data to DOE that included condenser fan power values at various ESPs and adjusted condenser fan power based on their suggested approach for several basic models offered.

IV. Denial of Interim Waiver

DOE has reviewed UCA's application for an interim waiver, the alternate test procedure requested by UCA, publicly available specification sheets and installation manuals relevant to these basic models, and additional confidential data from UCA regarding its petition. In submitting a petition for waiver, a petitioner must demonstrate that the subject basic model contains one or more design characteristics that prevent testing of the basic model according to the prescribed test procedures or cause the prescribed test procedures to evaluate the basic model in a manner so unrepresentative of its true energy and/or water consumption characteristics as to provide materially inaccurate comparative data. 10 CFR 431.401(a)(1); 10 CFR 431.401(f)(2). In determining whether to grant a request for an interim waiver, DOE considers whether: (1) it appears likely that the petition for waiver will be granted; and/or (2) it would be desirable for public policy reasons to grant immediate relief pending a determination on the petition for waiver. 10 CFR 431.401(e)(=3).

As described, UCA claims in its petition for a waiver that the subject basic models contain a design characteristic (*i.e.,* no outdoor section) that prevents testing according to the DOE test procedure. In response to this claim, DOE notes that the current DOE test procedure for double-duct air conditioners and heat pumps is the same as that for single-duct commercial air conditioning and heating equipment at appendix A. In a direct final rule published on January 15, 2016 (''January 2016 Direct Final Rule''), DOE clarified

[5] As referenced in footnote 4 of the petition, quoting 10 CFR 431.92, double-duct air conditioner or heat pump means air-cooled commercial package air conditioning and heating equipment that—(1) Is either a horizontal single package or split-system unit; or a vertical unit that consists of two components that may be shipped or installed either connected or split; (2) Is intended for indoor installation with ducting of outdoor air from the building exterior to and from the unit, as evidenced by the unit and/or all of its components being non-weatherized, including the absence of any marking (or listing) indicating compliance with UL 1995, ''Heating and Cooling Equipment,'' or any other equivalent requirements for outdoor use; (3) (i) If it is a horizontal unit, a complete unit has a maximum height of 35 inches; (ii) If it is a vertical unit, a complete unit has a maximum depth of 35 inches; and (4) Has a rated cooling capacity greater than or equal to 65,000 Btu/h and up to 300,000 Btu/h.

[6] ANSI/AHRI Standard 340/360–2007, *2007 Standard for Performance Rating of Commercial and Industrial Unitary Air-Conditioning and Heat Pump Equipment,* approved by ANSI on October 27, 2011, and updated by addendum 1 in December 2010 and addendum 2 in June 2011 (''AHRI 340/360–2007''). Available online at: *webstore.ansi.org.*

[7] ANSI/ARI/ISO Standard 13256–1:1998, *Water-source heat pumps—Testing and rating for performance—Part 1: Water-to-air and brine-to-air heat pumps,* ISO approved 1998. Available online at *webstore.ansi.org/.*

that double-duct air conditioners are tested and rated under the same test conditions as single-duct air conditioners, without any ducting connected to, or an external static pressure applied on, the condenser side. 81 FR 2420, 2445.

The DOE test procedure at appendix A references certain sections of both AHRI 340/360–2007 and ANSI/ASHRAE 37–2009.[8] As mentioned by UCA, Table 3 of AHRI 340/360–2007 uses the term ''outdoor section'' in a header for columns providing test conditions. This term refers to the section of an air conditioning or heat pump system that rejects or absorbs heat (during mechanical cooling or heating mode, respectively), and does not apply only to units installed outdoors. For an air-cooled air conditioner, the test conditions under the heading ''indoor section'' are used for indoor air (*i.e.,* the evaporator airstream) and the test conditions under the heating ''outdoor section'' are used for outdoor air (*i.e.,* the condenser airstream), regardless of whether the components are intended for indoor or outdoor installation. DOE notes that condenser temperature conditions for testing water-cooled commercial unitary air conditioners (''WCUACs'') are also specified under the ''outdoor section'' header, but similar to double-duct systems, both the indoor and outdoor sections of WCUACs are generally intended for indoor installation. Similarly, DOE notes that in rooftop air-cooled and evaporatively-cooled commercial unitary air conditioners, the ''indoor section'' (*i.e.,* the section conditioning indoor air) is located outdoors. Further, DOE notes that both ANSI/ASHRAE 37–2009 (which is referenced in the current DOE test procedure at appendix A) and ANSI/ASHRAE 37–2005 [9] (which is referenced by AHRI 340/360–2007) use the term ''outdoor side'' to refer to the condensing section of an air-conditioning system. Specifically, both versions of ASHRAE Standard 37 define ''outdoor side'' as ''that part of the system that rejects heat to or absorbs heat from a source external to the indoor airstream.'' This definition does not specify or require that the outdoor side is located outdoors. Therefore, DOE has tentatively determined that UCA has not demonstrated that the basic models subject to the petition contain a design characteristic that prevents testing of the basic model according to the prescribed test procedures because the test procedure applies to double-duct systems regardless of intended installation location.

DOE also evaluated UCA's petition to determine whether the prescribed test procedures evaluate the subject basic models in a manner so unrepresentative of their true energy consumption characteristics as to provide materially inaccurate comparative data. Relevant to this evaluation, DOE notes that the current energy conservation standards for double-duct air conditioners are defined in terms of the energy efficiency ratio (''EER'') metric, which as defined by the test procedure at appendix A, represent the performance of an air conditioner when operating at zero condenser ESP. DOE further notes that the rating conditions associated with a metric are integral to the metric—performance measured at a different condenser ESP, for example, would not represent an EER value (as that metric is currently defined in appendix A) and would therefore not provide comparative data with which to compare to other equipment on the market subject to the same EER standard. As such, DOE evaluated UCA's suggested alternate test procedure to determine whether it would provide a more representative measure of EER (*i.e.,* a more representative measure of performance at zero condenser ESP) compared to the current Federal test procedure.[10] DOE reviewed UCA's proposed alternate test procedure, including the additional confidential data provided to DOE by UCA, within this framework.

UCA's suggested alternate test procedure specifies testing at a manufacturer-specified non-zero condenser ESP and then adjusting the measured condenser fan power down to reflect operation at zero condenser ESP. This adjustment of the measured condenser fan power requires an assumption regarding the efficiency value of the condenser fan. In its petition, UCA requested to use an assumed fan efficiency value of 0.3. Based on its review, DOE has tentatively concluded that the fan efficiency value of 0.3 suggested by UCA is unrepresentatively low. In particular, confidential data provided by UCA suggests that for some of the models subject to UCA's petition for waiver, assuming a fan efficiency value of 0.3 would result in the fan power adjustment exceeding the actual fan power consumed at zero condenser ESP, thus resulting in negative condenser fan power being reflected in the metric.

As a result, the test procedure suggested by UCA would under-represent the condenser fan power that would be expected at zero condenser ESP because it subtracts an unrepresentatively high adjustment factor from the measured value of condenser fan power. This would result in EER ratings of performance at zero condenser ESP that are unrepresentatively high and therefore not comparable to EER ratings developed by other manufacturers of double-duct systems based on testing at zero condenser ESP (*i.e.,* ratings developed without any adjustment to measured condenser fan power). Therefore, DOE has tentatively concluded that the alternate test procedure suggested in UCA's petition for waiver would not evaluate the performance of the subject models in a manner more representative of the energy consumption characteristics of each basic model, within the context of representing EER performance at zero condenser ESP.

Additionally, DOE notes that multiple other manufacturers of double-duct systems list condenser fan motor performance at ESPs as low as zero in their product literature, demonstrating that there is nothing inherent to double-duct systems that prevents representing EER performance at zero condenser ESP in accordance with the current Federal test procedure.[11] Therefore, DOE has tentatively concluded that UCA has not demonstrated that the basic models subject to the petition contain a design characteristic that prevents testing of those models according to the prescribed test procedure or that the prescribed test procedure evaluates the basic model in a manner so

[8] ANSI/ASHRAE Standard 37–2009, *Methods of Testing for Rating Electrically Driven Unitary Air-Conditioning and Heat Pump Equipment* (''ANSI/ASHRAE 37–2009''). Available at online at: *webstore.ansi.org.*

[9] ANSI/ASHRAE Standard 37–2005, *Methods of Testing for Rating Electrically Driven Unitary Air-Conditioning and Heat Pump Equipment* (''ANSI/ASHRAE 37–2005''). Available at online at: *webstore.ansi.org.*

[10] DOE notes that it recently published a notice of proposed rulemaking (''NOPR'') regarding the test procedures for commercial unitary air conditioners and heat pumps, including double-duct air conditioners and heat pumps. 88 FR 56392 (August 17, 2023). This NOPR proposes a new test procedure that specifies the new metrics integrated ventilation, economizer, and cooling (''IVEC'') and integrated ventilation and heating efficiency (''IVHE''). These proposed new metrics would change the condenser ESP requirement from zero to 0.5 in. H_2O for double-duct air conditioners and heat pumps. Were DOE to adopt the test procedures for IVEC and IVHE for double-duct systems as proposed, testing to those metrics would not be required until DOE adopts energy conservation standards for double-duct systems in terms of those metrics.

[11] Condenser fan motor performance at condenser ESPs as low as zero is listed in the product datasheets for the Carrier Omnizone and Skypeak D-series double-duct model lines. These examples can be found on the docket at *regulations.gov/EERE-2023-BT-WAV-0016.*

unrepresentative of its true energy consumption characteristics as to provide materially inaccurate comparative data with other double-duct systems. Absent such data, DOE is unable to conclude that UCA's petition for waiver will likely be granted.

Further, DOE does not find that public policy reasons weigh in favor of granting immediate relief pending a determination on the petition for waiver. As previously indicated, multiple other manufacturers certify to DOE EER ratings for double-duct systems that are compliant with the currently applicable EER standards and are based on the current Federal test procedure, which reflects performance at zero condenser ESP. These models demonstrate that commercial consumers currently have multiple options for installing double-duct systems; therefore, DOE does not find granting immediate relief to UCA is necessary. For these reasons, DOE is denying UCA's petition for interim waiver and requesting comment.

DOE makes decisions on waivers and interim waivers for only those basic models specifically set out in the petition, not future models that may be manufactured by the petitioner. UCA may submit a new or amended petition for waiver and request for grant of interim waiver, as appropriate, for additional basic models of double-duct air conditioners and heat pumps.

While DOE declines to approve the use of UCA's suggested alternate test procedure in an interim waiver at this time, DOE may consider including an alternate procedure in a subsequent Decision and Order. DOE solicits comments from interested parties on all aspects of the petition, including any alternate test procedure.

V. Signing Authority

This document of the Department of Energy was signed on November 17, 2023, by Jeffrey Marootian, Principal Deputy Assistant Secretary for Energy Efficiency and Renewable Energy, pursuant to delegated authority from the Secretary of Energy. That document with the original signature and date is maintained by DOE. For administrative purposes only, and in compliance with requirements of the Office of the Federal Register, the undersigned DOE Federal Register Liaison Officer has been authorized to sign and submit the document in electronic format for publication, as an official document of the Department of Energy. This administrative process in no way alters the legal effect of this document upon publication in the **Federal Register**.

Signed in Washington, DC, on November 17, 2023.

Treena V. Garrett,

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

Before the United States Department of Energy, Washington, DC 20585

In the Matter of: Energy Efficiency Program: Test Procedure for Commercial Air Conditioners and Heat Pumps

Petition of United CoolAir Corporation for Waiver and Application for Interim Waiver of Test Procedure for Commercial Air Conditioners and Heat Pumps

United CoolAir Corporation (UCA) respectfully submits this Petition for Waiver and Application for Interim Waiver [12] from DOE's test procedure for commercial air conditioners and heat pumps. UCA seeks a waiver because the current DOE test procedure [13] does not address the unique characteristics of UCA's double-duct technology. Therefore, UCA's double-duct models cannot be tested under the DOE test procedure. UCA also requests expedited treatment of the Petition and Application.

I. UCA

Since 1988, UCA has been a small, family-owned and operated American company. It is a specialty manufacturer of double-duct commercial air conditioners and other air conditioning products. It is located at 491 E Princess Street, York, PA 17403 (tel. 717–843–4311; *https://unitedcoolair.com*). UCA's start came with the creation of air conditioning units built to meet extremely high standards for the U.S. Military. Since then, UCA has evolved into a full service provider of unique and often complex HVAC systems.

II. Double-Duct Commercial Air Conditioners

UCA specializes in double-duct commercial air conditioners. They are used to provide efficient central air conditioning in older buildings that are being renovated or updated and where there is only limited space available. These systems fit entirely inside a building and thus are dramatically different from the bulky products that have outdoor as well as indoor components. Their modular sections can be taken through standard doors or smaller openings, around corners, down hallways, and placed into service elevators. Indoor installation (above the ceiling and crawl spaces) minimizes expensive handling, rigging, or permits, and avoids the need for building modifications. It also eliminates expensive repairs and replacements due to weather damage, theft, and vandalism. All of these products are built-to-order and adapted to the different requirements of unique buildings, while providing the latest in control and design technologies.

III. Basic Models for Which a Waiver Is Requested

The basic models for which a waiver is requested are set forth in the Appendix. They are double-duct commercial air conditioners distributed in commerce under the UCA brand name. The models are within the following series: C-Series; C13-Series; VertiCool Classic; and VertiCool Aurora.[14] The C-Series and C13-Series are indoor horizontal air conditioners. The VertiCool Classic and VertiCool Aurora series have vertical cabinets that fit neatly along walls, in closet spaces, or in mechanical rooms.

IV. Need for the Requested Waiver

The UCA double-duct models are specialized, niche products intended for indoor installation—almost entirely in old buildings. They are ideal for replacement or renovation applications, where space constraints prohibit roof-top or other types of products. They do not have an outdoor section, and their energy characteristics are different from products that have one. They have ducting to an outside wall or window for the supply and discharge of outside air to and from the indoor condenser.[15]

[12] *See* 10 CFR 431.401 (Petitions for waiver and interim waiver).

[13] *Id.* § 431.96.

[14] To the best of UCA's knowledge, AboveAir Technologies, Skymark, Task Applied Products, Skil-aire, and Compu-Aire are the only manufacturers of other commercial air conditioning basic models distributed in commerce in the United States to incorporate design characteristic(s) similar to those found in the models that are the subject of this petition. To the best of UCA's knowledge, AirPac, Carrier, and Addison used to produce similar products but no longer do.

[15] *Double-duct air conditioner or heat pump means air-cooled commercial package air conditioning and heating equipment* that—

(1) Is either a horizontal single package or split-system unit; or a vertical unit that consists of two components that may be shipped or installed either connected or split;

(2) Is intended for indoor installation with ducting of outdoor air from the building exterior to and from the unit, as evidenced by the unit and/or all of its components being non-weatherized, including the absence of any marking (or listing) indicating compliance with UL 1995, ''Heating and Cooling Equipment,'' or any other equivalent requirements for outdoor use;

(3)(i) If it is a horizontal unit, a complete unit has a maximum height of 35 inches; (ii) If it is a vertical unit, a complete unit has a maximum depth of 35 inches; and

Continued

DOE's test procedure does not account for this technology and is therefore inapplicable for these products.

DOE has recognized the useful, unique nature of double-duct products such as UCA's.

DOE agrees that these [double-duct] units have features that justify establishing separate equipment classes for them. Double-duct units, as evidenced by several commenters, offer a unique utility that may otherwise become unavailable if these units were subjected to the more rigorous standards required by this direct final rule for other CUAC and CUHP equipment. DOE notes that double-duct units, which are installed within the building envelope and use ductwork to transfer outdoor air to and from the outdoor unit, would have added challenges in meeting more stringent energy conservation standards due to space constraints and added condenser fan power.[16]

Even though DOE has agreed that double-duct products are unique and useful, its test procedure has not yet been amended to address and take into account their unique characteristics. Rather, the test procedure is silent on these products.

Instead, DOE's test procedure [17] incorporates AHRI Standard 340/360–2007,[18] which was developed to test units that have *both outdoor and indoor sections.* Specifically, AHRI 340/360-2007 requires: ''Standard Ratings shall be established at the Standard Rating Conditions specified in Table 3.'' [19] Table 3, ''Conditions for Standard Rating and Operating Tests,'' mandates conditions for an ''Indoor Section'' and ''Outdoor Section.'' [20] ''Table 3 indicates the tests and test conditions which are required to determine values of standard capacity and ratings and values of energy efficiency.'' [21] Therefore, double-duct units, which do not have an outdoor section, simply cannot be tested by the DOE test procedure. Moreover, even though DOE acknowledges ''added condenser fan power'' as a distinguishing characteristic of double-duct products,[22] the DOE test procedure does not account for the higher condenser motor horsepower of these products. Nor does it account for the smaller but deeper coil required for the double-duct systems to move air through the duct and discharge it to the outside.

An outdoor condenser/condensing unit utilizes a propeller fan (light duty) to move large volumes of air against low air pressure (0″ External Static Pressure—ESP) and utilizes a relatively small motor. In addition, since space (footprint/volume/height) and air path (perimeter inlet and top discharge) through the outdoor coil of such models are not an issue, outdoor condensing sections typically utilize 1 or 2 row deep 'U/L' shaped condenser coils to maximize heat transfer and minimize air pressure drop.

In contrast, a double-duct unit's condenser fan (heavy duty—typically centrifugal and belt driven) has to be designed to move condenser air against significant air pressure (0.5–1.5″ ESP), and it utilizes a relatively larger motor. Double-duct models also have smaller and deeper condenser coils than models with outdoor condensing sections, since cabinet space is much smaller than an outdoor condensing section. An indoor condenser coil is typically 3–4 rows deep, with higher pressure drop than an outdoor condensing section. Such higher pressure drop consumes more energy than that associated with an outdoor condensing section.

Since the DOE test procedure does not address and account for double-duct technology, a waiver is necessary. DOE's rules provide that DOE ''will grant a waiver from the test procedure requirements'' in such circumstances.[23] Accordingly, UCA urges that a waiver be granted for the basic models in the Appendix that will allow use of the alternate test procedure discussed below. Unlike the current test procedure, the alternate test procedure is designed to properly take into account UCA double-duct technology. The waiver should continue until DOE adopts an applicable amended test procedure.

V. Proposed Alternate Test Procedure

UCA proposes the following alternate test procedure to evaluate the performance of the basic models listed in the Appendix. It is the same as the existing DOE test procedure for commercial air conditioners, except that it takes double-duct technology into account. It does so by utilizing a formula drawn from Section 4.1.3.2 of ANSI/ARI/ASHRAE ISO Standard 13256- 1:1998 [24] to adjust for the motor horsepower expended in moving air through the indoor ducts. It bears noting that AHRI 340/360–2007 provides that ISO 13256–1:1998 is among those publications ''essential to the formation and implementation of the standard [340/360]. All references in this appendix [to 340/360] are considered as part of the standard.'' [25]

The formula in Section 4.1.3.2 of ISO 13256–1 normalizes the double-duct condenser motor horsepower by adjusting the condenser motor horsepower to account *only* for the motor horsepower utilized in overcoming *internal* resistance of the unit.

The waiver should provide that UCA shall be required to test the performance of the basic models listed in the Appendix hereto according to the test procedure for commercial air conditioners and heat pumps in 10 CFR part 431, subpart F (including AHRI 340/360–2007), except as follows:

1. Duct the condenser fan, and impose ESP, each as per manufacturer's instructions.

2. Adjust kW input by subtracting ''added'' condenser motor horsepower utilizing the following formula. (No changes to unit cooling capacity or heating capacity is required.)

$$\varphi_{fa} = \frac{q \times \Delta p}{\eta}$$

Where:

φ_{fa} is the fan power adjustment, in watts;
η is 0.3×10^3 by convention;
ΔP is the measured ESP difference, in pascals; and
q is the nominal airflow rate, in litres per second.

VI. Application for Interim Waiver

UCA also hereby applies for an interim waiver of the applicable test procedure requirements for the UCA basic models set forth in the Appendix. UCA meets the criteria for an interim waiver. UCA's Petition for Waiver is likely to be granted, because the current DOE test procedure [26] clearly does not address the unique characteristics of these UCA basic models. Without waiver relief, UCA would be subject to

(4) Has a rated cooling capacity greater than or equal to 65,000 Btu/h and up to 300,000 Btu/h.

10 CFR 431.92.

[16] *Energy Conservation Program for Certain Industrial Equipment: Energy Conservation Standards for Small, Large, and Very Large Air-Cooled Commercial Package Air Condition and Heating Equipment and Commercial Warm-Air Furnaces,* 81 FR 2420, 2446 (Jan. 15, 2016).

[17] 10 CFR 431.96.

[18] ANSI/AHRI Standard 340/360–2007 (formerly ARI Standard 340/360–2007), 2007 Standard for Performance Rating of Commercial and Industrial Unitary Air-Conditioning and Heat Pump Equipment.

[19] AHRI 340/360–2007 § 6.1.

[20] *Id.* § 6.1, Table 3.

[21] *Id.* § 6.1.3.

[22] *Energy Conservation Program for Certain Industrial Equipment: Energy Conservation Standards for Small, Large, and Very Large Air-Cooled Commercial Package Air Condition and Heating Equipment and Commercial Warm-Air Furnaces,* 81 FR at 2446.

[23] 10 CFR 431.401(f)(2).

[24] ANSI/ARI/ASHRAE ISO Standard 13256–1:1998.

[25] AHRI 340/360–2007, App. A §§ A1, A1.7.

[26] 10 CFR part 431, subpart F.

requirements that are inappropriate for these products. Additionally, UCA will suffer economic hardship and be at a competitive disadvantage if it must wait to rate these basic models pending a determination on the petition for waiver. DOE approval of UCA's interim waiver application is also supported by sound public policy. As noted above, these products offer property owners and developers the ability to install new efficient central air conditioning in old buildings.

VII. Conclusion

UCA respectfully requests that DOE grant its Petition for Waiver of the applicable test procedure for specified basic models, and also grant its Application for Interim Waiver. UCA also requests expedited treatment of the Petition and Application.

Respectfully submitted,

/s/

Scott Blake Harris John Hodges, Harris, Wiltshire & Grannis LLP, 1919 M Street NW Washington, DC 20036, (202) 730–1313

November 19, 2018

Appendix

The waiver and interim waiver requested herein should apply to testing and rating of the following basic models that are manufactured by UCA:

C-Series commercial indoor horizontal double-duct air conditioner models C...T..., H...T..., E...T..., B...T..., and BC...T..., with nominally rated capacities of 72000, 96000, 120000, 144000 and 180000 Btu/h.

C13-Series commercial indoor horizontal double-duct air conditioner models C...H..., H...H..., E...H..., B...H..., and BC...H..., with nominally rated capacities of 72000, 96000 and 120000 Btu/h.

VertiCool Classic commercial indoor vertical double-duct air conditioner models VA...T..., VAR...T..., VARC...T..., BVA...T..., BCVA...T..., and EVA...T..., with nominally rated capacities of 72000, 96000, 120000, 144000, 180000, 240000 and 300000 Btu/h.

VertiCool Aurora commercial indoor vertical double-duct air conditioner models VA...H..., VAR...H..., VARC...H..., BVA...H..., BCVA...H..., and EVA...H..., with nominally rated capacities of 72000, 96000, 120000, 144000, 180000, 240000 and 300000 Btu/h.

[FR Doc. 2023–25872 Filed 11–21–23; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. CP24–14–000]

Total Peaking Services, LLC; Notice of Amendment of Authorization and Establishing Intervention Deadline

Take notice that on November 6, 2023 Total Peaking Services, LLC (TPS), 775 Oronoque Road, Milford, CT 06460, filed an application under section 7(b) of the Natural Gas Act (NGA), and Part 157 of the Commission's regulations requesting authorization to abandon by sale to its affiliate, the Southern Connecticut Gas Company (SCG), its liquefied natural gas (LNG) storage tank and associated liquefaction and revaporization facilities located in Milford, Connecticut (Milford Facility). TPS also requests authorization to cancel its FERC Gas Tariff in its entirety. Post-abandonment, the Milford Facility will be operated by SCG, the sole existing customer for the Milford Facility's output, and will remain in service under State of Connecticut jurisdiction. TPS states that the proposed abandonment by sale will not harm existing or prospective shippers and will not have any effect on the environment, all as more fully set forth in the application which is on file with the Commission and open for public inspection.

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 (*www.ferc.gov*) using the ''eLibrary'' link. Enter the docket number excluding the last three digits in the docket number field to access the document. At this time, the Commission has suspended access to the Commission's Public Reference Room. For assistance, contact the Federal Energy Regulatory Commission at *FercOnlineSupport@ferc.gov* or call toll-free, (886) 208–3676 or TTY (202) 502–8659.

Any questions regarding the proposed project should be directed to Danielle Mechling, Networks FERC Legal Director, Avangrid (UIL), 180 Marsh Hill Road, Orange, CT 06477, by phone at (203) 836–7464 or by email at *Danielle.mechling@avangrid.com*.

Pursuant to Section 157.9 of the Commission's Rules of Practice and Procedure,[1] within 90 days of this Notice the Commission staff will either: complete its environmental review and place it into the Commission's public record (eLibrary) for this proceeding; or issue a Notice of Schedule for Environmental Review. If a Notice of Schedule for Environmental Review is issued, it will indicate, among other milestones, the anticipated date for the Commission staff's issuance of the final environmental impact statement (FEIS) or environmental assessment (EA) for this proposal. The filing of an EA in the Commission's public record for this proceeding or the issuance of a Notice of Schedule for Environmental Review will serve to notify federal and state agencies of the timing for the completion of all necessary reviews, and the subsequent need to complete all federal authorizations within 90 days of the date of issuance of the Commission staff's FEIS or EA.

[1] 18 CFR (Code of Federal Regulations) § 157.9.

Public Participation

There are three ways to become involved in the Commission's review of this project: you can file comments on the project, you can protest the filing, and you can file a motion to intervene in the proceeding. There is no fee or cost for filing comments or intervening. The deadline for filing a motion to intervene is 5:00 p.m. Eastern Time on December 6, 2023. How to file protests, motions to intervene, and comments is explained below.

The Commission's Office of Public Participation (OPP) supports meaningful public engagement and participation in Commission proceedings. OPP can help members of the public, including landowners, environmental justice communities, Tribal members and others, access publicly available information and navigate Commission processes. For public inquiries and assistance with making filings such as interventions, comments, or requests for rehearing, the public is encouraged to contact OPP at (202) 502–6595 or *OPP@ferc.gov*.

Comments

Any person wishing to comment on the project may do so. Comments may include statements of support or objections, to the project as a whole or specific aspects of the project. The more specific your comments, the more useful they will be.

Protests

Pursuant to sections 157.10(a)(4)[2] and 385.211[3] of the Commission's

[2] 18 CFR 157.10(a)(4)

[3] 18 CFR 385.211

regulations under the NGA, any person [4] may file a protest to the application. Protests must comply with the requirements specified in section 385.2001 [5] of the Commission's regulations. A protest may also serve as a motion to intervene so long as the protestor states it also seeks to be an intervenor.

To ensure that your comments or protests are timely and properly recorded, please submit your comments on or before December 7, 2023.

There are three methods you can use to submit your comments or protests to the Commission. In all instances, please reference the Project docket number CP24–14–000 in your submission.

(1) You may file your comments electronically by using the eComment feature, which is located on the Commission's website at *www.ferc.gov* under the link to Documents and Filings. Using eComment is an easy method for interested persons to submit brief, text-only comments on a project;

(2) You may file your comments or protests electronically by using the eFiling feature, which is located on the Commission's website (*www.ferc.gov*) under the link to Documents and Filings. With eFiling, you can provide comments in a variety of formats by attaching them as a file with your submission. New eFiling users must first create an account by clicking on ''eRegister.'' You will be asked to select the type of filing you are making; first select ''General'' and then select ''Comment on a Filing''; or

(3) You can file a paper copy of your comments or protests by mailing them to the following address below. Your written comments must reference the Project docket number CP24–14–000.

To file via USPS: Kimberly D. Bose, Secretary, Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426.

To file via any other courier: Kimberly D. Bose, Secretary, Federal Energy Regulatory Commission, 12225 Wilkins Avenue, Rockville, Maryland 20852.

The Commission encourages electronic filing of comments (options 1 and 2 above) and has eFiling staff available to assist you at (202) 502–8258 or *FercOnlineSupport@ferc.gov*.

Persons who comment on the environmental review of this project will be placed on the Commission's environmental mailing list, and will receive notification when the environmental documents (EA or EIS) are issued for this project and will be notified of meetings associated with the Commission's environmental review process.

The Commission considers all comments received about the project in determining the appropriate action to be taken. However, the filing of a comment alone will not serve to make the filer a party to the proceeding. To become a party, you must intervene in the proceeding. For instructions on how to intervene, see below.

Interventions

Any person, which includes individuals, organizations, businesses, municipalities, and other entities,[6] has the option to file a motion to intervene in this proceeding. Only intervenors have the right to request rehearing of Commission orders issued in this proceeding and to subsequently challenge the Commission's orders in the U.S. Circuit Courts of Appeal.

To intervene, you must submit a motion to intervene to the Commission in accordance with Rule 214 of the Commission's Rules of Practice and Procedure [7] and the regulations under the NGA [8] by the intervention deadline for the project, which is December 7, 2023. As described further in Rule 214, your motion to intervene must state, to the extent known, your position regarding the proceeding, as well as your interest in the proceeding. For an individual, this could include your status as a landowner, ratepayer, resident of an impacted community, or recreationist. You do not need to have property directly impacted by the project in order to intervene. For more information about motions to intervene, refer to the FERC website at *https://www.ferc.gov/resources/guides/how-to/intervene.asp*.

There are two ways to submit your motion to intervene. In both instances, please reference the Project docket number CP24–14–000 in your submission.

(1) You may file your motion to intervene by using the Commission's eFiling feature, which is located on the Commission's website (*www.ferc.gov*) under the link to Documents and Filings. New eFiling users must first create an account by clicking on ''eRegister.'' You will be asked to select the type of filing you are making; first select ''General'' and then select ''Intervention.'' The eFiling feature includes a document-less intervention option; for more information, visit *https://www.ferc.gov/docs-filing/efiling/document-less-intervention.pdf*.; or

(2) You can file a paper copy of your motion to intervene, along with three copies, by mailing the documents to the address below. Your motion to intervene must reference the Project docket number CP24–14–000.

To file via USPS: Kimberly D. Bose, Secretary, Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426.

To file via any other courier: Kimberly D. Bose, Secretary, Federal Energy Regulatory Commission, 12225 Wilkins Avenue, Rockville, Maryland 20852.

The Commission encourages electronic filing of motions to intervene (option 1 above) and has eFiling staff available to assist you at (202) 502–8258 or *FercOnlineSupport@ferc.gov*.

Protests and motions to intervene must be served on the applicant either by mail or email at: Danielle Mechling, Networks FERC Legal Director, Avangrid (UIL), 180 Marsh Hill Road Orange, CT 06477, or by email at *Danielle.mechling@avangrid.com.* Any subsequent submissions by an intervenor must be served on the applicant and all other parties to the proceeding. Contact information for parties can be downloaded from the service list at the eService link on FERC Online. Service can be via email with a link to the document.

All timely, unopposed [9] motions to intervene are automatically granted by operation of Rule 214(c)(1).[10] Motions to intervene that are filed after the intervention deadline are untimely, and may be denied. Any late-filed motion to intervene must show good cause for being late and must explain why the time limitation should be waived and provide justification by reference to factors set forth in Rule 214(d) of the Commission's Rules and Regulations.[11] A person obtaining party status will be placed on the service list maintained by the Secretary of the Commission and will receive copies (paper or electronic) of all documents filed by the applicant and by all other parties.

Tracking the Proceeding

Throughout the proceeding, additional information about the project will be available from the Commission's Office of External Affairs, at (866) 208–FERC, or on the FERC website at *www.ferc.gov* using the ''eLibrary'' link as described above. The eLibrary link

[4] Persons include individuals, organizations, businesses, municipalities, and other entities. 18 CFR 385.102(d).

[5] 18 CFR 385.2001

[6] 18 CFR 385.102(d).

[7] 18 CFR 385.214.

[8] 18 CFR 157.10.

[9] The applicant has 15 days from the submittal of a motion to intervene to file a written objection to the intervention.

[10] 18 CFR 385.214(c)(1).

[11] 18 CFR 385.214(b)(3) and (d).

also provides access to the texts of all formal documents issued by the Commission, such as orders, notices, and rulemakings.

In addition, the Commission offers a free service called eSubscription which allows you to keep track of all formal issuances and submittals in specific dockets. This can reduce the amount of time you spend researching proceedings by automatically providing you with notification of these filings, document summaries, and direct links to the documents. For more information and to register, go to *www.ferc.gov/docs-filing/esubscription.asp*.

Intervention Deadline: 5:00 p.m. Eastern Time on December 7, 2023.

Dated: November 16, 2023.

Debbie-Anne A. Reese,

Deputy Secretary.

[FR Doc. 2023–25824 Filed 11–21–23; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ER20–1041–003]

Wabash Valley Power Association, Inc.; Order Establishing Additional Briefing Procedures

Before Commissioners: Willie L. Phillips, Acting Chairman; James P. Danly, Allison Clements, and Mark C. Christie.

1. This order establishes additional briefing procedures following the issuance of an Initial Decision on January 28, 2022,[1] involving Wabash Valley Power Association's (Wabash) proposed, unexecuted agreement for early termination of two wholesale power supply contracts between Wabash (as seller) and Tipmont Rural Electric Membership Cooperative (Tipmont) (as buyer). In this order, we establish a briefing schedule to develop a more comprehensive record on which to make a determination, as discussed below.

I. Background

2. This proceeding concerns Tipmont's desired early termination of its membership with Wabash and two of its contracts that are on file with the Commission: the 1977 Contract that governs all-requirements service from 1977 through until 2028, and the 2006 Contract that governs such service from 2006 through 2050 (each a Contract, and collectively, Contracts). At issue also in this proceeding is an unexecuted 2020 Agreement For Early Termination of Wholesale Power Supply Contracts (Termination Agreement).

3. On October 1, 2018, Tipmont filed a complaint (Complaint) against Wabash requesting that the Commission: (1) find that Tipmont may terminate its Contracts early, and (2) initiate a proceeding to establish the just and reasonable level of stranded costs resulting from Tipmont's early departure.[2] On February 20, 2020, Wabash filed the Termination Agreement pursuant to section 205 of the Federal Power Act. On April 20, 2020, the Commission concurrently: (1) issued an order granting, denying, and dismissing various aspects of the Complaint; [3] and (2) issued an order accepting and suspending Wabash's proposed Termination Agreement and established hearing and settlement judge procedures.[4]

4. On July 30, 2020, after the Settlement Judge declared an impasse, the Chief Judge issued an order terminating settlement judge procedures and designated Administrative Law Judge Andrea McBarnette as the Presiding Judge. The hearing commenced on May 20, 2021, and concluded on June 8, 2021. The Presiding Judge issued the Initial Decision on January 28, 2022. Subsequently, the participants filed Briefs on Exceptions and Briefs Opposing Exceptions on March 31, 2022, and April 20, 2022, respectively.

II. Discussion

5. We establish a briefing schedule to allow the participants to address the issues set forth in Appendices A and B. Further briefing on these issues will help develop a more comprehensive record for the Commission to evaluate the justness and reasonableness of the Termination Agreement. Accordingly, we provide questions directed at Wabash in Appendix A and one question directed at Tipmont in Appendix B. Wabash and Tipmont are required to submit initial briefs within 45 days of the date of this order. At the initial briefing stage, Wabash may address only questions in Appendix A of this order, and Tipmont may address only the question in Appendix B of this order. Further, participants are permitted to file reply briefs within 30 days of the date of filing of initial briefs.[5] At the reply briefing stage, participants may address questions directed at the other party. Briefs making any factual assertions must be accompanied by a sworn affidavit of one or more witnesses.

The Commission orders:

(A) Wabash and Tipmont are hereby required to submit initial briefs within 45 days of the date of this order, as discussed in the body of this order.

(B) Participants are hereby permitted to file reply briefs within 30 days of the date of filing of initial briefs.[6]

(C) The Secretary is hereby directed to publish this order in the **Federal Register**.

By the Commission.

Issued: November 16, 2023.

Debbie-Anne A. Reese,

Deputy Secretary.

Appendix A

Questions Directed at Wabash

A. Transmission

1. Section 3 of the 1977 Contract and section 5 of the 2006 Contract allow Wabash to own transmission in limited circumstances.[7]

a. For each transmission asset reflected in the Black & Veatch Study, please identify the agreements (*i.e.,* Transmission Participation Agreements and Transmission, Operation and Maintenance Agreements) [8] that allow(s) Wabash to own said transmission assets and explain in each instance how such ownership right is consistent with the exception criteria in the Contracts.

b. For each of the agreements identified in response to part a., please state the corresponding amounts of transmission plant and transmission capital expenditure balances reflected in the Black & Veatch Study for years 2019–2021.

c. In addition, please identify any transmission assets that were excluded from the proposed buyout amount due to limitations set forth in the Contracts.

[1] *Wabash Valley Power Ass'n, Inc.,* 178 FERC ¶ 63,005 (2022).

[2] Timpont Rural Electric Member Cooperative, Complaint, Docket No. EL19–2–000, at 1–2 (filed Oct. 1, 2018) (Complaint).

[3] *Tipmont Rural Elec. Member Coop.* v. *Wabash Valley Power Ass'n, Inc.,* 171 FERC ¶ 61,059 (2020).

[4] *Wabash Valley Power Ass'n, Inc.,* 171 FERC ¶ 61,053 (2020).

[5] As participants in the hearing proceeding, Trial Staff and United Power, Inc. may submit reply briefs. This Commission, however, is generally less likely to allow new participants to intervene after issuance of a merits order. *See, e.g., Conn. Yankee Atomic Power Co.,* 92 FERC ¶ 61,269, at 61,899 (2000) (denying the subsidiaries of the Northeast Utilities system's (NU) out-of-time motion to intervene because ''[t]o permit NU's late intervention after the issuance of the Initial Decision . . . would result in undue burden on the active parties to the hearing.'').

[6] *See supra* note 5.

[7] *See e.g.,* Ex. TIP–0003 at 3 (''It is understood by and between the Parties that the express intent of Wabash Valley is to not own, operate or maintain any transmission facilities and/or substations except as such ownership, operation and maintenance may inure to Wabash Valley by reason of Transmission Participation Agreements and Transmission, Operation and Maintenance Agreements with other suppliers which own and operate bulk transmission systems.'').

[8] *See supra* n.7.

2. Wabash's transmission plant in service balance for year 2019 is $354.9 million in the Black & Veatch Study [9] and $312.8 million in Wabash's annual FERC Form No. 1 filing.[10] Please explain the divergence between these two values. Wabash's transmission plant in service balance for year 2020 is $423.1 million in the Black & Veatch Study [11] and $321.2 million in Wabash's 2020 budget study.[12] In addition, Wabash states that this value is $348.9 million in the Adjusted Black & Veatch Study.[13]

a. Please explain why Wabash's transmission plant in service balance for year 2020 decreased by $74.2 million between the original and Adjusted Black & Veatch studies.

b. Please explain the $27.7 million divergence between Wabash's transmission plant in service balance for year 2020 in the Adjusted Black & Veatch Study and Wabash's 2020 budget study.

c. Please provide updated versions of the spreadsheets contained in Ex. TIP–0097 and Ex. TIP–0113 that reflect the updated transmission plant in service balance for year 2020, and all other modified values, used in the Adjusted Black & Veatch Study.

3. Wabash's annual transmission capital expenditure for year 2019 is $50.6 million in the Black & Veatch Study,[14] $41.9 million in Wabash's annual FERC Form No. 1 filing,[15] and $42.2 million according to Wabash's work orders.[16] Please explain the divergence among these values.

4. Wabash's annual transmission capital expenditure for year 2020 is $71.8 million in the Black & Veatch Study,[17] $41.6 million in Wabash's annual FERC Form No. 1 filing,[18] and $66.5 million according to Wabash's work orders.[19] Please explain the divergence among these values.

5. Please explain the transmission service that Wabash takes under the MISO Tariff in association with delivery to Tipmont.

6. Wabash states that the original and Adjusted Black & Veatch studies ''make no adjustment to Wabash Valley's forecasted transmission revenues.'' [20]

a. Please explain how Wabash estimated the annual transmission revenues it would receive if Tipmont remained a member of Wabash and describe the source(s) of those revenues. Describe all assumptions and provide supporting workpapers.

b. In addition, please describe how these revenues compare to what Wabash would receive if Tipmont departs and procures network service for its entire load.

B. Capacity Price Forecast

7. Please identify the source of the $22.34/MW-day initial value used in forecasting the Black & Veatch Study's capacity price for years 2020–2025.[21]

8. Please explain how the Black & Veatch Study determined the annual growth rate for its forecasted capacity prices for years 2021–2025.[22]

9. Please explain why the Black & Veatch Study switches from using the recent capacity price level observed in the MISO market as a starting point for the capacity price forecast for years 2020–2025 to using weighted average solar power purchase agreement costs beginning in year 2026 specifically.[23]

C. Energy Price Forecast

10. Please explain how the Black & Veatch Study selects the New York Mercantile Exchange Henry Hub forward price curve dated October 2, 2019, as the basis for the projected natural gas prices used in years 2021–2031 of its energy price forecast.[24] In addition, please explain why the Black & Veatch Study uses a single forward curve instead of averaging over multiple forward curves.

11. Please explain why the Black & Veatch Study assumes that the five-year compound annual growth rate implied in the natural gas forward prices for 2027–2031 will persist through 2050.[25]

D. Miscellaneous Issues

12. Wabash proposes a 10-year buyout period, arguing that for any termination initiated prior to April 14, 2028, Tipmont agreed to a ten-year notice and buyout period during which Tipmont remains a member, continues to purchase all-requirements service, and makes additional monthly escrow payments based on the rate set by the Wabash board of directors.[26] In contrast, Tipmont argues that the 10-year buyout period has not been found to be just and reasonable; that, as long as Tipmont pays the verifiable stranded costs associated with Tipmont's exit,[27] Wabash and its members are protected from any financial impacts associated with such exit, whether Tipmont leaves immediately or in 10 years; and that Tipmont's continued membership in Wabash is causing harm to Tipmont.[28] Tipmont requests that the Commission direct Wabash to make a compliance filing that sets the date of Tipmont's exit as ''the first day of the month one year after the date of that Commission order.'' [29]

Please address the manner in which an immediate buyout scenario should be effectuated in the event the Commission finds the 10-year buyout period is not required by the parties' contracts and otherwise has not been shown to be just and reasonable.[30]

13. Wabash's property insurance costs for year 2019 are $1.5 million in the Black & Veatch Study [31] and $169,871 in Wabash's annual FERC Form No. 1 filing.[32] Please explain the divergence between these values.

14. Wabash's property tax costs for year 2019 are $5.57 million in the Black & Veatch Study and $5.37 million in Wabash's Trial Balance workpaper.[33] Please explain the divergence between these values.

Appendix B

Question Directed at Tipmont

15. According to Trial Staff, the London Economics International (LEI) Study's energy price forecast projects an approximate $3/MMBtu seasonal spread in intra-year natural gas prices beginning in 2030.[34] Please explain how the seasonal natural gas price spreads observed in the LEI Study's energy price forecast are consistent with current and expected natural gas market dynamics in MISO.

[FR Doc. 2023–25823 Filed 11–21–23; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. CP24–12–000]

Transcontinental Gas Pipe Line Company, LLC; Notice of Application and Establishing Intervention Deadline

Take notice that on November 2, 2023, Transcontinental Gas Pipe Line Company, LLC (Transco), P.O. Box 1396, Houston, Texas 77251, filed an application under section 7b of the Natural Gas Act (NGA), and part 157 of the Commission's regulations requesting authorization for its Ship Shoal 246 to Ship Shoal 242 Abandonment Project (Project). The Project consists of Transco abandoning offshore laterals extending from Ship Shoal Block 246 Platform A to the Ship Shoal Block 242 underwater platform, and auxiliary facilities,

[9] Ex. TIP–0097; Ex. TIP–0113 at 'Depreciation' tab, cell C28.

[10] Wabash, FERC Form No. 1/3–Q, Rev. 02–04, at 207 (Electric Plant in Service (Account 101, 102, 103, and 106, line 58(g)) (2019).

[11] Ex. TIP–0097; Ex. TIP–0113 at 'Depreciation' tab, cell D28.

[12] Ex. TIP–0016 at 'BL Pg 20 Cost of Trans' tab, cell I44.

[13] Ex. WV–0035 at 35.

[14] Ex. TIP–0097; Ex. TIP–0113 at 'Depreciation' tab, cell C7.

[15] Wabash, FERC Form No. 1/3–Q, Rev. 02–04, at 206 (Electric Plant in Service (Account 101, 102, 103, and 106, line 58(c)) (2019).

[16] Ex. WV–0035 at 36 (citing Ex. WV–0049).

[17] Ex. TIP–0097; Ex. TIP–0113 at 'Depreciation' tab, cell D7.

[18] Wabash, FERC Form No. 1/3–Q, Rev. 02–04, at 206 (Electric Plant in Service (Account 101, 102, 103, and 106, line 58(c)) (2020).

[19] Ex. WV–0035 at 36 (citing Ex. WV–0049).

[20] *Id.* at 44–45.

[21] Ex. WV–0014 at 15 (''For the years 2020 through 2025, Black & Veatch increased the capacity prices from the recent capacity price level of $22.34/MW-day observed in the MISO market.'').

[22] *Id.* at 30.

[23] *Id.* at 15, 30.

[24] *Id.* at 15.

[25] *Id.*

[26] Wabash Br. Opposing Exceptions 13–14.

[27] Tipmont Br. Opposing Exceptions 2.

[28] *Id.* at 1 (citing Ex. TIP–0001 at 25).

[29] Tipmont Br. on Exceptions 13.

[30] *Id.*

[31] Ex. TIP–0097; Ex. TIP–0113 at 'Prop Ins' tab, cell E14.

[32] Wabash, FERC Form No. 1/3–Q, Rev. 02–04, at 323 (Electric Operation and Maintenance Expenses (line 185(d)) (2019).

[33] Ex. WV–0035 (citing Ex. TIP–0082).

[34] Trial Staff Initial Br. 40 (citing Tr. 528:23–529:22, 531:4–22).

located Offshore, Louisiana. Transco states that this proposal is related to QuarterNorth Energy, LLC's intention to abandon its SS 246 Platform which Transco holds a minority interest in. Transco estimates the total cost of the Project to be $5,843,818, all as more fully set forth in the application which is on file with the Commission and open for public inspection.

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 (*www.ferc.gov*) using the ''eLibrary'' link. Enter the docket number excluding the last three digits in the docket number field to access the document. At this time, the Commission has suspended access to the Commission's Public Reference Room. For assistance, contact the Federal Energy Regulatory Commission at *FercOnlineSupport@ferc.gov* or call toll-free, (886) 208–3676 or TTY (202) 502–8659.

Any questions regarding the proposed project should be directed to Travis Beach, Sr. Regulatory Analyst, P.O. Box 1396, Houston, Texas 77251 by phone at (281) 224–6248, or by email at *Travis.Beach@Williams.com.*

Pursuant to section 157.9 of the Commission's Rules of Practice and Procedure,[1] within 90 days of this Notice the Commission staff will either: complete its environmental review and place it into the Commission's public record (eLibrary) for this proceeding; or issue a Notice of Schedule for Environmental Review. If a Notice of Schedule for Environmental Review is issued, it will indicate, among other milestones, the anticipated date for the Commission staff's issuance of the final environmental impact statement (FEIS) or environmental assessment (EA) for this proposal. The filing of an EA in the Commission's public record for this proceeding or the issuance of a Notice of Schedule for Environmental Review will serve to notify Federal and State agencies of the timing for the completion of all necessary reviews, and the subsequent need to complete all Federal authorizations within 90 days of the date of issuance of the Commission staff's FEIS or EA.

Public Participation

There are three ways to become involved in the Commission's review of this project: you can file comments on the project, you can protest the filing, and you can file a motion to intervene in the proceeding. There is no fee or cost for filing comments or intervening. The deadline for filing a motion to intervene is 5:00 p.m. Eastern Time on December 7, 2023. How to file protests, motions to intervene, and comments is explained below.

The Commission's Office of Public Participation (OPP) supports meaningful public engagement and participation in Commission proceedings. OPP can help members of the public, including landowners, environmental justice communities, Tribal members and others, access publicly available information and navigate Commission processes. For public inquiries and assistance with making filings such as interventions, comments, or requests for rehearing, the public is encouraged to contact OPP at (202)502–6595 or *OPP@ferc.gov.*

Comments

Any person wishing to comment on the project may do so. Comments may include statements of support or objections, to the project as a whole or specific aspects of the project. The more specific your comments, the more useful they will be.

Protests

Pursuant to sections 157.10(a)(4)[2] and 385.211[3] of the Commission's regulations under the NGA, any person[4] may file a protest to the application. Protests must comply with the requirements specified in section 385.2001[5] of the Commission's regulations. A protest may also serve as a motion to intervene so long as the protestor states it also seeks to be an intervenor.

To ensure that your comments or protests are timely and properly recorded, please submit your comments on or before December 7, 2023.

There are three methods you can use to submit your comments or protests to the Commission. In all instances, please reference the Project docket number CP24–12–000 in your submission.

(1) You may file your comments electronically by using the eComment feature, which is located on the Commission's website at *www.ferc.gov* under the link to Documents and Filings. Using eComment is an easy method for interested persons to submit brief, text-only comments on a project;

(2) You may file your comments or protests electronically by using the eFiling feature, which is located on the Commission's website (*www.ferc.gov*) under the link to Documents and Filings. With eFiling, you can provide comments in a variety of formats by attaching them as a file with your submission. New eFiling users must first create an account by clicking on ''eRegister.'' You will be asked to select the type of filing you are making; first select ''General'' and then select ''Comment on a Filing''; or

(3) You can file a paper copy of your comments or protests by mailing them to the following address below. Your written comments must reference the Project docket number (CP24–12–000).

To file via USPS: Kimberly D. Bose, Secretary, Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426.

To file via any other courier: Kimberly D. Bose, Secretary, Federal Energy Regulatory Commission, 12225 Wilkins Avenue, Rockville, Maryland 20852.

The Commission encourages electronic filing of comments (options 1 and 2 above) and has eFiling staff available to assist you at (202) 502–8258 or *FercOnlineSupport@ferc.gov.*

Persons who comment on the environmental review of this project will be placed on the Commission's environmental mailing list, and will receive notification when the environmental documents (EA or EIS) are issued for this project and will be notified of meetings associated with the Commission's environmental review process.

The Commission considers all comments received about the project in determining the appropriate action to be taken. However, the filing of a comment alone will not serve to make the filer a party to the proceeding. To become a party, you must intervene in the proceeding. For instructions on how to intervene, see below.

Interventions

Any person, which includes individuals, organizations, businesses, municipalities, and other entities,[6] has the option to file a motion to intervene in this proceeding. Only intervenors have the right to request rehearing of Commission orders issued in this proceeding and to subsequently challenge the Commission's orders in the U.S. Circuit Courts of Appeal.

To intervene, you must submit a motion to intervene to the Commission in accordance with Rule 214 of the Commission's Rules of Practice and

[1] 18 CFR (Code of Federal Regulations)157.9.

[2] 18 CFR 157.10(a)(4).

[3] 18 CFR 385.211.

[4] Persons include individuals, organizations, businesses, municipalities, and other entities. 18 CFR 385.102(d).

[5] 18 CFR 385.2001.

[6] 18 CFR 385.102(d).

Procedure [7] and the regulations under the NGA [8] by the intervention deadline for the project, which is December 7, 2023. As described further in Rule 214, your motion to intervene must state, to the extent known, your position regarding the proceeding, as well as your interest in the proceeding. For an individual, this could include your status as a landowner, ratepayer, resident of an impacted community, or recreationist. You do not need to have property directly impacted by the project in order to intervene. For more information about motions to intervene, refer to the FERC website at *https://www.ferc.gov/resources/guides/how-to/intervene.asp.*

There are two ways to submit your motion to intervene. In both instances, please reference the Project docket number CP24–12–000 in your submission.

(1) You may file your motion to intervene by using the Commission's eFiling feature, which is located on the Commission's website (*www.ferc.gov*) under the link to Documents and Filings. New eFiling users must first create an account by clicking on ''eRegister.'' You will be asked to select the type of filing you are making; first select ''General'' and then select ''Intervention.'' The eFiling feature includes a document-less intervention option; for more information, visit *https://www.ferc.gov/docs-filing/efiling/document-less-intervention.pdf.;* or

(2) You can file a paper copy of your motion to intervene, along with three copies, by mailing the documents to the address below. Your motion to intervene must reference the Project docket number CP24–12–000.

To file via USPS: Kimberly D. Bose, Secretary, Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426.

To file via any other courier: Kimberly D. Bose, Secretary, Federal Energy Regulatory Commission, 12225 Wilkins Avenue, Rockville, Maryland 20852.

The Commission encourages electronic filing of motions to intervene (option 1 above) and has eFiling staff available to assist you at (202) 502–8258 or *FercOnlineSupport@ferc.gov.*

Protests and motions to intervene must be served on the applicant either by mail or email at: Travis Beach, Sr. Regulatory Analyst, P.O. Box 1396, Houston, Texas 77251, or by email at *Travis.Beach@Williams.com.* Any subsequent submissions by an intervenor must be served on the applicant and all other parties to the proceeding. Contact information for parties can be downloaded from the service list at the eService link on FERC Online. Service can be via email with a link to the document.

All timely, unopposed [9] motions to intervene are automatically granted by operation of Rule 214(c)(1).[10] Motions to intervene that are filed after the intervention deadline are untimely, and may be denied. Any late-filed motion to intervene must show good cause for being late and must explain why the time limitation should be waived and provide justification by reference to factors set forth in Rule 214(d) of the Commission's Rules and Regulations.[11] A person obtaining party status will be placed on the service list maintained by the Secretary of the Commission and will receive copies (paper or electronic) of all documents filed by the applicant and by all other parties.

Tracking the Proceeding

Throughout the proceeding, additional information about the project will be available from the Commission's Office of External Affairs, at (866) 208–FERC, or on the FERC website at *www.ferc.gov* using the ''eLibrary'' link as described above. The eLibrary link also provides access to the texts of all formal documents issued by the Commission, such as orders, notices, and rulemakings.

In addition, the Commission offers a free service called eSubscription which allows you to keep track of all formal issuances and submittals in specific dockets. This can reduce the amount of time you spend researching proceedings by automatically providing you with notification of these filings, document summaries, and direct links to the documents. For more information and to register, go to *www.ferc.gov/docs-filing/esubscription.asp.*

Intervention Deadline: 5:00 p.m. Eastern Time on December 7, 2023.

Dated: November 16, 2023.

Debbie-Anne A. Reese,

Deputy Secretary.

[FR Doc. 2023–25825 Filed 11–21–23; 8:45 am]

BILLING CODE 6717–01–P

[7] 18 CFR 385.214.

[8] 18 CFR 157.10.

[9] The applicant has 15 days from the submittal of a motion to intervene to file a written objection to the intervention.

[10] 18 CFR 385.214(c)(1).

[11] 18 CFR 385.214(b)(3) and (d).

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings #1

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

Docket Numbers: EG24–31–000.

Applicants: Sparta Solar, LLC.

Description: Sparta Solar, LLC submits Notice of Self–Certification of Exempt Wholesale Generator Status.

Filed Date: 11/16/23.

Accession Number: 20231116–5138.

Comment Date: 5 p.m. ET 12/7/23.

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

Docket Numbers: ER10–2265–021; ER10–2355–011; ER10–2947–016; ER10–3223–010; ER11–1846–012; ER11–1847–012; ER11–1850–012; ER11–2062–029; ER11–2175–007; ER11–2176–006; ER11–2598–015; ER11–3188–007; ER11–3418–009; ER11–4307–030; ER11–4308–030; ER12–224–008; ER12–225–008; ER12–261–029; ER12–2301–007; ER13–1192–009; ER16–10–004; ER17–764–007; ER17–765–007; ER17–767–007; ER21–2826–002; ER10–2784–017.

Applicants: Astoria Gas Turbine Power LLC, NRG Curtailment Solutions, Inc., Stream Energy Delaware, LLC, Stream Energy Illinois, LLC, Stream Ohio Gas & Electric, LLC, NRG Chalk Point CT LLC, Hess Energy Marketing LLC, Stream Energy New York, LLC, Independence Energy Group LLC, Stream Energy New Jersey, LLC, Stream Energy Columbia, LLC, Reliant Energy Northeast LLC, Green Mountain Energy Company, Xoom Energy, LLC, Stream Energy Maryland, LLC, Gateway Energy Services Corporation, Stream Energy Pennsylvania, LLC, SGE Energy Sourcing, LLC, Energy Plus Holdings LLC, Direct Energy Business, LLC, Direct Energy Marketing Inc., Direct Energy Services, LLC, Indian River Power LLC, Vienna Power LLC, Midwest Generation LLC, NRG Power Marketing LLC.

Description: Response to October 6, 2023, Deficiency Letter of NRG Power Marketing LLC, et. al.

Filed Date: 11/6/23.

Accession Number: 20231106–5177.

Comment Date: 5 p.m. ET 11/27/23.

Docket Numbers: ER23–1956–001.

Applicants: Earthrise Tilton Interconnection, LLC.

Description: Compliance filing: Compliance Filing Reflecting Actual Effective Date of Tariff Records to be effective N/A.

Filed Date: 11/16/23.
Accession Number: 20231116–5141.
Comment Date: 5 p.m. ET 12/7/23.
Docket Numbers: ER23–1958–001.
Applicants: Earthrise Shelby County Interconnection, LLC.
Description: Compliance filing: Compliance Filing Reflecting Actual Effective Date of Tariff Records to be effective N/A.
Filed Date: 11/16/23.
Accession Number: 20231116–5137.
Comment Date: 5 p.m. ET 12/7/23.
Docket Numbers: ER23–2018–001.
Applicants: Shelby County Energy Center, LLC.
Description: Compliance filing: Compliance Filing Reflecting Actual Effective Date of Tariff Records to be effective N/A.
Filed Date: 11/16/23.
Accession Number: 20231116–5143.
Comment Date: 5 p.m. ET 12/7/23.
Docket Numbers: ER23–2019–001.
Applicants: Tilton Energy LLC.
Description: Compliance filing: Compliance Filing Reflecting Actual Effective Date of Tariff Records to be effective N/A.
Filed Date: 11/16/23.
Accession Number: 20231116–5148.
Comment Date: 5 p.m. ET 12/7/23.
Docket Numbers: ER24–406–000.
Applicants: PJM Interconnection, L.L.C.
Description: § 205(d) Rate Filing: Amendment to WMPA, Service Agreement No. 6365; Queue No. AE2–309 to be effective 1/16/2024.
Filed Date: 11/16/23.
Accession Number: 20231116–5002.
Comment Date: 5 p.m. ET 12/7/23.
Docket Numbers: ER24–407–000.
Applicants: ITC Midwest LLC.
Description: § 205(d) Rate Filing: Filing of Communications Pathway Sharing Agreement (Rate Schedule No. 230) to be effective 1/16/2024.
Filed Date: 11/16/23.
Accession Number: 20231116–5028.
Comment Date: 5 p.m. ET 12/7/23.
Docket Numbers: ER24–408–000.
Applicants: Midcontinent Independent System Operator, Inc., Michigan Electric Transmission Company, LLC.
Description: § 205(d) Rate Filing: Midcontinent Independent System Operator, Inc. submits tariff filing per 35.13(a)(2)(iii: 2023–11–16_SA 4191 METC-Consumers Energy E&P (J2874) to be effective 11/10/2023.
Filed Date: 11/16/23.
Accession Number: 20231116–5043.
Comment Date: 5 p.m. ET 12/7/23.
Docket Numbers: ER24–409–000.
Applicants: Midcontinent Independent System Operator, Inc., Northern States Power Company, a Minnesota corporation, Northern States Power Company, a Wisconsin corporation.
Description: § 205(d) Rate Filing: Midcontinent Independent System Operator, Inc. submits tariff filing per 35.13(a)(2)(iii: 2023–11–16_NSP Request for Transmission Rate Incentives to be effective 1/16/2024.
Filed Date: 11/16/23.
Accession Number: 20231116–5044.
Comment Date: 5 p.m. ET 12/7/23.
Docket Numbers: ER24–410–000.
Applicants: Northeastern Power & Gas, LLC.
Description: Baseline eTariff Filing: Application for Market-Based Rate Authorization, Request for Related Waivers to be effective 11/30/2023.
Filed Date: 11/16/23.
Accession Number: 20231116–5048.
Comment Date: 5 p.m. ET 12/7/23.
Docket Numbers: ER24–411–000.
Applicants: AEP Texas Inc.
Description: § 205(d) Rate Filing: AEPTX–CED Peregrine Solar 1st A&R Generation Interconnection Agreement to be effective 10/25/2023.
Filed Date: 11/16/23.
Accession Number: 20231116–5061.
Comment Date: 5 p.m. ET 12/7/23.
Docket Numbers: ER24–412–000.
Applicants: McFarland Solar A, LLC.
Description: § 205(d) Rate Filing: McFarland Solar A, LLC Shared Facilities Agreement to be effective 11/17/2023.
Filed Date: 11/16/23.
Accession Number: 20231116–5085.
Comment Date: 5 p.m. ET 12/7/23.
Docket Numbers: ER24–413–000.
Applicants: McFarland Solar B, LLC.
Description: § 205(d) Rate Filing: McFarland Solar B, LLC Shared Facilities Agreement to be effective 11/17/2023.
Filed Date: 11/16/23.
Accession Number: 20231116–5107.
Comment Date: 5 p.m. ET 12/7/23.
Docket Numbers: ER24–414–000.
Applicants: California Independent System Operator Corporation.
Description: § 205(d) Rate Filing: 2023–11–16 Reconciliation Filing of FERC-Approved Tariff Language to be effective 7/1/2023.
Filed Date: 11/16/23.
Accession Number: 20231116–5123.
Comment Date: 5 p.m. ET 12/7/23.
Docket Numbers: ER24–415–000.
Applicants: Bowline, LLC.
Description: § 205(d) Rate Filing: Market Based Tariff to be effective 11/17/2023.
Filed Date: 11/16/23.
Accession Number: 20231116–5135.
Comment Date: 5 p.m. ET 12/7/23.

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, to protest, or to answer a complaint in any of the above proceedings must file in accordance with Rules 211, 214, or 206 of the Commission's Regulations (18 CFR 385.211, 385.214, or 385.206) 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.

The Commission's Office of Public Participation (OPP) supports meaningful public engagement and participation in Commission proceedings. OPP can help members of the public, including landowners, environmental justice communities, Tribal members and others, access publicly available information and navigate Commission processes. For public inquiries and assistance with making filings such as interventions, comments, or requests for rehearing, the public is encouraged to contact OPP at (202) 502–6595 or *OPP@ferc.gov*.

Dated: November 16, 2023.

Debbie-Anne A. Reese,

Deputy Secretary.

[FR Doc. 2023–25830 Filed 11–21–23; 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:

Filings Instituting Proceedings

Docket Numbers: RP24–157–000.
Applicants: Algonquin Gas Transmission, LLC.
Description: § 4(d) Rate Filing: Negotiated Rates—Salem Harbor 511199 eff 11–1–23 to be effective 11/15/2023.
Filed Date: 11/15/23.
Accession Number: 20231115–5126.
Comment Date: 5 p.m. ET 11/27/23.
Docket Numbers: RP24–158–000.

Applicants: Midwestern Gas Transmission Company.

Description: § 4(d) Rate Filing: Tariff Part 5.0 Metadata Correction to be effective 11/1/2023.

Filed Date: 11/15/23.

Accession Number: 20231115–5146.

Comment Date: 5 p.m. ET 11/27/23.

Docket Numbers: RP24–159–000.

Applicants: Southern Star Central Gas Pipeline, Inc.

Description: Compliance filing: Annual Operational Flow Order Report 2023 to be effective N/A.

Filed Date: 11/16/23.

Accession Number: 20231116–5069.

Comment Date: 5 p.m. ET 11/28/23.

Docket Numbers: RP24–160–000.

Applicants: Adelphia Gateway, LLC.

Description: § 4(d) Rate Filing: Adelphia Gateway NCA–NRA Filing to be effective 12/1/2023.

Filed Date: 11/16/23.

Accession Number: 20231116–5093.

Comment Date: 5 p.m. ET 11/28/23.

Docket Numbers: RP24–161–000.

Applicants: National Fuel Gas Supply Corporation.

Description: § 4(d) Rate Filing: Correction of Metadata to be effective 11/1/2023.

Filed Date: 11/16/23.

Accession Number: 20231116–5096.

Comment Date: 5 p.m. ET 11/28/23.

Any person desiring to intervene, to protest, or to answer a complaint in any of the above proceedings must file in accordance with Rules 211, 214, or 206 of the Commission's Regulations (18 CFR 385.211, 385.214, or 385.206) 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.

Filings in Existing Proceedings

Docket Numbers: RP19–57–007.

Applicants: Algonquin Gas Transmission, LLC.

Description: Compliance filing: AGT New York Delivery Surcharge Cancellation to be effective 1/1/2024.

Filed Date: 11/15/23.

Accession Number: 20231115–5131.

Comment Date: 5 p.m. ET 11/27/23.

Any person desiring to protest in any the above proceedings must file in accordance with Rule 211 of the Commission's Regulations (18 CFR 385.211) on or before 5:00 p.m. Eastern time on the specified comment date.

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

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.

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Dated: November 16, 2023.

Debbie-Anne A. Reese,

Deputy Secretary.

[FR Doc. 2023–25829 Filed 11–21–23; 8:45 am]

BILLING CODE 6717–01–P

ENVIRONMENTAL PROTECTION AGENCY

[Petitions IV–2023–9; FRL–11547–01–R4]

Clean Air Act Operating Permit Program; Order on Petition for Objection to State Operating Permit for Century Aluminum of South Carolina, Inc. (Berkeley County, South Carolina)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of final order on petition.

SUMMARY: The EPA Administrator signed an order dated November 2, 2023, granting in part, and denying in part the petition dated June 9, 2023, from Sierra Club and the Environmental Integrity Project. The petition requested that EPA object to Clean Air Act (CAA) title V operating permit issued by the South Carolina Department of Health and Environmental Control (SCDHEC) to the Century Aluminum of South Carolina, Inc. for its primary aluminum reduction facility located near Mt. Holly, in Berkeley County, South Carolina.

FOR FURTHER INFORMATION CONTACT: Art Hofmeister, Air Permits Section, EPA Region 4, (404) 562–9115, *hofmeister.art@epa.gov.* The final order and petitions are available at: *https://www.epa.gov/title-v-operating-permits/title-v-petition-database.*

SUPPLEMENTARY INFORMATION: EPA received a petition from Sierra Club and the Environmental Integrity Project dated June 9, 2023, requesting that EPA object to the issuance of operating permit no. TV–0420–0015 v1.1, issued by SCDHEC to Century Aluminum of South Carolina, Inc. near Mt. Holly, in Berkeley County, South Carolina. On November 2, 2023, the EPA Administrator issued an order granting in part and denying in part the petition. The order itself explains the bases for EPA's decision. Sections 307(b) and 505(b)(2) of the CAA provide that a petitioner may request review of those portions of an order that deny issues in a petition. Any petition for review shall be filed in the United States Court of Appeals for the appropriate circuit no later than January 22, 2024.

Dated: November 16, 2023.

Jeaneanne Gettle,

Acting Regional Administrator, Region 4.

[FR Doc. 2023–25831 Filed 11–21–23; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OPPT–2023–0098; FRL–10582–06–OCSPP]

Certain New Chemicals or Significant New Uses; Statements of Findings for September 2023

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The Toxic Substances Control Act (TSCA) requires EPA to publish in the **Federal Register** a statement of its findings after its review of certain TSCA submissions when EPA makes a finding that a new chemical substance or significant new use is not likely to present an unreasonable risk of injury to health or the environment. Such statements apply to premanufacture notices (PMNs), microbial commercial activity notices (MCANs), and significant new use notices (SNUNs) submitted to EPA under TSCA. This document presents statements of findings made by EPA on such submissions during the period from September 1, 2023, to September 30, 2023.

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA–HQ–OPPT–2023–0098, is available online at *https://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. 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: Rebecca Edelstein, New Chemical Division (7405M), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave., NW, Washington, DC 20460–0001; telephone number: (202) 564–1667 email address: *edelstein.rebecca@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. Executive Summary

A. Does this action apply to me?

This action provides information that is directed to the public in general.

B. What action is the Agency taking?

This document lists the statements of findings made by EPA after review of submissions under TSCA section 5(a) that certain new chemical substances or significant new uses are not likely to present an unreasonable risk of injury to health or the environment. This document presents statements of findings made by EPA during the reporting period.

C. What is the Agency's authority for taking this action?

TSCA section 5(a)(3) requires EPA to review a submission under TSCA section 5(a) and make one of several specific findings pertaining to whether the substance may present unreasonable risk of injury to health or the environment. Among those potential findings is that the chemical substance or significant new use is not likely to present an unreasonable risk of injury to health or the environment per TSCA section 5(a)(3)(C).

TSCA section 5(g) requires EPA to publish in the **Federal Register** a statement of its findings after its review of a submission under TSCA section 5(a) when EPA makes a finding that a new chemical substance or significant new use is not likely to present an unreasonable risk of injury to health or the environment. Such statements apply to PMNs, MCANs, and SNUNs submitted to EPA under TSCA section 5.

Anyone who plans to manufacture (which includes import) a new chemical substance for a non-exempt commercial purpose and any manufacturer or processor wishing to engage in a use of a chemical substance designated by EPA as a significant new use must submit a notice to EPA at least 90 days before commencing manufacture of the new chemical substance or before engaging in the significant new use.

The submitter of a notice to EPA for which EPA has made a finding of ''not likely to present an unreasonable risk of injury to health or the environment'' may commence manufacture of the chemical substance or manufacture or processing for the significant new use notwithstanding any remaining portion of the applicable review period.

D. Does this action have any incremental economic impacts or paperwork burdens?

No.

II. Statements of Findings Under TSCA Section 5(a)(3)(C)

In this unit, EPA provides the following information (to the extent that such information is not claimed as Confidential Business Information (CBI)) on the PMNs, MCANs and SNUNs for which, during this period, EPA has made findings under TSCA section 5(a)(3)(C) that the new chemical substances or significant new uses are not likely to present an unreasonable risk of injury to health or the environment:

The following list provides the EPA case number assigned to the TSCA section 5(a) submission and the chemical identity (generic name if the specific name is claimed as CBI).

- P–22–0057, Polysaccharide, polymer with 2-propenoic acid, sodium salt (Generic Name).

To access EPA's decision document describing the basis of the ''not likely to present an unreasonable risk'' finding made by EPA under TSCA section 5(a)(3)(C), look up the specific case number at *https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/chemicals-determined-not-likely.*

Authority: 15 U.S.C. 2601 *et seq.*

Dated: November 16, 2023.

Shari Z. Barash,

Acting Director, New Chemicals Division, Office of Pollution Prevention and Toxics.

[FR Doc. 2023–25760 Filed 11–21–23; 8:45 am]

BILLING CODE 6560–50–P

FEDERAL COMMUNICATIONS COMMISSION

[FR ID: 185258]

Privacy Act of 1974; System of Records

AGENCY: Federal Communications Commission.

ACTION: Notice of a modified system of records.

SUMMARY: The Federal Communication Commission (FCC or Commission, or the Agency) proposes to modify an existing system of records, FCC/OMD–25, Financial Operations Information System (FOIS), subject to the Privacy Act of 1974 (5 U.S.C. 552a) as amended. This action is necessary to meet the requirements of the Privacy Act to publish in the **Federal Register** notice of the existence and character of records maintained by the agency. The records in this system pertain to the mission and activities of the FCC's Financial Operations (FO) organization in the Office of Managing Director (OMD), which are associated with the Commission's financial and budgetary operations, programs, activities, and transactions. This modification makes various necessary changes and updates, including slightly renaming the system to reflect the fact that the system of records covers multiple systems and applications, clerical and clarity edits, formatting changes required by the Office of Management and Budget (OMB) Circular A–108 since its previous publication, the addition of one new routine use, the deletion of two routine uses, and the revision of multiple existing routine uses.

DATES: This modified system of records will become effective on November 22, 2023. Written comments on the routine uses are due by December 22, 2023. The routine uses in this action will become effective on December 22, 2023 unless comments are received that require a contrary determination.

ADDRESSES: Send comments to Katherine C. Clark, Attorney-Advisor, Office of General Counsel, Federal Communications Commission, 45 L Street NE, Washington, DC 20554, or to *privacy@fcc.gov.*

FOR FURTHER INFORMATION CONTACT: Katherine C. Clark, (202) 418–1773, or *privacy@fcc.gov* (and to obtain a copy of the Narrative Statement and the Supplementary Document, which includes details of the modifications to this system of records).

SUPPLEMENTARY INFORMATION: As required by the Privacy Act of 1974, as amended, 5 U.S.C. 552a(e)(4) and

(e)(11), this document sets forth notice of the proposed modification of a system of records maintained by the FCC. The FCC previously provided notice of the system of records FCC/OMD–25, Financial Operations Information System (FOIS), by publication in the **Federal Register** on October 6, 2016 (81 FR 69522). This notice serves to update and modify FCC/OMD–25 as a result of various necessary changes and updates. The substantive changes and modifications to the previously published version of the FCC/OMD–25 system of records include:

1. Updating the name of the system of records to Financial Operations Information Systems (FOIS), to reflect that this system of records covers multiple systems and applications;

2. Updating the language in the Security Classification to follow OMB guidance;

3. Updating the Purposes section for clarity and to reflect modernization of the CORES system to incorporate functionalities that were previously provided through separate systems and forms;

4. Modifying the language in the Categories of Individuals and Categories of Records to be consistent with the language and phrasing now used in FCC SORNs;

5. Deleting two routine uses (listed by former routine use number): (7) ''Do Not Pay'' System, which has been consolidated into modified Routine Use (6) Financial Obligations Under the Debt Collection Acts; and (4) Audits and Oversight, for which disclosures are covered under another exception to the Privacy Act;

6. Updating and/or revising language in the following routine uses (listed by the routine use number provided in this notice): (1) Public Access; (2) Drug Debarment List; (5) Financial Obligations Under the Debt Collection Acts and Do Not Pay; (6) Financial Obligations as Required by the National Finance Center (USDA), *et al.;* (7) Litigation and (8) Adjudication (formerly a single routine use); (9) Law Enforcement and Investigation; (10) Congressional Inquiries; (11) Government-wide Program Management and Oversight; (18) Statistical/Analytical Studies; (19) Breach Notification, the revision of which is as required by OMB Memorandum No. M–17–12; and (21) Non-Federal Personnel;

7. Adding one new routine use: (20) Assistance to Federal Agencies and Entities Related to Breaches, the addition of which is required by OMB Memorandum No. M–17–12; and

8. Updating the existing records retention and disposal schedule with a new records schedule: N1–173–00–001, Commission Registration System (CORES).

The system of records is also revised for clarity and updated to reflect various administrative changes related to the system managers and system addresses; policies and practices for storage and retrieval of the information; administrative, technical, and physical safeguards; and updated notification, records access, and contesting records procedures.

SYSTEM NAME AND NUMBER:

FCC/OMD–25, Financial Operations Information Systems (FOIS).

SECURITY CLASSIFICATION:

No information in the system is classified.

SYSTEM LOCATION:

Financial Operations (FO), Office of Managing Director (OMD), Federal Communications Commission (FCC), 45 L Street NE, Washington, DC 20554.

SYSTEM MANAGER(S):

Financial Operations (FO), Office of Managing Director (OMD), Federal Communications Commission (FCC), 45 L Street NE, Washington, DC 20554.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

5 U.S.C. chapter 57; 31 U.S.C. 525, 3302(e); 44 U.S.C. 3101, 3102, 3309; Debt Collection Act of 1982 (Pub. L. 97–365), as amended by Debt Collection Improvement Act of 1996 (Pub. L. 104–134); section 639 of the Consolidated Appropriations Act of 2005 (Pub. L. 108–447); Federal Financial Management Improvement Act of 1996 (Pub. L. 104–208); Chief Financial Officers Act of 1990 (Pub. L. 101–576); Federal Managers Financial Integrity Act of 1982 (Pub. L. 97–255); Executive Order 9397; Budget and Accounting Procedures Act of 1950 (Pub. L. 81–784); section 5301 of the Anti-Drug Abuse Act of 1988 (Pub. L. 100–690), as amended by section 1002(d) of the Crime Control Act of 1990 (Pub. L. 100–647); and 47 U.S.C. 154(i) and (j).

PURPOSE(S) OF THE SYSTEM:

This system collects and maintains records contained in the information systems, subsystems, databases, and paper document files of the Financial Operations organization (FO) within OMD.[1] Collecting and maintaining this information allows staff access to documents necessary for key activities discussed in this SORN, including maintaining identity, regulatory, and financial information regarding individuals and entities doing business with the Commission, as well as information regarding the Commission's financial and budgetary operations, programs, functions, and transactions. These various systems include, but are not limited to FCC User Registration System, Commission Registration System (CORES), Financial Operations API, Financial Operations API Cloud, the Financial Operations Administration System, Genesis and related applications (*i.e.,* Genesis Portal, Genesis E2 WSDL, Genesis E2, and Genesis Reports), Alfresco, databases, and related FO documents and forms. Authorized FCC personnel (including authorized contract employees) use these records on a need-to-know basis to conduct the Commission financial and budgetary operations, programs, transactions, and statements, which include but are not limited to:

1. Processing and tracking payments made and monies owed from or to individuals (including FCC employees and authorized contract employees), FCC regulatees and licensees, and the FCC, and to ensure that payments by the FCC are based on a lawful official commitment and obligation of government funds, including but not limited to payments to cover administrative charges, penalties, forfeitures assessed, fees collected, services rendered, and direct loans;

2. Establishing records of ''receivables'' and tracking repayment status for any amount(s) claimed in the event of a debt owed to the FCC, which include but are not limited to repayment of overpayments and excess disbursements (including reimbursements and/or refunds for incorrect payments or overpayments), and other debts, advance payments, including but not limited to application processing fees, travel advances (including reimbursements authorized under the Travel Reimbursement Program covered by GSA/GOVT–3 and GSA/GOVT–4), advanced sick leave, and advanced annual leave, and withholding services from individuals who owe delinquent debt to the FCC or an FCC component, including billing and collection of bad checks;

3. Developing reports of taxable income using the records of payments

[1] The FO specifically maintains the FCC's Registration Number (FRN) system, the Commission-wide method for identifying and interacting with those individuals who have registered to do business with the FCC under 31 U.S.C. 7701(c)(2) and who incur application and/or regulatory fee obligations. An FRN collaterally allows that monies paid are properly matched with debts and obligations.

and uncollectible debts that are provided to the Internal Revenue Service (IRS) and applicable State and local taxing officials;

4. Tracking overdue and delinquent federal debts for debt collection purposes;

5. Initiating and completing computer matching to verify benefit and payment eligibility under relevant related Federal Government systems such as, but not limited to Treasury's ''Do Not Pay'' portal verification system, the GSA Excluded Parties and Debarment List, and the Department of Justice Drug Debarment Roster in connection with implementation of section 5301 of the Anti-Drug Abuse Act of 1998;

6. Populating FCC forms, which include but are not limited to Forms 44 and 45, 159 series, 160 and 161, and 1064, and other financial and budgetary forms and related documents and records, which are used to carry out these various financial, accounting, and budgetary activities, functions, and purposes;

7. Providing the viewing function for images of auction loans that the FCC has made to customers, to provide them access to their loan payment history (retained for historical purposes); and

8. Storing the information that the Department of Justice (DOJ) exchanges with the FCC in connection with the implementation of section 5301 of the Anti-Drug Abuse Act of 1988.[2]

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

1. FCC staff, including but not limited to employees (including interns), and contractors and vendors, who handle information in the FCC's financial and budgetary operations, which include but are not limited to FO's programs, processes, activities, and functions;

2. Individuals and representatives of entities who register with the FCC to receive a FCC Registration Number (FRN) to conduct business with the Commission; and

3. Individuals who intend to or do conduct business with the FCC as a regulatee, licensee, contractor, or vendor and who are listed on the Drug Debarment Roster (as a result of drug convictions for the distribution or possession of controlled substances) who have been denied all Federal benefits as part of their sentence pursuant to section 5301 of the Anti-Drug Abuse Act of 1988, and who have filed application(s) for any FCC professional or commercial license(s) and/or authorization(s).

CATEGORIES OF RECORDS IN THE SYSTEM:

1. FCC employees (including interns)—individual's name, Social Security Number (SSN), home address, phone number, bank account data, and miscellaneous monies received by the Commission (including, but not limited to reimbursement(s) authorized under the Travel Reimbursement Program covered by the government-wide system of records GSA/GOVT–3 and GSA/GOVT–4,[3] and related financial requirements);

2. Independent contractors—individual's name and Social Security Number (SSN) (required when the fee exceeds the minimum $600.00 threshold authorized by IRS Form 1099);

3. Individuals and representatives of entities who register to do business with the FCC and receive a FCC Registration Number (FRN)—individual's name, address(es), Social Security Number (SSN), Individual Taxpayer Identification Number (ITIN), telephone number(s), fax number(s), email address(es), records of services rendered, loan payment information, forfeitures assessed and collected, billing and collection of bad checks, bank deposit information, transaction type information, United States Treasury deposit data (notification of completion of FCC financial transactions with the US Treasury), and information substantiating fees collected, refunds issues, and interest, penalties, and administrative charges assessed to individuals.

4. Individuals on the DOJ's Drug Debarment List—individual's name, DOJ identification number (ID) (for the person denied Federal benefits), Individual Taxpayer Identification Number (ITIN), starting and ending date of the denial of Federal benefits, address, zip code, and (if required by the FCC application) birthdate, and confirmation report for DOJ matching; (Upon such a match, the FCC will initiate correspondence with the applicant, which will also be associated with the application. The confirmation report and any correspondence with the applicant will be among the records found in this system.); and

5. FCC Forms which include, but are not limited to, Forms 44 and 45; 159 series; 160 and 161; 1064, and other related financial and/or budgetary forms, assessments, and related documents.

RECORD SOURCE CATEGORIES:

Information in this system is provided by the following individuals: FCC employees (including interns), contractor employees, and individuals or representatives of entities who register to do business with the FCC, and the information obtained from the Federal Drug Debarment List database(s).

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

In addition to those disclosures generally permitted under 5 U.S.C. 552a(b) of the Privacy Act, all or a portion of the records or information contained in this system may be disclosed to authorized entities, as is determined to be relevant and necessary, outside the FCC as a routine use pursuant to 5 U.S.C. 552a(b)(3). In each of these cases, however, the FCC will determine whether disclosure of the records is compatible with the purpose(s) for which the records were collected:

1. Public Access—FCC Registration Numbers (FRNs) and certain information (excluding security/sensitive information) provided by individuals and representatives who register to do business with the Commission by obtaining an FRN are routinely made public. Individuals who have so registered also can use the Commission's automated reporting tools to access their own nonpublic information, which includes but is not limited to Regulatory Fees, fines, forfeitures, penalties, Debt Collection Improvement Act and other administrative changes, and related payments and assessments, and to determine the amount(s) owed.

2. Drug Debarment List—Records from CORES may be matched against the Department of Justice Drug Debarment List, and any results (not including the DOJ ID Number) and any correspondence with the applicant regarding this match will be associated with the FCC applicant for a license or authorization or recipient of FCC funds, and thus, be made routinely available (with redactions for date of birth and Social Security Number) for public

[2] This permits the FCC to perform the General Services Administration (GSA) Debarment List check as provided for in the Office of National Drug Control Policy plan for implementation of section 5301 through use of information generated by DOJ. The FCC will use the automated records obtained from DOJ only to make an initial determination of whether an individual applicant is subject to a denial of all Federal benefits or FCC benefits imposed under section 5301 of the Anti-Drug Abuse Act of 1988.

[3] The PII contained in the FCC's Travel and Reimbursement Program is covered by one or the other of the two government-wide systems of records maintained by the General Services Administration (GSA): GSA/GOV–3, ''Travel Charge Card Program,'' 78 FR 20108; or GSA/GOVT–4, ''Contracted Travel Services Program,'' 64 FR 20108.

inspection as part of the applicant's or recipient's file within the relevant FCC system.

3. ''*Pay.gov*'' System—To disclose the name and address of individuals to the Department of the Treasury to facilitate the collection of any fees owed to the FCC when an individual chooses to pay online using the Treasury's *Pay.gov* system.

4. Compliance with Welfare Reform Requirements—Names, Social Security Numbers, home addresses, dates of birth, dates of hire, quarterly earnings, employer identifying information, and State of hire of employees may be disclosed to the Office of Child Support Enforcement, Administration for Children and Families, Department of Health and Human Services for the purposes of locating individuals to establish paternity, establishing and modifying orders of child support, identifying sources of income, and for other child support enforcement actions as required by the Personal Responsibility and Work Opportunity Reconciliation Act.

5. Financial Obligations Under the Debt Collection Acts and ''Do Not Pay''—To other Federal agencies (including the Treasury Department, Bureau of Public Debt, and its authorized contractors) for the purpose of collecting and reporting on delinquent debts as authorized by the Debt Collection Improvement Act of 1996, as amended, and to prevent improper payment and to verify payment eligibility using Treasury's ''Do Not Pay'' (DNP) system and effecting payments. Records may also be disclosed to the Treasury Department and its contractors, pursuant to a DNP computer matching agreement between the FCC and Treasury for purposes authorized by 31 U.S.C. 3321, if the matching program requires data from this system of records, and to the Treasury Department and the Department of Justice, and their representatives and contractors, to report the results of debt collection or debt compromise to prepare necessary Federal, State, or local income and tax reporting records and reports (*e.g.,* IRS Form 1099). A record from this system also may be disclosed to any Federal, State, Tribal, or local agency to conduct an authorized computer matching program to identify and locate individuals who are delinquent in their repayment of certain debts owed to the U.S. Government. A record from this system may be used to prepare information on items included, but not limited to, income assessments required for taxation or other purposes to be disclosed to Federal (*i.e.,* IRS), State, and local governments.

6. Financial Obligations as Required by the National Finance Center (USDA), *et al.*—To the National Finance Center (the FCC's authorized payroll office), the Department of the Treasury Debt Management Services, and/or a current employer for financial obligations that include, but are not limited to those that effect a salary, IRS tax refund, tax or other debt liabilities of State, Municipality or other government agencies and entities, or administrative offsets necessary to satisfy an indebtedness; and to Federal agencies to identify and locate former employees for the purposes of collecting such indebtedness, including through administrative, salary, or tax refund offsets. Identifying and locating former employees, and the subsequent referral to such agencies for offset purposes, may be accomplished through authorized computer matching programs, following procedures required by the Debt Collection Act of 1982, the Debt Collection Improvement Act of 1996, and the computer matching provisions of the Privacy Act.

7. Litigation—To disclose records to DOJ when: (a) the FCC or any component thereof; (b) any employee of the FCC in his or her official capacity; (c) any employee of the FCC in his or her individual capacity where the DOJ or the FCC has agreed to represent the employee; or (d) the United States Government is a party to litigation or has an interest in such litigation, and by careful review, the FCC determines that the records are both relevant and necessary to the litigation, and the use of such records by the DOJ is for a purpose that is compatible with the purpose for which the FCC collected the records.

8. Adjudication—To disclose records in a proceeding before a court or adjudicative body, when: (a) the FCC or any component thereof; or (b) any employee of the FCC in his or her official capacity; or (c) any employee of the FCC in his or her individual capacity; or (d) the United States Government, is a party to litigation or has an interest in such litigation, and by careful review, the FCC determines that the records are both relevant and necessary to the litigation, and that the use of such records is for a purpose that is compatible with the purpose for which the agency collected the records.

9. Law Enforcement and Investigation—Where the FCC becomes aware of an indication of a violation or potential violation of civil or criminal law, rule, regulation, or order to disclose pertinent information to appropriate Federal, State, Tribal, local, international, or multinational agencies, or a component of such an agency, responsible for investigating, prosecuting, enforcing, or implementing a statute, rule, regulation, or order.

10. Congressional Inquiries—To provide information to a Congressional office from the record of an individual in response to an inquiry from that Congressional office made at the written request of that individual.

11. Government-wide Program Management and Oversight—To the DOJ to obtain that department's advice regarding disclosure obligations under FOIA; or to OMB to obtain that office's advice regarding obligations under the Privacy Act.

12. Employment, Clearances, Licensing, Contract, Grant, or other Benefits Decisions by the Agency—To a Federal, State, local, foreign, Tribal, or other public agency or authority maintaining civil, criminal, or other relevant enforcement records, or other pertinent records, or to another public authority or professional organization, if necessary to obtain information relevant to an investigation concerning the hiring or retention of an employee or other personnel action, the issuance or retention of a security clearance, the classifying of jobs, the letting of a contract, or the issuance or retention of a license, grant, or other benefit by the requesting agency, to the extent that the information is relevant and necessary to the requesting agency's decisions on the matter.

13. Employment, Clearances, Licensing, Contract, Grant, or other Benefits Decisions by Other than the Agency—To a Federal, State, local, foreign, Tribal, or other public agency or authority of the fact that this system of records contains information relevant to the hiring or retention of an employee, the issuance or retention of a security clearance, the conducting of a suitability or security investigation of an individual, the classifying of jobs, the letting of a contract, or the issuance or retention of a license, grant, or other benefit by the requesting agency, to the extent that the information is relevant and necessary to the agency's decision on the matter. The other agency or licensing organization may then make a request supported by the written consent of the individual for the entire records if it so chooses. No disclosure will be made unless the information has been determined to be sufficiently reliable to support a referral to another office within the agency or to another Federal agency for criminal, civil, administrative, personnel, or regulatory action.

14. Labor Relations—To officials of labor organizations recognized under 5 U.S.C. Chapter 71 upon receipt of a formal request and in accord with the conditions of 5 U.S.C. 7114 when relevant and necessary to their duties of exclusive representation concerning personnel policies, practices, and matters affecting working conditions.

15. Federal Labor Relations Authority—To disclose information to the Federal Labor Relations Authority when requested in connection with investigations of allegations of unfair labor practices or matters before the Federal Service Impasses Panel (FSIP).

16. Merit Systems Protection Board—To disclose information to officials of the Merit Systems Protection Board or the Office of the Special Counsel, when requested in connection with appeals, special studies of the civil service and other merit systems, review of the FCC rules and regulations, investigations of alleged or possible prohibited personnel practices, and such other functions, *e.g.,* as promulgated in 5 U.S.C. 1205 and 1206, or as may be authorized by law.

17. Equal Employment Opportunity Commission (EEOC)—To disclose information to the EEOC when requested in connection with investigations into alleged or possible discrimination practices in the Federal sector, compliance by Federal agencies with the Uniform Guidelines on Employee Selection Procedures or other functions vested in the Commission and to otherwise ensure compliance with the provisions of 5 U.S.C. 7201.

18. Statistical/Analytical Studies—To provide to Congress and OMB summary descriptive statistics and analytical studies in support of the financial and budgetary functions for which the records are collected and maintained, or for related FCC studies and reports. While published studies do not contain individual identifiers, in some instances the selection of elements of data included in the study may be structured in such a way as to make the data individually identifiable by inference.

19. Breach Notification—To appropriate agencies, entities, and persons when: (a) the Commission suspects or has confirmed that there has been a breach of the system of records; (b) the Commission has determined that as a result of the suspected or confirmed compromise there is a risk of harm to individuals, the Commission (including its information systems, programs, and operations), the Federal Government, or national security; and (c) the disclosure made to such agencies, entities, and persons is reasonably necessary to assist in connection with the Commission's efforts to respond to the suspected or confirmed breach or to prevent, minimize, or remedy such harm.

20. Assistance to Federal Agencies and Entities Related to Breaches—To another Federal agency or Federal entity, when the Commission determines that information from this system is reasonably necessary to assist the recipient agency or entity in: (a) responding to a suspected or confirmed breach or (b) preventing, minimizing, or remedying the risk of harm to individuals, the recipient agency or entity (including its information systems, program, and operations), the Federal Government, or national security, resulting from a suspected or confirmed breach.

21. Non-Federal Personnel—To disclose information to non-Federal personnel, including contractors, other vendors (*e.g.,* identity verification services), grantees, and volunteers who have been engaged to assist the FCC in the performance of a contract, service, grant, cooperative agreement, or other activity related to this system of records and who need to have access to the records in order to perform their activity.

POLICIES AND PRACTICES FOR STORAGE OF RECORDS:

Information in this system is maintained as follows:

1. The electronic data, records, and files reside on the FCC's network or on an FCC vendor's network;

2. The DOJ maintains the Drug Debarment data at its facilities and transfers the Drug Debarment data files to the FCC under the terms of the matching agreement. These files are immediately discarded by the FCC after being loaded into the secure database on the FCC's computer network; and

3. Paper documents, including printouts and other related materials, records, and files are stored in the FO office suite and at a FCC authorized contractors.

POLICIES AND PRACTICES FOR RETRIEVAL OF RECORDS:

1. Records in the financial and budgetary (electronic and paper) system of records can be retrieved by category field, *e.g.,* the individual's name(s), the type of transaction, call sign, processing number, SSN, ITIN, FRN, vendor code, fee control number, payment ID number, and/or sequential number.

2. Records in the DOJ Drug Debarment (electronic) system of records are retrieved and matched between CORES and that database (primarily using name and ITIN or name and zip code or additional data elements but also by address, date of birth, or other data elements obtained from the DOJ Drug Debarment database).

POLICIES AND PRACTICES FOR RETENTION AND DISPOSAL OF RECORDS:

The information in this system is maintained and disposed of in accordance with the National Archives and Records Administration (NARA) Records Schedule N1–173–00–001, Commission Registration System (CORES).

ADMINISTRATIVE, TECHNICAL, AND PHYSICAL SAFEGUARDS:

The electronic records, files, and data are stored within FCC or a vendor's accreditation boundaries and maintained in a database housed in the FCC's or vendor's computer network databases. Access to the electronic files is restricted to authorized employees and contractors; and to IT staff, contractors, and vendors who maintain the IT networks and services. Other employees and contractors may be granted access on a need-to-know basis. The electronic files and records are protected by the FCC and third-party privacy safeguards, a comprehensive and dynamic set of IT safety and security protocols and features that are designed to meet all Federal privacy standards, including those required by the Federal Information Security Modernization Act of 2014 (FISMA), OMB, and the National Institute of Standards and Technology (NIST). Paper records (generally only Form 1876 and occasional print-outs, as needed) are stored in secured cabinets in the Financial Office.

RECORD ACCESS PROCEDURES:

Individuals wishing to request an amendment of records about them should follow the Notification Procedures below.

CONTESTING RECORD PROCEDURES:

Individuals wishing to contest information pertaining to him or her in the system of records should follow the Notification Procedures below.

NOTIFICATION PROCEDURES:

Individuals wishing to determine whether this system of records contains information about themselves may do so by writing to *privacy@fcc.gov.* Individuals requesting record access or amendment must also comply with the FCC's Privacy Act regulations regarding verification of identity as required under 47 CFR part 0, subpart E.

EXEMPTIONS PROMULGATED FOR THE SYSTEM:

None.

HISTORY:

81 FR 69522 (October 6, 2016).

Federal Communications Commission.

Marlene Dortch,

Secretary.

[FR Doc. 2023–25805 Filed 11–21–23; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL COMMUNICATIONS COMMISSION

[OMB 3060–0120; FR ID 185887]

Information Collection Being Reviewed by the Federal Communications Commission

AGENCY: Federal Communications Commission.

ACTION: Notice and request for comments.

SUMMARY: As part of its continuing effort to reduce paperwork burdens, and as required by the Paperwork Reduction Act of 1995 (PRA), the Federal Communications Commission (FCC or Commission) invites the general public and other Federal agencies to take this opportunity to comment on the following information collections. Comments are requested concerning: whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; the accuracy of the Commission's burden estimate; ways to enhance the quality, utility, and clarity of the information collected; ways to minimize the burden of the collection of information on the respondents, including the use of automated collection techniques or other forms of information technology; and ways to further reduce the information collection burden on small business concerns with fewer than 25 employees. The FCC may not conduct or sponsor a collection of information unless it displays a currently valid Office of Management and Budget (OMB) control number. No person shall be subject to any penalty for failing to comply with a collection of information subject to the PRA that does not display a valid OMB control number.

DATES: Written PRA comments should be submitted on or before January 22, 2024. If you anticipate that you will be submitting comments but find it difficult to do so within the period of time allowed by this notice, you should advise the contact listed below as soon as possible.

ADDRESSES: Direct all PRA comments to Cathy Williams, FCC, via email to *PRA@fcc.gov* and to *Cathy.Williams@fcc.gov.*

FOR FURTHER INFORMATION CONTACT: For additional information about the information collection, contact Cathy Williams at (202) 418–2918.

SUPPLEMENTARY INFORMATION:

OMB Control Number: 3060–0120.

Title: Broadcast EEO Model Program Report, FCC Form 396–A.

Form Number: FCC–396–A.

Type of Review: Extension of a currently approved collection.

Respondents: Business or other for-profit entities, not-for-profit institutions.

Number of Respondents and Responses: 5,000 respondents, 5,000 responses.

Estimated Time per Response: 1 hour.

Frequency of Response: On occasion reporting requirement.

Obligation to Respond: Required to obtain benefits. The statutory authority for this collection of information is contained in section 154(i) and 303 of the Communications Act of 1934, as amended.

Total Annual Burden: 5,000 hours.

Total Annual Cost: No cost.

Needs and Uses: The Broadcast Equal Employment Opportunity (EEO) Model Program Report, FCC Form 396–A, is filed in conjunction with applicants seeking authority to: construct a new broadcast station; to obtain assignment of construction permit or license; and/or seeking authority to acquire control of an entity holding a construction permit or license. This program report is designed to assist the applicant in establishing an effective EEO program for its stations.

Federal Communications Commission.

Marlene Dortch,

Secretary, Office of the Secretary.

[FR Doc. 2023–25804 Filed 11–21–23; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL COMMUNICATIONS COMMISSION

[OMB 3060–XXXX; FR ID 186010]

Information Collection Being Submitted for Review and Approval to Office of Management and Budget

AGENCY: Federal Communications Commission.

ACTION: Notice and request for comments.

SUMMARY: As part of its continuing effort to reduce paperwork burdens, as required by the Paperwork Reduction Act (PRA) of 1995, the Federal Communications Commission (FCC or the Commission) invites the general public and other Federal Agencies to take this opportunity to comment on the following information collection. Pursuant to the Small Business Paperwork Relief Act of 2002, the FCC seeks specific comment on how it might ''further reduce the information collection burden for small business concerns with fewer than 25 employees.'' The Commission may not conduct or sponsor a collection of information unless it displays a currently valid Office of Management and Budget (OMB) control number. No person shall be subject to any penalty for failing to comply with a collection of information subject to the PRA that does not display a valid OMB control number.

DATES: Written comments and recommendations for the proposed information collection should be submitted on or before December 22, 2023.

ADDRESSES: Comments should be sent 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. Your comment must be submitted into *www.reginfo.gov* per the above instructions for it to be considered. In addition to submitting in *www.reginfo.gov* also send a copy of your comment on the proposed information collection to Nicole Ongele, FCC, via email to *PRA@fcc.gov* and to *Nicole.Ongele@fcc.gov.* Include in the comments the OMB control number as shown in the **SUPPLEMENTARY INFORMATION** below.

FOR FURTHER INFORMATION CONTACT: For additional information or copies of the information collection, contact Nicole Ongele at (202) 418–2991. To view a copy of this information collection request (ICR) submitted to OMB: (1) go to the web page *http://www.reginfo.gov/public/do/PRAMain,* (2) look for the section of the web page called ''Currently Under Review,'' (3) click on the downward-pointing arrow in the ''Select Agency'' box below the ''Currently Under Review'' heading, (4) select ''Federal Communications Commission'' from the list of agencies presented in the ''Select Agency'' box, (5) click the ''Submit'' button to the right of the ''Select Agency'' box, (6) when the list of FCC ICRs currently under review appears, look for the Title of this ICR and then click on the ICR Reference Number. A copy of the FCC submission to OMB will be displayed.

SUPPLEMENTARY INFORMATION: As part of its continuing effort to reduce paperwork burdens, as required by the Paperwork Reduction Act (PRA) of 1995

(44 U.S.C. 3501–3520), the FCC invited the general public and other Federal Agencies to take this opportunity to comment on the following information collection. Comments are requested concerning: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; (b) the accuracy of the Commission's burden estimates; (c) ways to enhance the quality, utility, and clarity of the information collected; and (d) ways to minimize the burden of the collection of information on the respondents, including the use of automated collection techniques or other forms of information technology. Pursuant to the Small Business Paperwork Relief Act of 2002, Public Law 107–198, see 44 U.S.C. 3506(c)(4), the FCC seeks specific comment on how it might ''further reduce the information collection burden for small business concerns with fewer than 25 employees.''

OMB Control Number: 3060–XXXX.

Title: Enhanced A–CAM Cybersecurity and Supply Chain Risk Management Plan Requirements.

Form Number: N/A.

Type of Review: New information collection.

Respondents: Business or other for-profit entities and State, local or Tribal governments.

Number of Respondents and Responses: 450 respondents; 900 responses.

Estimated Time per Response: 10–50 hours.

Frequency of Response: One-time and on occasion reporting requirements.

Obligation to Respond: Required to obtain or retain benefits. Statutory authority for this information collection is contained in 47 U.S.C. 154(i), 214, 218–220, 254, 303(r), and 403.

Total Annual Burden: 27,000 hours.

Total Annual Cost: No cost.

Needs and Uses: On July 24, 2023, the Commission released the *Enhanced A–CAM Order* (Order), 88 FR 55918, August 17, 2023, WC Docket No. 10–90 et al., FCC 23–60, which adopted a voluntary path for supporting the widespread deployment of 100/20 Mbps broadband service throughout the rural areas served by carriers currently receiving Alternative Connect America Cost Model (A–CAM) support and in areas served by rate-of-return carriers eligible to receive legacy support by the end of 2028. The Commission extended by 10 years beyond the remaining five years, for a total of 15 years, the term of support for electing carriers and set a methodology for determining support amounts for locations without 100/20 Mbps broadband service within a potential budget of no more than $1.27 billion annually, or no more than $1.33 billion annually if certain conditions are met, using an updated version of the A–CAM. By adopting this program, the Commission furthered its long-standing goals by promoting the universal availability of voice and broadband networks, while also taking measures to minimize the burden on the nation's ratepayers. The Commission also adopted requirements for the Enhanced A–CAM program to complement existing Federal, State, and local funding programs, so that broadband funding can be used efficiently to maximize the deployment of high-quality broadband service across the United States.

To ensure that the Enhanced A–CAM program does not deprive rural consumers in high-cost areas of broadband service that is as secure as the service deployed pursuant to other Federal funding initiatives, the Commission required Enhanced A–CAM carriers to implement operational cybersecurity and supply chain risk management plans by January 1, 2024—the start of the Enhanced A–CAM support term. Enhanced A–CAM carriers must submit such plans to the Universal Service Administrative Company (USAC) and certify they have done so, by January 2, 2024 or within 30 days of approval under the Paperwork Reduction Act, whichever is later. Failure to submit the plans and make the certification shall result in 25% of monthly support being withheld until the carrier comes into compliance. If a carrier makes a substantive modification to its cybersecurity or supply chain risk management plan, the Commission requires that the carrier submit its updated plan to USAC within 30 days of making that modification.

The purpose of this information collection is to collect the operational cybersecurity and supply chain risk management plans required of the Enhanced A–CAM carriers by the start of the Enhanced A–CAM support term and address the burdens associated with that requirement.

Federal Communications Commission.

Marlene Dortch,

Secretary, Office of the Secretary.

[FR Doc. 2023–25806 Filed 11–21–23; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL DEPOSIT INSURANCE CORPORATION

Designated Reserve Ratio for 2024

AGENCY: Federal Deposit Insurance Corporation.

ACTION: Notice of Designated Reserve Ratio for 2024.

SUMMARY: Pursuant to the Federal Deposit Insurance Act (FDI Act), the Board of Directors (Board) of the Federal Deposit Insurance Corporation (FDIC) designates that the Designated Reserve Ratio (DRR) for the Deposit Insurance Fund shall remain at 2 percent for 2024. The Board is publishing this notice as required by the FDI Act.

FOR FURTHER INFORMATION CONTACT: Ashley Mihalik, Associate Director, Financial Risk Management, Division of Insurance and Research, 202–898–3793, *amihalik@fdic.gov*; Daniel Hoople, Chief, Fund Analysis and Pricing Section, Division of Insurance and Research, 202–898–3835, *dhoople@fdic.gov*; or Kathryn Marks, Counsel, Legal Division, 202–898–3896, *kmarks@fdic.gov*.

SUPPLEMENTARY INFORMATION: Pursuant to the FDI Act, the Board designates that the DRR for the Deposit Insurance Fund shall remain at 2 percent for 2024. The Board is publishing this notice as required by section 7(b)(3)(A)(i) of the FDI Act (12 U.S.C. 1817(b)(3)(A)(i)). There is no need to amend 12 CFR 327.4(g), the section of the FDIC's regulations which sets forth the DRR, because the DRR for 2024 is the same as the current DRR.

Federal Deposit Insurance Corporation.

By order of the Board of Directors.

Dated at Washington, DC, on November 16, 2023.

James P. Sheesley,

Assistant Executive Secretary.

[FR Doc. 2023–25814 Filed 11–21–23; 8:45 am]

BILLING CODE 6714–01–P

FEDERAL MARITIME COMMISSION

Notice of Agreements Filed

The Commission hereby gives notice of filing of the following agreements under the Shipping Act of 1984. Interested parties may submit comments, relevant information, or documents regarding the agreements to the Secretary by email at *Secretary@fmc.gov,* or by mail, Federal Maritime Commission, 800 North Capitol Street, Washington, DC 20573. Comments will be most helpful to the Commission if received within 12 days of the date this

notice appears in the **Federal Register**, and the Commission requests that comments be submitted within 7 days on agreements that request expedited review. Copies of agreements are available through the Commission's website (*www.fmc.gov*) or by contacting the Office of Agreements at (202) 523–5793 or *tradeanalysis@fmc.gov.*

Agreement No.: 201307–001.

Agreement Name: Crowley/Sealand Space Charter Agreement.

Parties: Crowley Latin America Services, LLC; Maersk A/S DBA Sealand.

Filing Party: Wayne Rohde; Cozen O'Connor.

Synopsis: The amendment deletes Haiti from the geographic scope of the agreement and adjusts the amount of space being chartered.

Proposed Effective Date: 11/16/2023.

Location: https://www2.fmc.gov/FMC.Agreements.Web/Public/AgreementHistory/22408.

Dated: November 17, 2023.

Carl Savoy,

Federal Register Alternate Liaison Officer.

[FR Doc. 2023–25815 Filed 11–21–23; 8:45 am]

BILLING CODE 6730–02–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS–10418]

Agency Information Collection Activities: Submission for OMB Review; Comment Request

AGENCY: Centers for Medicare & Medicaid Services, Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: The Centers for Medicare & Medicaid Services (CMS) is announcing an opportunity for the public to comment on CMS' intention to collect information from the public. Under the Paperwork Reduction Act of 1995 (the PRA), federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information (including each proposed extension or reinstatement of an existing collection of information) and to allow a second opportunity for public comment on the notice. Interested persons are invited to send comments regarding our burden estimates or any other aspect of this collection of information, including any of the following subjects: the necessity and utility of the proposed information collection for the proper performance of the agency's functions; the accuracy of the estimated burden; ways to enhance the quality, utility, and clarity of the information to be collected; and the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

DATES: Comments must be received by the OMB desk officer by December 22, 2023.

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

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, please access the CMS PRA website by copying and pasting the following web address into your web browser: *https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing.*

FOR FURTHER INFORMATION CONTACT: William Parham at (410) 786–4669.

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3520), federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. The term ''collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA requires federal agencies to publish a 30-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, CMS is publishing this notice that summarizes the following proposed collection(s) of information for public comment:

1. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Annual MLR and Rebate Calculation Report and MLR Rebate Notices; *Use:* Under section 2718 of the Affordable Care Act and implementing regulation at 45 CFR part 158, a health insurance issuer (issuer) offering group or individual health insurance coverage must submit a report to the Secretary concerning the amount the issuer spends each year on claims, quality improvement expenses, non-claims costs, Federal and State taxes and licensing and regulatory fees, the amount of earned premium, and beginning with the 2014 reporting year, the amounts related to the transitional reinsurance and risk adjustment programs established under sections 1341 and 1343, respectively, of the Affordable Care Act. An issuer must provide an annual rebate if the amount it spends on certain costs compared to its premium revenue (excluding Federal and States taxes and licensing and regulatory fees) does not meet a certain ratio, referred to as the medical loss ratio (MLR). Each issuer is required to submit annually MLR data, including information about any rebates it must provide, on a form prescribed by CMS, for each State in which the issuer conducts business. Each issuer is also required to provide a rebate notice to each policyholder that is owed a rebate and each subscriber of policyholders that are owed a rebate for any given MLR reporting year. Additionally, each issuer is required to maintain for a period of seven years all documents, records and other evidence that support the data included in each issuer's annual report to the Secretary.

Based upon CMS' experience in the MLR data collection and evaluation process, CMS is updating its annual burden hour estimates to reflect the actual numbers of submissions, rebates and rebate notices.

The 2022 MLR Reporting Form and Instructions reflect changes for the 2020 reporting year and beyond. For 2022, it is expected that issuers will submit fewer reports and on average, send fewer notices and rebate checks in the mail to policyholders and subscribers, which will reduce burden on issuers. *Form Number:* CMS–10418 (OMB control number: 0938–1164); *Frequency:* Annually; *Affected Public:* Private Sector, Business or other for-profit and not-for-profit institutions; *Number of Respondents:* 480; *Number of Responses:* 1,677; *Total Annual Hours:* 170,091. For policy questions regarding this collection contact Jiyun Lim at 667–290–9650.

Dated: November 17, 2023.

William N. Parham, III,

Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2023–25861 Filed 11–21–23; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–P–4223]

Determination That BUPRENEX (Buprenorphine Hydrochloride) Injection, 0.3 Milligram/Milliliter, Was Not Withdrawn From Sale for Reasons of Safety or Effectiveness

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) has determined that BUPRENEX (buprenorphine hydrochloride) Injection, 0.3 milligram (mg)/milliliter (mL), was not withdrawn from sale for reasons of safety or effectiveness. This determination means that FDA will not begin procedures to withdraw approval of abbreviated new drug applications (ANDAs) that refer to this drug product, and it will allow FDA to continue to approve ANDAs that refer to the product as long as they meet relevant legal and regulatory requirements.

FOR FURTHER INFORMATION CONTACT: Caitlin Callahan, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6269, Silver Spring, MD 20993–0002, 301–796–3600, *Caitlin.Callahan@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Section 505(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355(j)) allows the submission of an ANDA to market a generic version of a previously approved drug product. To obtain approval, the ANDA applicant must show, among other things, that the generic drug product: (1) has the same active ingredient(s), dosage form, route of administration, strength, conditions of use, and (with certain exceptions) labeling as the listed drug, which is a version of the drug that was previously approved and (2) is bioequivalent to the listed drug. ANDA applicants do not have to repeat the extensive clinical testing otherwise necessary to gain approval of a new drug application (NDA).

Section 505(j)(7) of the FD&C Act requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the ''Approved Drug Products With Therapeutic Equivalence Evaluations,'' which is known generally as the ''Orange Book.'' Under FDA regulations, drugs are removed from the list if the Agency withdraws or suspends approval of the drug's NDA or ANDA for reasons of safety or effectiveness or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).

A person may petition the Agency to determine, or the Agency may determine on its own initiative, whether a listed drug was withdrawn from sale for reasons of safety or effectiveness. This determination may be made at any time after the drug has been withdrawn from sale, but must be made prior to approving an ANDA that refers to the listed drug (§ 314.161 (21 CFR 314.161)). FDA may not approve an ANDA that does not refer to a listed drug.

BUPRENEX (buprenorphine hydrochloride) Injection, 0.3 mg/mL, is the subject of NDA 018401, held by Indivior, Inc., and initially approved on December 29, 1981. BUPRENEX is indicated for the management of pain severe enough to require an opioid analgesic and for which alternate treatments are inadequate.

BUPRENEX (buprenorphine hydrochloride) Injection, 0.3 mg/mL, is currently listed in the ''Discontinued Drug Product List'' section of the Orange Book. Odin Pharmaceuticals LLC submitted a citizen petition dated September 27, 2023 (Docket No. FDA–2023–P–4223), under 21 CFR 10.30, requesting that the Agency determine whether BUPRENEX (buprenorphine hydrochloride) Injection, 0.3 mg/mL, was withdrawn from sale for reasons of safety or effectiveness.

After considering the citizen petition and reviewing Agency records and based on the information we have at this time, FDA has determined under § 314.161 that BUPRENEX (buprenorphine hydrochloride) Injection, 0.3 mg/mL, was not withdrawn for reasons of safety or effectiveness. The petitioner has identified no data or other information suggesting that this drug product was withdrawn for reasons of safety or effectiveness. We have carefully reviewed our files for records concerning the withdrawal of BUPRENEX (buprenorphine hydrochloride) Injection, 0.3 mg/mL, from sale. We have also independently evaluated relevant literature and data for possible postmarketing adverse events. We have found no information that would indicate that this drug product was withdrawn from sale for reasons of safety or effectiveness.

Accordingly, the Agency will continue to list BUPRENEX (buprenorphine hydrochloride) Injection, 0.3 mg/mL, in the ''Discontinued Drug Product List'' section of the Orange Book. The ''Discontinued Drug Product List'' delineates, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness. FDA will not begin procedures to withdraw approval of approved ANDAs that refer to this drug product. Additional ANDAs for this drug product may also be approved by the Agency as long as they meet all other legal and regulatory requirements for the approval of ANDAs. If FDA determines that labeling for this drug product should be revised to meet current standards, the Agency will advise ANDA applicants to submit such labeling.

Dated: November 17, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–25857 Filed 11–21–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–D–4719]

Translation of Good Laboratory Practice Study Reports: Questions and Answers; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry entitled ''Translation of GLP Study Reports: Questions and Answers.'' This guidance provides information to sponsors and nonclinical laboratories regarding the translation of study reports for studies conducted in compliance with good laboratory practice (GLP) regulations. GLP studies are nonclinical safety studies that include, but are not limited to nonclinical toxicology studies, safety pharmacology studies, and device safety studies. When study reports of GLP studies are translated from the original language into English, adequate documentation is critical to ensure

accurate and complete study data are submitted to FDA. This question-and-answer document is intended to clarify FDA's recommendations concerning the translation of GLP study reports from a non-English language into English for nonclinical studies conducted in compliance with GLP regulations.

DATES: Submit either electronic or written comments on the draft guidance by February 20, 2024 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2023–D–4719 for ''Translation of GLP Study Reports: Questions and Answers.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002; or to the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Tahseen Mirza, Center for Drug Evaluation and Research, Office of Study Integrity and Surveillance, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 2211, Silver Spring, MD 20993, 301–796–7645; Anne Taylor, Office of the Center Director, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993, 240–402–7911; Judith Davis, Office of Device Evaluation, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 1216, Silver Spring, MD 20993, 301–796–6636; Tong Zhou, Center for Veterinary Medicine, Office of New Animal Drug Evaluation, HFV–153, Food and Drug Administration, 7500 Standish Place, Rockville, MD, 20855, 240–402–0826; Yuguang Wang, Center for Food Safety and Applied Nutrition, Office of the Center Director, Food and Drug Administration, 5001 Campus Dr., Rm. 4A035, College Park, MD, 20740, 240-402–1757; Hans Rosenfeldt, Center for Tobacco Products, Office of Science, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. G335, Silver Spring, MD 20993, 301–796–1327; Darby Hull, Office of Regulatory Affairs, Food and Drug Administration, 12420 Parklawn Dr., Element Building, Rockville, MD 20857, 301–796–5949.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Translation of GLP Study Reports: Questions and Answers.'' Nonclinical laboratory studies conducted in compliance with GLP regulations (21 CFR part 58) are being conducted by testing facilities located in foreign countries. In instances where the GLP study report is generated in a non-English language, the study report is often translated into English for submission to FDA. When translating a study report into English from a study conducted in compliance with GLP regulations, the translation should be clear, accurate, complete, and follow written processes and procedures. The sponsor should ensure that the

translated report is an accurate representation of the original GLP study report.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on ''Translation of GLP Study Reports: Questions and Answers.'' It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

While this guidance contains no collection of information, it does refer to previously approved FDA collections of information. The previously approved collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501–3521). The collections of information in 21 CFR part 58 for good laboratory practice for nonclinical laboratory studies have been approved under OMB control number 0910–0119.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at *https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs, https://www.regulations.gov,* or *https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances.*

Dated: November 17, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–25859 Filed 11–21–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–N–4996]

Advancing Drug Development for the Prevention of Spontaneous Preterm Birth; Public Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is announcing the following public meeting entitled ''Advancing Drug Development for the Prevention of Spontaneous Preterm Birth.'' The meeting will be convened by Duke University's Robert J. Margolis, MD, Center for Health Policy (Duke-Margolis) and supported by a cooperative agreement with FDA. The meeting is intended to gather industry, family, clinician, researcher, ethicist, professional society, and other stakeholder input on the impact of preterm birth on families and on society, as well as on the ethical, regulatory, and clinical trial considerations surrounding the drug development for the prevention of spontaneous preterm birth.

DATES: The public meeting will be held on January 23 and 24, 2024, from 1 p.m. to 4:30 p.m. Eastern Time each day. See the **SUPPLEMENTARY INFORMATION** section for registration information.

ADDRESSES: The public meeting will be held virtually via Zoom.

FOR FURTHER INFORMATION CONTACT: Luke Durocher, Duke-Margolis Center for Health Policy, *margolisevents@duke.edu,* 202–621–2800; or Christina Chang, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993, 301–796–2078.

SUPPLEMENTARY INFORMATION:

I. Background Information

In the United States in 2021, 1 in every 10 infants was born prematurely (before 37 weeks of pregnancy). Infants born too early have higher rates of death and disability, resulting in a significant public health concern. The exact mechanisms and risk factors associated with spontaneous preterm birth are not fully understood, resulting in a dearth of interventions demonstrated to be effective and safe.

FDA endorses an informed and balanced approach to gathering data supporting the safe and effective use of drugs and biological products for the prevention of spontaneous preterm birth. Currently, there is a significant medical need for such therapies, as there are no FDA approved therapies for reducing the risk of neonatal morbidity/mortality resulting from spontaneous preterm birth. Input from this meeting will help provide guidance on the development of therapies for the prevention of spontaneous preterm birth.

II. Topics for Discussion at the Public Meeting

The meeting will allow participants (including clinicians, patients, family, researchers, ethicists, professional societies, and other stakeholders) to provide input on key topics, including:

- The current understanding of spontaneous preterm birth, including the epidemiology of the condition, etiologies, and pathophysiology
- Ethical and regulatory considerations and challenges associated with the development of therapeutics for the prevention of spontaneous preterm birth
- Impact of preterm birth on families and society
- Assessing efficacy and safety in clinical programs for therapeutics for spontaneous preterm birth prevention
- Dose-finding and clinical trial design considerations

For more information on the meeting topics and discussion questions, visit *https://duke.is/g/gde6.* Duke-Margolis will publish a discussion guide outlining background information and current thinking on the topic areas to this website approximately 2 weeks before the meeting date. FDA will also post the agenda and other meeting materials to this website approximately 5 business days before the meeting.

The format of the public meeting will consist of a series of presentations, panel discussions, and open discussion.

III. Participating in the Public Meeting

Registration: To register for the virtual public meeting, please visit the following website: *https://duke.is/g/gde6.* Please provide complete contact information for each attendee, including name, title, affiliation, address, email, and telephone.

Registration is free. Persons interested in attending this virtual public meeting must register. Early registration is recommended. Registrants will receive confirmation once they have been accepted. If you need special accommodations due to a disability, please contact Luke Durocher, Duke-Margolis Center for Health Policy, at *margolisevents@duke.edu* or at 202–621–2800.

Streaming Webcast of the Public Meeting: This virtual public meeting will be webcast via Zoom and the archived video footage will be available at the event website. The link for registration is the same as above: *https://duke.is/g/gde6.* Registered webcast participants will be sent technical system requirements in advance of the event. It is recommended that you review these technical system requirements prior to joining the streaming webcast of the public meeting. Although FDA has verified the website addresses in this document, please note that websites are subject to change over time.

Transcripts: Please be advised that transcripts of the public meeting will not be available.

Dated: November 16, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–25816 Filed 11–21–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–N–4965]

Advancing the Use of Complex Innovative Designs in Clinical Trials: From Pilot to Practice; Public Workshop; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop; request for comments.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is announcing the following public workshop entitled ''Advancing the Use of Complex Innovative Designs in Clinical Trials: From Pilot to Practice.'' The purpose of the public workshop is to discuss aspects of complex adaptive, Bayesian, and other novel clinical trial designs. This workshop is being conducted to meet the performance goal of convening a public workshop on complex innovative design (CID) included in the seventh authorization of the Prescription Drug User Fee Act (PDUFA VII). The workshop may also inform a draft guidance on the use of Bayesian methodology in clinical trials of drugs and biological products. In conjunction with the workshop, FDA is seeking comments on the use of CID to inform regulatory decision making, including high-level case examples of CIDs and approaches that can advance the use of these designs. The public workshop will be held on March 5, 2024, from 9 a.m. to 3:30 p.m. Eastern Time.

DATES: Either electronic or written comments on this public workshop must be submitted by April 5, 2024. See the **SUPPLEMENTARY INFORMATION** section for registration date and information.

ADDRESSES: The public workshop will be held at the FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room, Silver Spring, MD 20993–0002. Entrance for the public workshop participants (non-FDA employees) is through Building 1 where routine security check procedures will be performed. For parking and security information, please refer to *https://www.fda.gov/about-fda/visitor-information.* The public workshop will use an online platform for the webcast.

You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of April 5, 2024. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2023–N–4965 for ''Advancing the Use of Complex Innovative Designs in Clinical Trials: From Pilot to Practice; Public Workshop; Request for Comments.'' Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

FOR FURTHER INFORMATION CONTACT: Tuan Pham, Food and Drug Administration, Center for Drug Evaluation and Research, 10903 New Hampshire Ave., Bldg. 21, Rm. 3670, Silver Spring, MD 20993–0002, 301–348–1595, *CID.Meetings@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

This public workshop is intended to meet a performance goal FDA agreed to under the FDA User Fee Reauthorization Act of 2022, in accordance with the PDUFA Reauthorization Performance Goals and Procedures Fiscal Years 2023 Through 2027 letter (PDUFA VII letter), which is available at *https://www.fda.gov/media/151712/download.* Specifically, section I.4.e of the PDUFA VII letter outlines goals to enhance FDA's capacity to review complex innovative designs and convene a public workshop to discuss aspects of complex adaptive, Bayesian, and other novel clinical trial designs.

II. Topics for Discussion at the Public Workshop

The purpose of this public workshop is to facilitate discussion on the use of external data sources, Bayesian statistical methods, and simulations in complex innovative trial designs as well as trial implementation (*e.g.,* examples of defining and mitigating bias when using select trial design methods). Discussion topics will include considerations for external data sources, Bayesian statistical methods, simulations, and clinical trial implementation and will be based on FDA accumulated experience both within and outside of the Complex Innovative Trial Design Meeting Program (*https://www.fda.gov/drugs/development-resources/complex-innovative-trial-design-meeting-program*).

The workshop will consist of two sessions. The first session will focus on case studies that will illustrate various aspects of complex innovative designs and implementation. The second session will consist of panel discussions motivated by the case studies. There will be an opportunity for public comment.

Workshop updates, agenda, and background materials (if any) will be made available at *https://www.fda.gov/news-events/advancing-use-complex-innovative-designs-clinical-trials-pilot-practice-03052024* prior to the workshop.

III. Participating in the Public Workshop

Registration: To register for the public workshop, please visit *https://ComplexInnovativeDesignsWorkshop.eventbrite.com* by February 27, 2024, 11:59 p.m. Eastern Time. Registration will be available starting January 16, 2024. Please provide complete contact information for each attendee, including name, affiliation, and email. If you are unable to attend the workshop in person, you can register to view a live webcast of the workshop. You will be asked to indicate in your registration if you plan to attend in person or via the webcast.

Registration is free and based on space availability, with priority given to early registrants. Persons interested in attending this public workshop must register by February 27, 2024, 11:59 p.m. Eastern Time. Early registration is recommended because onsite seating is limited; therefore, FDA may limit the number of in-person participants from each organization. Registrants will receive a confirmation email after they register.

If you need special accommodations due to a disability, please contact Tuan Pham (see **FOR FURTHER INFORMATION CONTACT**) at least 14 days before the workshop.

Streaming Webcast of the Public Workshop: This public workshop will also be available on webcast. To register for the webcast of this public workshop, visit *https://ComplexInnovativeDesignsWorkshop.eventbrite.com* by February 27, 2024, 11:59 p.m. Eastern Time. Please provide complete contact information for each attendee, including name, affiliation, and email. A link to the webcast will be provided following registration. Although FDA verified the website addresses in this document, please note that websites are subject to change over time.

Transcripts: Please be advised that as soon as a transcript of the public workshop is available, it will be accessible at *https://www.regulations.gov.* It may be viewed at the Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. A link to the transcript will also be available on the internet at *https://www.fda.gov/news-events/advancing-use-complex-innovative-designs-clinical-trials-pilot-practice-03052024.*

Dated: November 17, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–25854 Filed 11–21–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Biomedical Imaging and Bioengineering; Notice of Closed Meeting

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting of the National Institute of Biomedical Imaging and Bioengineering Special Emphasis Panel.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Biomedical Imaging and Bioengineering Special Emphasis Panel; Brain Initiative RFA (EB–22–003) Review SEP.

Date: February 2, 2024.

Time: 10:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Democracy II, Suite 920, 6707 Democracy Blvd., Bethesda, MD 20817 (Virtual Meeting).

Contact Person: Yoon-Young Jang, M.D., Ph.D., Scientific Review Officer, National Institute of Biomedical Imaging and Bioengineering, National Institutes of Health, 6707 Democracy Blvd., Bethesda, MD 20892, (301) 451–3397, *yoon-young.jang@nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.866, National Institute of Biomedical Imaging and Bioengineering, National Institutes of Health.)

Dated: November 16, 2023.

Patricia B. Hansberger,

Deputy Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2023–25847 Filed 11–21–23; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HOMELAND SECURITY

[Docket No. DHS–2023–0041]

Establishment of Homeland Security Academic Partnership Council Subcommittees

AGENCY: The Office of Partnership and Engagement (OPE), The Department of Homeland Security (DHS).

ACTION: Notice of new taskings for the Homeland Security Academic Partnership Council (HSAPC).

SUMMARY: On November 14, 2023, the Secretary of DHS, Alejandro N. Mayorkas, issued three memoranda tasking the Homeland Security Academic Partnership Council (HSAPC) to establish three subcommittees further outlined below. This notice is not a solicitation for membership.

FOR FURTHER INFORMATION CONTACT: Zarinah ''Traci'' Silas, Executive Director of the Office of Academic Engagement and Designated Federal Officer, Homeland Security Academic Partnership Council, Department of Homeland Security at *HSAPC@hq.dhs.gov* or 202–891–2876.

SUPPLEMENTARY INFORMATION: The HSAPC provides organizationally independent, strategic, timely, specific, and actionable recommendations to the Secretary on key issues at the intersection of education, academia, and the DHS mission.

The Secretary has requested that the HSAPC form new subcommittees to study and provide recommendations in three critical areas for the Department:

1. Supporting K–12 school and higher education communities in fostering safety and inclusivity in schools and on campuses and supporting campus law enforcement professionals and others charged with keeping academic communities safe.

2. Combatting online child sexual exploitation and abuse (CSEA), including development of guidelines and best practices for educators and academic institutions to understand and reduce the risk of CSEA; establish processes and protocols to detect and report online CSEA and; partner with law enforcement and support communities to support investigations and victims. Additionally, the review and recommendation should include an assessment of DHS educational, awareness, and school safety resources to prevent, detect, and report CSEA. This should include best practices for content delivery, how it is delivered, who is delivering, and audience prioritization.

3. Foreign malign influence in higher education, including guidelines and best practices for higher education institutions to reduce the risk of and counter foreign malign influence; consideration of a public-private partnership to enhance collaboration and information sharing on foreign malign influence; and an assessment of how the U.S. Government can enhance its internal operations and posture to effectively coordinate and address foreign malign influence-related national security risks posed to higher education institutions.

Schedule: The subcommittees' findings and recommendations will be submitted to the HSAPC for its deliberation and vote during a public meeting on December 13, 2023 and a public meeting in Spring 2024.

Zarinah T. Silas,

Designated Federal Officer, Homeland Security Academic Partnership Council, U.S. Department of Homeland Security.

[FR Doc. 2023–25781 Filed 11–21–23; 8:45 am]

BILLING CODE 9112–FN–P

DEPARTMENT OF HOMELAND SECURITY

[Docket No. DHS–2023–0046]

Establishment of Faith-Based Security Advisory Council Subcommittee

AGENCY: The Office of Partnership and Engagement (OPE), The Department of Homeland Security (DHS).

ACTION: Notice of a new tasking for the Faith-Based Security Advisory Council (FBSAC).

SUMMARY: On November 14, 2023, the Secretary of DHS, Alejandro N. Mayorkas, issued a memorandum tasking the Faith-Based Security Advisory Council (FBSAC) to establish a subcommittee further outlined below. This notice is not a solicitation for membership.

FOR FURTHER INFORMATION CONTACT: Sameer Hossain, Designated Federal Officer, Faith-Based Security Advisory Council of Department of Homeland Security, at *FBSAC@hq.dhs.gov* or 202–891–2876.

SUPPLEMENTARY INFORMATION: The FBSAC provides organizationally independent, strategic, timely, specific, and actionable advice to the Secretary through the OPE Assistant Secretary, who serves as the DHS Faith-Based Organizations Security Coordinator on security and preparedness matters related to places of worship, faith communities, and faith-based organizations. The Council consists of members who are: faith-based organization security officials; faith-based organization leaders; faith leaders; State and local public safety, law enforcement, and emergency management leaders; and a representative from the Department of Justice or Federal Bureau of Investigation.

The Secretary has requested that the FBSAC form a new subcommittee to study and provide recommendations in the following critical area for the Department:

1. Combatting online child sexual exploitation and abuse (CSEA), providing recommendations on how DHS can partner with faith-based organizations to inform faith-based leaders and communities about how to recognize and respond appropriately to incidents of online CSEA; and an assessment to gauge the strengths, gaps, and opportunities in faith-based community awareness, engagement, and whole-of-community involvement. This assessment should include recommendations for faith-based organization collaboration to raise public awareness of online CSEA.

Schedule: The subcommittees findings and recommendations will be submitted to the FBSAC for its deliberation and vote during a public meeting within 150 days of November 14, 2023.

Dated: November 16, 2023.

Sameer Hossain,

Designated Federal Officer, Faith-Based Security Advisory Council, U.S. Department of Homeland Security.

[FR Doc. 2023–25774 Filed 11–21–23; 8:45 am]

BILLING CODE 9112–FN–P

DEPARTMENT OF HOMELAND SECURITY

[Docket No. DHS–2023–0043]

Establishment of Homeland Security Advisory Council Subcommittee

AGENCY: Office of Partnership and Engagement (OPE), Department of Homeland Security (DHS).

ACTION: Notice of new tasking for the Homeland Security Advisory Council (HSAC).

SUMMARY: On November 14, 2023, DHS Secretary Alejandro Mayorkas issued a memorandum tasking the HSAC with establishing a subcommittee to provide recommendations to the Department to combat online child sexual exploitation and abuse. Details of the tasking are included below. This notice is not a solicitation for membership.

FOR FURTHER INFORMATION CONTACT: Rebecca Sternhell, Principal Deputy Assistant Secretary & Acting Executive Director, Homeland Security Advisory Council, Office of Partnership and Engagement, U.S. Department of Homeland Security at *HSAC@hq.dhs.gov* or 202–891–2876.

SUPPLEMENTARY INFORMATION: The Homeland Security Advisory Council provides organizationally independent, strategic, timely, specific, and

actionable advice and recommendations for the consideration of the Secretary of the Department of Homeland Security on matters related to homeland security. The Homeland Security Advisory Council is comprised of leaders in local law enforcement, first responders, public health, State, local and tribal government, national policy, the private sector, and academia.

The Secretary has requested that the HSAC form a new subcommittee to provide recommendations to the Department to combat online child sexual exploitation and abuse. Specifically, the tasking requested the following:

1. An assessment of how DHS can streamline and strengthen internal operations across components to effectively coordinate and collectively address online child sexual exploitation and abuse alongside our international partners, the technology industry, and non-governmental organizations.

2. An assessment and development of recommended actions for the technology industry to proactively identify, report, and prevent future sexual exploitation and abuse of children online. The assessment should include:

a. A review of existing authorities and how DHS could utilize these authorities to move our interests forward; and

b. Identification of the barriers impeding industry from providing actionable information to law enforcement to identify victims and perpetrators.

3. An assessment to gauge the strengths, gaps, and opportunities in public awareness, industry engagement, and whole-of-community involvement. This assessment should include recommendations for cross-industry collaboration to raise public awareness of online Child Sexual Exploitation and Abuse (CSEA).

A full report of findings and recommendations is due to be submitted from the HSAC by April 2024.

Dated: November 16, 2023.

Rebecca Sternhell,

Acting Executive Director, Homeland Security Advisory Council, Department of Homeland Security.

[FR Doc. 2023–25775 Filed 11–21–23; 8:45 am]

BILLING CODE 9112–FN–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–6429–C–02]

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

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

ACTION: Notification of benchmarks; correction.

SUMMARY: The Department of the Housing and Urban Development (HUD) published a notice in the **Federal Register** on October 5, 2023, to inform members of the public that HUD was updating its 2020 version of the Section 3 benchmark notice pursuant to HUD's regulations, which require that HUD set Section 3 benchmarks by publishing a notification, subject to public comment, in the **Federal Register** and update the benchmarks no less frequently than once every three years by the same method of notification. The notice provided an opportunity for public comment about the Section 3 benchmark goals but did not include the option of electronic submission through *Regulations.gov.* The notice also did not specify a period of time for the public comment period. This notice corrects these omissions and establishes a public comment period of sixty days to submit comments.

DATES: *Effective Date:* December 22, 2023. The public comment period for the notice published in the **Federal Register** on October 5, 2023 (88 FR 69219) is January 22, 2024.

FOR FURTHER INFORMATION CONTACT: Nathan Roush, Program Analyst, Office of Field Policy and Management, Department of Housing and Urban Development, Five Points Plaza, 40 Marietta St. NW, Atlanta, GA 30303, telephone number 202–708–2426 (this is not a toll-free number). General email inquiries regarding Section 3 may be sent to *Section3@hud.gov.* HUD welcomes and is prepared to receive calls from individuals who are deaf or hard of hearing, as well as individuals with speech or communication disabilities. To learn more about how to make an accessible telephone call, please visit *https://www.fcc.gov/consumers/guides/telecommunications-relay-service-trs.*

SUPPLEMENTARY INFORMATION:

Correction

In the **Federal Register** of October 5, 2023, in FR Doc 2023–22183, on page 69219, in the first column, the following corrections are made:

1. On page 69219, in the first column, in the Dates caption, revise the ''Dates'' section to read as follows:

DATES: *Effective Date:* December 22, 2023. *Comment Due Date:* January 22, 2024.

2. On page 69219, in the first column, after the dates section, add a section to read as follows:

ADDRESSES: HUD invites interested persons to submit comments to the Office of the General Counsel, Regulations Division, Department of Housing and Urban Development, 451 7th Street SW, Room 10276, Washington, DC 20410–0500. Communications should refer to the above docket number and title and should contain the information specified in the ''Request for Comments'' section. There are two methods for submitting public comments.

1. *Electronic Submission of Comments.* Comments may be submitted electronically through the Federal eRulemaking Portal at *www.regulations.gov.* HUD strongly encourages commenters to submit comments electronically. Electronic submission of comments allows the commenter maximum time to prepare and submit a comment, ensures timely receipt by HUD, and enables HUD to make comments immediately available to the public. Comments submitted electronically through the website can be viewed by other commenters and interested members of the public. Commenters should follow instructions provided on that site to submit comments electronically.

2. *Submission of Comments by Mail.* Comments may be submitted by mail to the Regulations Division, Office of General Counsel, Department of Housing and Urban Development, 451 7th Street SW, Room 10276, Washington, DC 20410–0500. Due to security measures at all Federal agencies, however, submission of comments by mail often results in delayed delivery. To ensure timely receipt, HUD recommends that comments be mailed at least two weeks in advance of the public comment deadline.

Aaron Santa Anna,

Associate General Counsel, Office of Legislation and Regulations.

[FR Doc. 2023–25846 Filed 11–21–23; 8:45 am]

BILLING CODE 4210–67–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–7070–N–87]

30-Day Notice of Proposed Information Collection: Evaluation of the Moving To Work (MTW) Expansion Asset Building Cohort, OMB Control No.: 2528–NEW

AGENCY: Office of Policy Development and Research, Chief Data Officer, HUD.

ACTION: Notice.

SUMMARY: HUD is seeking approval from the Office of Management and Budget (OMB) for the information collection described below. In accordance with the Paperwork Reduction Act, HUD is requesting comment from all interested parties on the proposed collection of information. The purpose of this notice is to allow for an additional 30 days of public comment.

DATES: *Comments Due Date:* December 22, 2023.

ADDRESSES: Interested persons are invited to submit comments regarding this proposal. Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function. Interested persons are also invited to submit comments regarding this proposal and comments should refer to the proposal by name and/or OMB Control Number and should be sent to: Anna Guido, Clearance Officer, REE, Department of Housing and Urban Development, 451 7th Street SW, Room 8210, Washington, DC 20410–5000; email *PaperworkReductionActOffice@hud.gov.*

FOR FURTHER INFORMATION CONTACT: Anna P. Guido, Reports Management Officer, REE, Department of Housing and Urban Development, 451 7th Street SW, Room 8210, Washington, DC 20410; email: *PaperworkReductionActOffice@hud.gov.* telephone (202)–402–5535. This is not a toll-free number, HUD welcomes and is prepared to receive calls from individuals who are deaf or hard of hearing, as well as individuals with speech or communication disabilities. To learn more about how to make an accessible telephone call, please visit: *https://www.fcc.gov/consumers/guides/telecommunications-relay-service-trs.* Copies of available documents submitted to OMB may be obtained from Ms. Guido.

SUPPLEMENTARY INFORMATION: This notice informs the public that HUD is seeking approval from OMB for the information collection described in Section A.

The **Federal Register** notice that solicited public comment on the information collection for a period of 60 days was published on July 21, 2023 at 88 FR 47158.

A. Overview of Information Collection

Title of Information Collection: Evaluation of the Moving to Work (MTW) Expansion Asset Building Cohort.

OMB Approval Number: 2528–New.

Type of Request: New collection.

Form Number: N/A.

Description of the need for the information and proposed use: The purpose of this proposed information collection is to evaluate the Moving to Work Expansion Asset Building Cohort (hereinafter ''Asset Building Cohort''). This 60-day Notice informs the public of intent to collect data about the asset building programs implemented by the PHAs in the Asset Building Cohort and about the HUD-assisted residents selected to participate in the asset building programs. HUD selected 18 Public Housing Agencies (PHAs) to participate in the Asset Building Cohort, and 17 of these PHAs joined the MTW demonstration. Each PHA will implement an opt-out savings program, a rent reporting for credit building program, or a custom asset building program. The savings account and rent reporting programs are described in PIH Notice 2022–11. For the savings account program, PHAs will contribute at least $10 per month for 24 months to at least 25 residents to support buildup of emergency savings. For the rent reporting program, PHAs will report on-time rent payments made by participating public housing residents to credit agencies so that the residents' credit reports will gain a tradeline (rental tradeline). The added rental tradeline may increase residents' credit visibility and credit scores. HUD's Office of Policy Development and Research (PD&R) will evaluate the impacts of these asset building programs. The evaluation requires data from several sources, including the new information collection described in this Notice.

The first phase of the evaluation of the Asset Building Cohort is guided by a few overarching questions: (1) What programs are PHAs implementing? What are the characteristics of the group of residents participating in the programs? (2) How do participants understand the programs? And what do the programs mean for them personally? The programs will run for two years. The first phase of the evaluation will collect data from the following samples:

(1) PHA staff (n = 51), staff of partner organizations (n = 12), and PHA residents (n= 10)

(2) Residents that volunteered for the rent reporting for credit building pilot program, including households that were randomly assigned to have their rent payments reported to credit agencies and households that were assigned to a control group (who don't have their rent payments reported to credit agencies) (n = 300)

(3) Residents that volunteered for the rent reporting for credit building pilot program and agree to participate in in-depth qualitative interviews at up to four time points during the two years that the PHA is required to offer the program (n = 40)

The evaluator will conduct interviews of about 1 hour with staff from participating PHAs, organizational partners (*e.g.,* a bank that partners with a PHA to set up savings accounts for unbanked residents), and PHA residents to better understand facilitators and challenges to starting and running the asset building programs. The evaluator will interview up to 3 staff per PHA at all 17 PHAs, up to 3 partners at 4 PHAs selected for in-depth case studies, and up to 5 residents at 2 of the case study PHAs.

Residents participating in the rent reporting programs must complete an Informed Consent Form (ICF) and Baseline Information Form (BIF). The BIF will provide important information not otherwise available from HUD's administrative data, such as whether the household has significant barriers to employment. The BIF will take on average 15 minutes to complete. After enrollment in the program, 40 participants, including 20 members of the treatment group and 20 members of the control group, will be asked to participate in qualitative interviews of about 90 minutes each at two different time points during the first year of the rent reporting programs. The qualitative interviews will focus on experiences with the rent reporting program, household budgeting, and the broader context of interactions with banking, credit, and financial institutions. The **Federal Register** Notice provides an opportunity to comment on the data collection instruments and associated materials to be administered to the respondents at PHAs (including staff and residents) in the Asset Building Cohort and at partner organizations.

Respondents: Adults who work at, provide services at, or are assisted by

PHAs participating in the Asset Building Cohort.

Information collection	Number of respondents	Frequency of response	Responses per annum	Burden hour per response	Annual burden hours	Hourly cost per response	Annual cost
Program Implementation PHA staff interview guide	51	1	.33	1	17	$57.60	$979.20
Program Implementation partner staff interview guide	12	1	.33	1	4	42.48	169.92
Program Implementation resident interview guide	10	1	.33	1	3.33	10.31	34.37
Rent Reporting Informed Consent Form	300	1	.33	.25	25	11.05	276.25
Rent Reporting Baseline Information Form	300	1	.33	.25	25	11.05	276.25
Rent Reporting Qualitative Interview Guide 1	40	1	.6667	1.5	40	11.05	442.00
Rent Reporting Qualitative Interview Guide 2	40	1	.6667	1.5	40	11.05	442.00

Total burden annualized over 3-year period.

The average hourly rate for HUD-assisted households is calculated as follows: (1) For the Program Implementation resident interview guide we averaged the minimum wages of all states with a PHA implementing a Savings Account option, which includes California, Florida, Massachusetts, New Hampshire, Ohio, Oregon, and South Carolina, and calculate the average hourly minimum wage as $10.31. (2) For the interviews that apply only to PHAs in the rent reporting study, we averaged the minimum wages of all states with a PHA in the rent reporting study, which includes Connecticut, Florida, Idaho, Illinois, Maine, and New Hampshire, and and calculate the average hourly minimum wage as $11.05.

The average hourly rate for PHA staff ($57.60) is based on the average employer costs for State and Local Government employees. (Source: Bureau of Labor Statistics, December 2022 Employer Costs for Employee Compensation) The average hourly rate for partner organization staff ($42.48) is based on the average employer costs for civilian employees.

(Source: Bureau of Labor Statistics, December 2022 Employer Costs for Employee Compensation)

B. Solicitation of Public Comment

This notice is soliciting comments from members of the public and affected parties concerning the collection of information described in Section A on the following:

(1) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) The accuracy of the agency's estimate of the burden of the proposed collection of information;

(3) Ways to enhance the quality, utility, and clarity of the information to be collected; and

(4) Ways to minimize the burden of the collection of information on those who are to respond; including through the use of appropriate automated collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

(5) ways to minimize the burden of the collection of information on those who are to respond, including the use of automated collection techniques or other forms of information technology.

HUD encourages interested parties to submit comments in response to these questions.

C. Authority

Section 3507 of the Paperwork Reduction Act of 1995, 44 U.S.C. chapter 35.

Anna P. Guido,

Department Reports Management Office, Office of Policy Development and Research, Chief Data Officer.

[FR Doc. 2023–25855 Filed 11–21–23; 8:45 am]

BILLING CODE 4210–67–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[BLM_ID_FRN_MO4500175813]

Notice of Intent To Prepare an Environmental Impact Statement for the Caldwell Canyon Revised Mine and Reclamation Plan, Caribou County, Idaho

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of intent.

SUMMARY: In compliance with the National Environmental Policy Act of 1969, as amended (NEPA), and the Federal Land Policy and Management Act of 1976, as amended, the Bureau of Land Management (BLM) Idaho Falls District intends to prepare an Environmental Impact Statement (EIS) to consider the effects of P4 Production, LLC's (P4 Production) Caldwell Canyon Revised Mine and Reclamation Plan (RMRP) in Caribou County, Idaho. This notice announces the beginning of the scoping process to solicit public comments and identify issues and alternatives.

DATES: This notice initiates the public scoping process for the EIS. The BLM requests that the public submit comments concerning the scope of the analysis, potential alternatives, and identification of relevant information and studies by December 22, 2023. In order to be considered during the preparation of the Draft EIS, please ensure your comments are received prior to the close of the 30-day scoping period or 15 days after the last public meeting, whichever is later. Additional information will be distributed through a press release, newspaper notice, BLM's ePlanning website, and email to the mailing list.

ADDRESSES: You may submit comments related to the Caldwell Canyon RMRP by any of the following methods:

- *Website: https://eplanning.blm.gov/eplanning-ui/project/2026858/510.*
- *Email: BLM_ID_CaldwellRevisedMRP_EIS@blm.gov.*
- *Fax:* (208) 478–6376.

• *Mail:* Caldwell Canyon Mine EIS, C/O Stantec Consulting Services Inc., 2890 East Cottonwood Parkway, Suite 300, Salt Lake City, UT 84121.

Documents pertinent to this proposal may be examined online at *https://eplanning.blm.gov/eplanning-ui/project/2026858/510* and at the BLM Pocatello Field Office.

FOR FURTHER INFORMATION CONTACT: Barry Myers, project manager, telephone (208) 559–3662; address 4350 Cliffs Drive, Pocatello, ID 83204; email *bmyers@blm.gov*. Contact Mr. Myers to have your name added to our mailing list. Individuals in the United States who are deaf, deafblind, hard of hearing, or have a speech disability may dial 711 (TTY, TDD, or TeleBraille) to access telecommunications relay services for contacting Mr. Myers. Individuals outside the United States should use the relay services offered within their country to make international calls to the point-of-contact in the United States.

SUPPLEMENTARY INFORMATION: Following the preparation of a Final EIS, the Caldwell Canyon Mine and Reclamation project was approved in a 2019 Record of Decision (ROD). Since that approval in 2019 and continuing through May 2023, P4 Production developed and constructed various components of the original project including a service road, haul roads, various utility lines, loadout facilities, and earthwork to prepare for ore removal.

In June 2023, as a result of legal action challenging the BLM's decision and analysis, the Final EIS and ROD were vacated by the United States District Court for the District of Idaho (Case No. 4:21–cv–00182–BLM). As a result of this vacatur, P4 Production submitted a new RMRP, which the BLM will analyze under NEPA. The RMRP proposes modifying existing lease boundaries, developing two new open mine pits, constructing haul and access roads, installing various utility lines, and constructing water management features, monitoring wells, and shop and office facilities (the Project).

Purpose and Need for the Proposed Action

The purpose of the Project is for the BLM to evaluate and respond to the RMRP submitted for the recovery of phosphate ore and to modify leases, in accordance with the Mineral Leasing Act of 1920. P4 Production has certain rights and privileges to recover phosphate from their leases, including the exploration, mining, and disposal of the phosphate or phosphate rock, subject to applicable requirements. The need for the Project is to develop the phosphate resources, using an economically viable method, in accordance with federal laws and regulations governing federal mineral leases, consistent with applicable law.

Preliminary Proposed Action and Alternatives

P4 Production's RMRP proposes to mine phosphate ore in Caribou County, Idaho, from three existing federal phosphate leases by constructing two open pits, constructing haul and access roads, installing various utility lines, and constructing water management features, monitoring wells, and shop and office facilities, while implementing environmental protection measures and reclamation.

The Project would create two open pits, portions of which extend beyond the existing federal lease boundaries. To accommodate those portions of the pits that extend outside the current federal leases, P4 Production proposes to expand their leases in accordance with 43 CFR subpart 3510.

The mining and the support facilities would encompass approximately 1,830 acres. The expected mine life would be approximately 40 years. Reclamation would be concurrent with mining and is scheduled to conclude two years after mining ceases.

In addition to the No Action Alternative (not approving the RMRP and lease modifications) and the Proposed Action, other possible alternatives may include a new proposed haul and access road and utility corridor that avoid federal surface as much as possible, and alternatives that address the sage-grouse issues identified by the Court. The BLM welcomes comments on all preliminary alternatives, as well as suggestions for additional alternatives.

Summary of Expected Impacts

The BLM expects mining and hauling operations to: change groundwater and surface water quantity and quality within regulatory limits; remove and change the structure and composition of vegetation, including species important to Native American Tribes; disturb wetlands and riparian habitat; modify wildlife habitat, including sage-grouse habitat; change scenery; disturb soil; permanently remove mineral resources; create air and fugitive dust emissions; extend economic activity such as employment and the continued operation of an existing elemental phosphorous processing plant; support businesses and generate tax revenue; and reduce livestock grazing.

Anticipated Permits and Authorizations

The BLM anticipates that the following permits and approvals may be required for the Project:

- BLM; MRP approval or modification of approved MRP; 43 CFR 3590.2(a), 3592.1(a)
- BLM; Lease Modification/Fringe Lease; 43 CFR 3510
- BLM; Right-of-way; 90 Statute 2776; 43 U.S. Code (U.S.C.) 1761
- BLM; Phosphate Use Permit; 43 CFR 3501.10, 43 CFR 3516
- High Explosives Permit; 18 U.S.C. 40; 27 CFR 555
- Idaho Department of Environmental Quality; Point of Compliance under the Idaho Groundwater Quality Rule; IDAPA 58.01.11.401
- Idaho Department of Environmental Quality; Certification of Water Quality (Clean Water Act, Section 401); IDAPA 39–101, *et seq.;* Idaho Code Parts 39–3601, *et seq.*
- Idaho Department of Water Resources; Water Rights; Idaho Code Parts 42–201, *et seq.;* IDAPA 37.03.08, Water Appropriation Rules and 37.03.11 Conjunctive Management of Surface and Ground Water
- Idaho Department of Environmental Quality; Stormwater Pollution Prevention Plan, Idaho Pollutant Discharge Elimination System; (IDAPA 58.01.25)
- USACE; Section 404 Permit—required if surface disturbance and placement of fill is more than 0.5 acres of wetlands and 500 feet of stream channels; Clean Water Act [Title 33 U.S.C. 1344, Section 404(a)]
- Idaho Department of Water Resources; Stream Channel Alteration Permit; IDAPA 42–3801
- Idaho Department of Environmental Quality; Air Quality Permit to Construct; IDAPA 58.01.01
- Idaho Department of Lands; Reclamation Plan approval and modification of approved Reclamation Plan; IDAPA 20.03.02.010, 20.03.02.120, and 20.03.02.140
- Caribou County; Conditional Use Permit for facilities within an approved land use; Caribou County Zoning Ordinance, Chapter 13.

Schedule for the Decision-Making Process

The BLM will provide additional opportunities for public participation consistent with the NEPA process, including a 45-day comment period on the Draft EIS. The Draft EIS is anticipated to be available for public review in summer 2024 and the Final EIS is anticipated to be released in December 2024, with a Record of

Decision no sooner than 30 days after the release of the Final EIS.

Public Scoping Process

This notice of intent initiates the scoping period. The BLM will be holding a virtual public scoping meeting. The specific date and time of the virtual meeting, including information on how to register, will be announced in advance via press release, newspaper notice, the ePlanning project page, and email.

Cooperating Agencies

The Idaho Department of Environmental Quality, U.S. Army Corps of Engineers, Idaho Department of Lands, and Idaho Governor's Office of Energy and Minerals are Cooperating Agencies.

Responsible Official

Idaho Falls District Manager Mary D'Aversa is the BLM responsible official.

Nature of Decision To Be Made

The BLM Idaho Falls District Manager will decide whether and under what conditions to approve land use authorizations on BLM-managed public land and the RMRP on leased lands, and to recommend the approval or disapproval of proposed lease modifications to the BLM Idaho State Office Branch Chief for Minerals, Land Tenure, and Water Rights. The decision and recommendation will be documented in a ROD.

Additional Information

The BLM will identify, analyze, and consider mitigation to address the reasonably foreseeable impacts to resources from the Proposed Action and all analyzed reasonable alternatives and, in accordance with 40 CFR 1502.14(e), include appropriate mitigation measures not already included in the Proposed Action or Action Alternative(s). Mitigation may include avoidance, minimization, rectification, reduction or elimination over time, and compensation, and it may be considered at multiple scales, including the landscape scale.

The BLM will utilize and coordinate the NEPA process to help support compliance with applicable procedural requirements under the Endangered Species Act (16 U.S.C. 1536) and Section 106 of the National Historic Preservation Act (54 U.S.C. 306108) as provided in 36 CFR 800.2(d)(3), including public involvement requirements of Section 106. Information about historic and cultural resources and threatened and endangered species within the area potentially affected by the Project will assist the BLM in identifying and evaluating impacts to such resources.

The BLM will consult with Indian Tribal Nations on a government-to-government basis in accordance with Executive Order 13175, BLM MS 1780, and other Departmental policies. The BLM will send invites to potentially affected Tribal Nations prior to consultations. Tribal concerns, including impacts on Indian trust assets and potential impacts to cultural resources, will be given due consideration. Federal, State, and local agencies, along with Indian Tribal Nations and other stakeholders that may be interested in or affected by the proposed Project that the BLM is evaluating, are invited to participate in the scoping process and, if eligible, may request or be requested by the BLM to participate in the development of the environmental analysis as a Cooperating Agency. The BLM will also provide additional opportunities for government-to-government consultation at other times during the NEPA process.

Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you may ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

(Authority: 40 CFR 1501.9)

Mary D'Aversa,

District Manager, Idaho Falls District.

[FR Doc. 2023–25756 Filed 11–21–23; 8:45 am]

BILLING CODE 4331–19–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–WASO–NRNHL–DTS#–36802; PPWOCRADI0, PCU00RP14.R50000]

National Register of Historic Places; Notification of Pending Nominations and Related Actions

AGENCY: National Park Service, Interior.

ACTION: Notice.

SUMMARY: The National Park Service is soliciting electronic comments on the significance of properties nominated before October 28, 2023, for listing or related actions in the National Register of Historic Places.

DATES: Comments should be submitted electronically by December 7, 2023.

ADDRESSES: Comments are encouraged to be submitted electronically to *National_Register_Submissions@nps.gov* with the subject line ''Public Comment on <property or proposed district name, (County) State>.'' If you have no access to email, you may send them via U.S. Postal Service and all other carriers to the National Register of Historic Places, National Park Service, 1849 C Street NW, MS 7228, Washington, DC 20240.

FOR FURTHER INFORMATION CONTACT: Sherry A. Frear, Chief, National Register of Historic Places/National Historic Landmarks Program, 1849 C Street NW, MS 7228, Washington, DC 20240, *sherry_frear@nps.gov,* 202–913–3763.

SUPPLEMENTARY INFORMATION: The properties listed in this notice are being considered for listing or related actions in the National Register of Historic Places. Nominations for their consideration were received by the National Park Service before October 28, 2023. Pursuant to Section 60.13 of 36 CFR part 60, comments are being accepted concerning the significance of the nominated properties under the National Register criteria for evaluation.

Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Nominations submitted by State or Tribal Historic Preservation Officers:

Key: State, County, Property Name, Multiple Name (if applicable), Address/Boundary, City, Vicinity, Reference Number.

INDIANA

Dubois County

Zoar Public School, Zoar Methodist Church, Zoar Cemetery (Indiana's Public Common and High Schools MPS), 8818 West Old State Road 64 and Zoar Church Road, Zoar, MP100009589

Marion County

North Pennsylvania Street Historic District (Historic Residential Suburbs in the United States, 1830–1960 MPS), Roughly bound by Westfield Boulevard on the north, the east side of New Jersey Street on the east, 46th Street on the south, and the west side of Pennsylvania Street on the west, Indianapolis, MP100009591

Ohio County

Speakman-Miller-Kittle Farm, 10405 Old State Road 56, Rising Sun, SG100009592

Rush County

Dr. Jefferson and Eliza Arnold Helm House, Address Restricted, Rushville, SG100009593

Vanderburgh County

Baptisttown Historic District, Roughly each side of Evans A venue and the east side of Linwood A venue between Walnut and Lincoln, each side of Lincoln Avenue between Motion and Garvin, the west side of Garvin Street and each side of Elliott Street between Mulberry and Chandler, and ea, Evansville, SG100009594

MISSISSIPPI

Marshall County

Newsom—Adams Family Farm House, 461 Adam Springs Road, Waterford, SG100009585

NEW YORK

Monroe County

Third Ward Historic District (Boundary Increase), Roughly bounded by Adams and Peach Sts., I–490, and both sides of Troup and Fitzhugh Sts., Rochester, BC100009601

Steuben County

Village of Hammondsport Historic District, Bauder Ave, Church St., Curtiss Ave, Davis Ave, Grape St., Lake St., Liberty St., Main St., Mechanic St., Myrtle Ave, Orchard St., Pulteney St., Shethar St., Thorpe St., Vine St., Water St., Wheeler Ave, William St., Hammondsport, SG100009603

OHIO

Portage County

Mantua Center District (Boundary Increase), 4103–3991 State Route 82, 11670–11755 Mantua Center Road, 11653–11677 Diagonal Road, 11701–11715 School Lan, Mantua Center, BC100009586

TEXAS

Brazos County

Bryan Federal Building and Post Office, 216 W. 26th Street, Bryan, SG100009605

WYOMING

Fremont County

St. Andrew s Episcopal Church, 90 East Forbes Street, Atlantic City, SG100009595

Laramie County

Capitol North Historic District (Boundary Increase), Roughly bounded by E. 29th, and E. 25th St., Warren and Pioneer Aves., Cheyenne, BC100009596

Park County

American Legion Hall, 324 East 1st Street, Powell, SG100009598

Sage Creek Community Club, 5677 Greybull Highway, Cody, SG100009599

Additional documentation has been received for the following resource(s):

INDIANA

Franklin County

Whitewater Canal Historic District (Additional Documentation), From Laurel Feeder Dam to Brookville, Metamora, AD73000272

NEW YORK

Columbia County

Sweet-Herman Homestead (Additional Documentation), 582–614 Center Hill Rd., Copake, AD100007955

Monroe County

Third Ward Historic District, Roughly bounded by Adams and Peach Sts., I–490, and both sides of Troup and Fitzhugh Sts., Rochester, AD74001262

Ulster County

Balsam Lake Mountain Fire Observation Station (Additional Documentation), (Fire Observation Stations of New York State Forest Preserve MPS), Balsam Lake Mountain, Hardenburgh, AD01001038

OHIO

Portage County

Mantua Center District (Additional Documentation), Roughly bounded by OH 82 and Mantua Center Rd., Mantua Center, AD74001607

OKLAHOMA

Tulsa County

Church Studio, The, 304 S. Trenton Ave., Tulsa, AD100001595

WYOMING

Laramie County

Capitol North Historic District (Additional Documentation), Roughly bounded by E. 29th, and E. 25th St., Warren and Pioneer Aves., Cheyenne, AD80004048

Authority: Section 60.13 of 36 CFR part 60.

Sherry A. Frear,

Chief, National Register of Historic Places/National Historic Landmarks Program.

[FR Doc. 2023–25827 Filed 11–21–23; 8:45 am]

BILLING CODE 4312–52–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–WASO–NRNHL–DTS#–36933; PPWOCRADI0, PCU00RP14.R50000]

National Register of Historic Places; Notification of Pending Nominations and Related Actions

AGENCY: National Park Service, Interior.

ACTION: Notice.

SUMMARY: The National Park Service is soliciting electronic comments on the significance of properties nominated before October 21, 2023, for listing or related actions in the National Register of Historic Places.

DATES: Comments should be submitted electronically by December 7, 2023.

ADDRESSES: Comments are encouraged to be submitted electronically to *National_Register_Submissions@nps.gov* with the subject line ''Public Comment on <property or proposed district name, (County) State>.'' If you have no access to email, you may send them via U.S. Postal Service and all other carriers to the National Register of Historic Places, National Park Service, 1849 C Street NW, MS 7228, Washington, DC 20240.

FOR FURTHER INFORMATION CONTACT: Sherry A. Frear, Chief, National Register of Historic Places/National Historic Landmarks Program, 1849 C Street NW, MS 7228, Washington, DC 20240, *sherry_frear@nps.gov,* 202–913–3763.

SUPPLEMENTARY INFORMATION: The properties listed in this notice are being considered for listing or related actions in the National Register of Historic Places. Nominations for their consideration were received by the National Park Service before October 21, 2023. Pursuant to Section 60.13 of 36 CFR part 60, comments are being accepted concerning the significance of the nominated properties under the National Register criteria for evaluation.

Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Nominations submitted by State or Tribal Historic Preservation Officers:

Key: State, County, Property Name, Multiple Name (if applicable), Address/Boundary, City, Vicinity, Reference Number.

ARIZONA

Pima County

El Dorado Lodge, 6400 E. El Dorado Circle, Tucson, SG100009580

CALIFORNIA

Los Angeles County

Toad Hall, 353 Anita Drive, Pasadena, SG100009582

COLORADO

Denver County

Machebeuf Hall, 3040 South Loretto Way, Denver, SG100009576

CONNECTICUT

Hartford County

Bedford-Garden Streets Historic District, roughly bounded by Mather Street, Brook Street and Bedford Street, Hartford, SG100009583

GEORGIA

Fulton County

Paces Ferry Tower, 374 East Paces Ferry Road, Atlanta, SG100009574

LOUISIANA

Iberia Parish

Freetown-Lil' Brooklyn Historic District, Roughly including the eastern sides of Rosier St, Johnson Alley, and partially Hortense Street, New Iberia, SG100009575

TENNESSEE

Shelby County

Omicron Sigma Chapter House of Sigma Gamma Rho Sorority, Incorporated, 805 Saxon Avenue, Memphis, SG100009581

VIRGINIA

Northampton County

Eyreville, 3259 Eyreville Drive, Cheriton vicinity, SG100009579

WYOMING

Fremont County

Chief Washakie Hot Springs Site, Address Restricted, Fort Washakie vicinity, SG100009578

Authority: Section 60.13 of 36 CFR part 60.

Sherry A. Frear,

Chief, National Register of Historic Places/National Historic Landmarks Program.

[FR Doc. 2023–25826 Filed 11–21–23; 8:45 am]

BILLING CODE 4312–52–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–WASO–NRNHL–DTS#–36934; PPWOCRADI0, PCU00RP14.R50000]

National Register of Historic Places; Notification of Pending Nominations and Related Actions

AGENCY: National Park Service, Interior.

ACTION: Notice.

SUMMARY: The National Park Service is soliciting electronic comments on the significance of properties nominated before November 4, 2023, for listing or related actions in the National Register of Historic Places.

DATES: Comments should be submitted electronically by December 7, 2023.

ADDRESSES: Comments are encouraged to be submitted electronically to *National_Register_Submissions@nps.gov* with the subject line ''Public Comment on <property or proposed district name, (County) State≤.'' If you have no access to email, you may send them via U.S. Postal Service and all other carriers to the National Register of Historic Places, National Park Service, 1849 C Street NW, MS 7228, Washington, DC 20240.

FOR FURTHER INFORMATION CONTACT: Sherry A. Frear, Chief, National Register of Historic Places/National Historic Landmarks Program, 1849 C Street NW, MS 7228, Washington, DC 20240, *sherry_frear@nps.gov,* 202–913–3763.

SUPPLEMENTARY INFORMATION: The properties listed in this notice are being considered for listing or related actions in the National Register of Historic Places. Nominations for their consideration were received by the National Park Service before November 4, 2023. Pursuant to Section 60.13 of 36 CFR part 60, comments are being accepted concerning the significance of the nominated properties under the National Register criteria for evaluation.

Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Nominations submitted by State or Tribal Historic Preservation Officers:

Key: State, County, Property Name, Multiple Name(if applicable), Address/Boundary, City, Vicinity, Reference Number.

FLORIDA

Palm Beach County

Pearl City National Register Historic District bounded by NE 15th Terr. N Federal Hwy., NE 10th St. & N Dixie Hwy., Boca Raton, SG100009609

MISSISSIPPI

Adams County

Beulah Missionary Baptist Church (Civil Rights Resources of Natchez and Adams County, Mississippi MPS), 710 Beulah Street, Natchez, MP100009623

Shaw-Nosser House (Civil Rights Resources of Natchez and Adams County, Mississippi MPS), 207 Linton Avenue, Natchez, MP100009624

Rose Hill Missionary Baptist Church (Civil Rights Resources of Natchez and Adams County, Mississippi MPS), 607½ Madison Street, Natchez, MP100009625

NORTH CAROLINA

Buncombe County

Walton Street Park and Pool, 570 Walton Street, Asheville, SG100009617

Forsyth County

Winston Lake Golf Course, 3535 Winston Lake Road, 2790 New Walkertown Road, Winston-Salem, SG100009618

Mecklenburg County

Ervin Building, 4037 East Independence Boulevard, Charlotte, SG100009619

Orange County

Ridge Road School, 2705 Coleman Loop Road, Hillsborough vicinity, SG100009620

OHIO

Montgomery County

Steele's Hill-Grafton Hill Historic District (Boundary Increase), Roughly bounded by Grand, Plymouth, Forest, and Salem, Dayton, BC100009613

OKLAHOMA

Okfuskee County

Abe Lincoln Trading Company, North side of Main Street, 175 feet west of Clearview Road, Clearview, SG100009607

WASHINGTON

Thurston County

Tugboat Parthia, 650 Marina Drive, Olympia, SG100009615

WISCONSIN

La Crosse County

Oak Grove Cemetery, 1407 La Crosse Street, La Crosse, SG100009621

A request for removal has been made for the following resource(s):

INDIANA

Dearborn County

ELIZABETH LEA–JOSEPH THROCKMORTON (Towboat), 11042 St. Rd. 56, Lighthouse Point Yacht Club, Aurora vicinity, OT100004044

Hendricks County

Smith Farm, 2698 S Cty. Rd. 900 E, Plainfield vicinity, OT07001279

Additional documentation has been received for the following resource(s):

OHIO

Montgomery County

Steele's Hill-Grafton Hill Historic District (Additional Documentation) Roughly bounded by Grand, Plymouth, Forest, and Salem, Dayton, AD86001237

Authority: Section 60.13 of 36 CFR part 60.

Sherry A. Frear,

Chief, National Register of Historic Places/National Historic Landmarks Program.

[FR Doc. 2023–25828 Filed 11–21–23; 8:45 am]

BILLING CODE 4312–52–P

DEPARTMENT OF THE INTERIOR

Office of Natural Resources Revenue

[Docket No. ONRR–2011–0002; DS63644000 DRT000000.CH7000 245D1113RT]

States' Decisions on Participating in Accounting and Auditing Relief for Federal Oil and Gas Marginal Properties

AGENCY: Office of Natural Resources Revenue, Interior.

ACTION: Notice.

SUMMARY: In accordance with Office of Natural Resources Revenue (ONRR) regulations, ONRR provides two types of accounting and auditing relief for Federal oil and gas production from marginal properties: the cumulative royalty reports and payments relief option, which allows a lessee or designee to submit one royalty report and payment for the calendar year's production; and other requested relief, which allows a lessee or designee to request any type of accounting and auditing relief that is appropriate for production from the marginal property and meets certain requirements. By October 1 of each calendar year, ONRR provides a list of qualifying marginal Federal oil and gas properties to the States receiving a portion of Federal royalties from those properties. Each State then decides whether to participate in neither, one, or both relief options. This Notice provides the public each State's decision on whether to participate in marginal property relief.

DATES: Applicable January 1, 2024.

FOR FURTHER INFORMATION CONTACT: Mr. Robert Sudar, Market & Spatial Analytics, Research, Enforcement, Guidance, and Appeals, ONRR, at (303) 231–3511; or by email to *Robert.Sudar@onrr.gov.*

SUPPLEMENTARY INFORMATION: Pursuant to the Federal Oil and Gas Royalty Simplification and Fairness Act of 1996 (30 U.S.C. 1726) and 30 CFR part 1204, subpart C, ONRR and States can relieve the lessee of a marginal Federal oil and gas property from certain reporting, accounting, and auditing requirements. ONRR's rules under 30 CFR 1204.202 and 1204.203 authorize two relief options: (1) cumulative royalty reports and payments relief option, which allows a lessee or designee to submit one royalty report and payment during a calendar year; and (2) other requested relief, which allows a lessee or designee to request any type of appropriate marginal property accounting and auditing relief that meets the requirements under § 1204.5 and is not prohibited under § 1204.204.

To qualify for the first relief option, *cumulative royalty reports and payments relief option,* properties must produce less than 1,000 barrels-of-oil-equivalent (BOE) per year for the base period (July 1, 2022, through June 30, 2023). Annual reporting relief will begin January 1, 2024, with the annual report and payment due February 28, 2025. If a lessee has an estimated payment on file, the payment due date is March 31, 2025. To qualify for the second relief option, *other requested relief,* the combined equivalent production of the marginal properties during the base period must equal an average daily well production of less than 15 BOE per well per day, as calculated under 30 CFR 1204.4(c).

Each State makes an annual determination as to whether it will participate in neither, one, or both relief options. This Notice fulfills the requirement in ONRR's rules to publish a notice of the State's ''intent to allow or not allow certain relief options . . . in the **Federal Register** no later than 30 days before the beginning of the applicable calendar year.'' *See* 30 CFR 1204.208(f).

The following table shows the States with qualifying marginal properties and those States' decisions on whether to participate in neither, one, or both relief options for calendar year 2024. An ''N/A'' means that no properties within the State met that condition for that type of relief:

State	Cumulative royalty report and payment relief (less than 1,000 BOE per year)	Other accounting and auditing relief (less than 15 BOE per well per day)
Alabama	No	No.
Arkansas	No	No.
California	No	No.
Colorado	No	No.
Kansas	No	No.
Louisiana	Yes	Yes.
Michigan	Yes	Yes.
Montana	No	No.
Nebraska	No	No.
Nevada	Yes	Yes.
New Mexico	No	Yes.
North Dakota	Yes	Yes.
Oklahoma	Yes	Yes.
South Dakota	Yes	Yes.
Utah	No	No.
Wyoming	Yes	No.

Pursuant to 30 U.S.C. 1726(c), a Federal oil and gas property located in a State where ONRR does not share a portion of Federal royalties with that State (that is, for 2024, a State not listed in the table above) is eligible for relief if it qualifies as a marginal property. For more information on how to obtain relief, please refer to 30 CFR 1204.205.

Unless the information that ONRR receives is proprietary data, all correspondence, records, or information received in response to this notice may be subject to disclosure under the Freedom of Information Act (FOIA, 5 U.S.C. 552 *et seq.*). If applicable, please highlight the proprietary portions, including any supporting documentation, or mark the page(s) containing proprietary data. ONRR protects proprietary information under the Trade Secrets Act (18 U.S.C. 1905), FOIA Exemption 4 (5 U.S.C. 552(b)(4)), and the Department of the Interior's FOIA regulations (43 CFR part 2).

Authority: Federal Oil and Gas Royalty Management Act of 1982, 30 U.S.C. 1701 *et seq.,* as amended by Federal Oil and Gas Royalty Simplification and Fairness Act of 1996 (RSFA, Pub. L. 104–185—Aug. 13, 1996,

as corrected by Pub. L. 104–200—Sept. 22, 1996).

Howard M. Cantor,

Director, Office of Natural Resources Revenue.

[FR Doc. 2023–25795 Filed 11–21–23; 8:45 am]

BILLING CODE 4335–30–P

INTERNATIONAL BOUNDARY AND WATER COMMISSION UNITED STATES AND MEXICO

Notice of Availability of a Draft Environmental Assessment (EA) and Finding of No Significant Impact (FONSI) for the Management of Federal Grazing Leases at the Falcon Dam and Reservoir, Starr and Zapata Counties, Texas

AGENCY: United States Section, International Boundary and Water Commission, United States and Mexico (USIBWC).

ACTION: Notice of availability; request for comments.

SUMMARY: The USIBWC hereby gives notice that the *Draft Environmental Assessment* (*EA) and Finding of No Significant Impact (FONSI) for the Management of Federal Grazing Leases at the Falcon Dam and Reservoir, Starr and Zapata Counties, Texas* is available. The EA evaluates land management alternatives to grazing leases that address low grazing lease values and limited access by USIBWC to leased lands. An Environmental Impact Statement will not be prepared unless additional information which may affect this decision is brought to our attention within 30 days from the date of this Notice.

DATES: Comments are due by December 28, 2023.

ADDRESSES: The electronic version of the amended Draft EA is available at the USIBWC web page: *https://www.ibwc.gov/reports-studies/eis-ea-public-comment/.* Physical copies of the Draft EA are available at the Joe A. Guerra Laredo Public Library, 1120 E. Calton Rd., Laredo, Texas 78041; the Olga V. Figueroa Zapata County Public Library, 901 Kennedy St., Zapata, Texas 78076; and the Roma Public Library, 1705 N Athens St., Roma, Texas 78584.

Comments should be sent to: Mark Howe, Cultural Resources Specialist, USIBWC, 4191 N Mesa; El Paso, Texas 79902. Email: *falconcomments@ibwc.gov.* All comments received may be made publicly available without change, including any personal information provided.

FOR FURTHER INFORMATION CONTACT: Mark Howe, Cultural Resources Specialist, Telephone: (915) 832–4767, email: *falconcomments@ibwc.gov.*

SUPPLEMENTARY INFORMATION: The USIBWC is updating or eliminating active and inactive grazing leases in use for commercial, residential, or recreational purposes on federal land in the Falcon Project (*i.e.,* Falcon Dam and Reservoir). Rights-of-way for the Falcon Project totaled 63,192 acres on the U.S. side of the Falcon Project as of 2000. This project will assist USIBWC in determining if grazing leases should be allowed or discontinued and/or whether land management alternatives should be established in lieu of grazing.

The grazing lease program has continued for areas along the Falcon Reservoir that were originally ranches and farms before the land was acquired by the federal Government pursuant to the Water Treaty of 1944 between the U.S. and Mexico, with construction of the Falcon Project completed on October 19, 1953. The grazing lease program assured those areas not under water or flooded and owned by the federal Government would be economically used as they were in the past by the local community. Initially leases allowed for agricultural uses in addition to grazing, but agricultural activities and any clearing of leased lands were later restricted to reduce potential impacts on cultural resources in accordance with National Historic Preservation Act requirements. Active leases currently only allow grazing activities.

Grazing leases, licenses, and permits consist of any written permit or other legal document for an individual, corporation, etc., to use and improve land owned by the U.S. Government under the jurisdiction of the USIBWC at Falcon Reservoir. In the past, 22,270.57 acres of land were under 159 active grazing leases originally issued in 1956. As of 2020, there were 117 active grazing leases with many that are still held by the descendants of the original permittees and/or stakeholders.

The purpose for the Proposed Action is to successfully manage federal land in the Falcon Project. Federal lands associated with the Falcon Project have been utilized by the public for various activities, including grazing leases, since the Falcon Project was established. However, the economic value of these leases and the challenges to successful land management require a reevaluation of the grazing lease program. The need is to implement land management alternatives to grazing leases that address low grazing lease values, limited access by USIBWC to leased lands, and unauthorized activities on leased lands.

Pursuant to Section 102(2)(c) of the National Environmental Policy Act (NEPA) of 1969; the Council on Environmental Quality Final Regulations, and the USIBWC Operational Procedures for Implementing Section 102 of NEPA, published in the **Federal Register** September 2, 1981, USIBWC developed and analyzed eight alternatives for modifying the grazing lease program at the Falcon Project, including the No Action Alternative. Alternative 1, No Action Alternative, is a requirement of the NEPA process and is included to provide a baseline against which the other alternatives can be evaluated. The action alternatives include: Alternative 2—Terminate Leases, Alternative 3—Change Rental Rates on Active Leases and Implement Improved Program Management, Alternative 4—Allow Hunting on Existing Grazing Leases, Alternative 5—Terminate Leases Not Directly Accessible from Public Rights-of-Way, Alternative 6—Negotiate Access Easements on Private Property for Existing Leases, Alternative 7—Amend Leases to Allow Vegetation Management, and Alternative 8—Form a Citizens' Committee to Provide Lease Management Support. The USIBWC has identified that one or any combination of the alternatives could be implemented to manage the grazing lease program at the Falcon Project.

Potential impacts on natural, cultural, and other resources were evaluated in the Draft EA. The USIBWC prepared a FONSI for the Action Alternatives, based on a review of the facts and analyses contained in the Draft EA.

Dated: November 15, 2023.

Rebecca A. Rizzuti,

Deputy Chief Legal Counsel, International Boundary and Water Commission, United States Section.

[FR Doc. 2023–25784 Filed 11–21–23; 8:45 am]

BILLING CODE 7010–01–P

INTERNATIONAL TRADE COMMISSION

[USITC SE–23–055]

Sunshine Act Meetings

AGENCY HOLDING THE MEETING: United States International Trade Commission.

TIME AND DATE: November 30, 2023 at 11 a.m.

PLACE: Room 101, 500 E Street SW, Washington, DC 20436, Telephone: (202) 205–2000.

STATUS: Open to the public.

MATTERS TO BE CONSIDERED:

1. *Agendas for future meetings:* none.
2. Minutes.
3. Ratification List.
4. Commission vote on Inv. No. 731–TA–1658 (Preliminary) (Truck and Bus Tires from Thailand). The Commission currently is scheduled to complete and file its determinations on December 1, 2023; views of the Commission currently are scheduled to be completed and filed on December 8, 2023.
5. Commission vote on Inv. Nos. 701–TA–566 and 731–TA–1342 (Review) (Softwood Lumber Products from Canada). The Commission currently is scheduled to complete and file its determinations and views of the Commission on December 20, 2023.
6. *Outstanding action jackets:* none.

CONTACT PERSON FOR MORE INFORMATION: Sharon Bellamy, Supervisory Hearings and Information Officer, 202–205–2000.

The Commission is holding the meeting under the Government in the Sunshine Act, 5 U.S.C. 552(b). In accordance with Commission policy, subject matter listed above, not disposed of at the scheduled meeting, may be carried over to the agenda of the following meeting.

By order of the Commission.

Issued: November 20, 2023.

Lisa Barton,

Secretary to the Commission.

[FR Doc. 2023–26001 Filed 11–20–23; 4:15 pm]

BILLING CODE 7020–02–P

DEPARTMENT OF JUSTICE

[OMB Number 1125–0017]

Agency Information Collection Activities; Proposed eCollection eComments Requested; Certification and Release of Records

AGENCY: Executive Office for Immigration Review, Department of Justice.

ACTION: 30-Day notice.

SUMMARY: The Executive Office for Immigration Review (EOIR), Department of Justice (DOJ), will be submitting the following information collection (ICR) request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995. The proposed information collection was previously published in the **Federal Register** on September 7, 2023, allowing a 60-day comment period.

DATES: Comments are encouraged and will be accepted for 30 days until December 22, 2023.

FOR FURTHER INFORMATION CONTACT: If you have comments especially on the estimated public burden or associated response time, suggestions, or need a copy of the proposed information collection instrument with instructions or additional information, please contact: Lauren Alder Reid, Assistant Director, Office of Policy, Executive Office for Immigration Review, 5107 Leesburg Pike, Suite 2500, Falls Church, VA 22041, telephone: 703–305–0289, email: *lauren.alder.reid@usdoj.gov.*

SUPPLEMENTARY INFORMATION: Written comments and suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Your comments should address one or more of the following four points:

—Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
—Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
—Enhance the quality, utility, and clarity of the information to be collected; and/or
—Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

Written comments and recommendations for this information collection should be submitted within 30 days of the publication of this notice on the following website *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function and entering either the title of the information collection or the OMB Control Number 1125–0017. This information collection request may be viewed at *www.reginfo.gov.* Follow the instructions to view Department of Justice, information collections currently under review by OMB.

DOJ seeks PRA authorization for this information collection for three (3) years. OMB authorization for an ICR cannot be for more than three (3) years without renewal. The DOJ notes that information collection requirements submitted to the OMB for existing ICRs receive a month-to-month extension while they undergo review.

Overview of This Information Collection

1. *Type of Information Collection:* Revision and extension of a previously approved collection.

2. *Title of the Form/Collection:* Certification and Release of Records.

3. *Agency form number, if any, and the applicable component of the Department of Justice sponsoring the collection:* EOIR–59, Executive Office for Immigration Review.

4. *Affected public who will be asked or required to respond, as well as a brief abstract:* Individuals or households. The obligation to respond is optional and voluntary.

This ICR is used by EOIR to standardize and streamline requests for records related to cases or proceedings before EOIR pursuant to the Privacy Act and Freedom of Information Act (FOIA). An individual who is in or has been in proceedings before EOIR and seeks to authorize the disclosure of their information, including information retained in case files or a Record of Proceeding (documents, and if applicable, audio recordings), to an attorney, accredited representative, qualified organization, or other third party may use this form to authorize the disclosure. Revisions were made to the form to improve the Agency's implementation of the identity and guardianship verification requirements set forth in 28 CFR 16.41 and to ensure that privacy-protected information is not improperly released.

5. *Obligation to Respond:* Voluntary.

6. *Total Estimated Number of Respondents:* 55,475.

7. *Estimated Time per Respondent:* 10 minutes.

8. *Frequency:* Once a year or annually.

9. Total Estimated Annual Time Burden: 9,246 hours.

10. *Total Estimated Annual Other Costs Burden:* $0.

If additional information is required, contact: Darwin Arceo, Department Clearance Officer, Policy and Planning Staff, Justice Management Division, United States Department of Justice, Two Constitution Square, 145 N Street NE, 4W–218, Washington, DC 20530.

Dated: November 16, 2023.

Darwin Arceo,

Department Clearance Officer for PRA, U.S. Department of Justice.

[FR Doc. 2023–25763 Filed 11–21–23; 8:45 am]

BILLING CODE 4410–30–P

DEPARTMENT OF LABOR

Occupational Safety and Health Administration

[Docket No. OSHA–2011–0009]

Fire Brigades Standard; Extension of the Office of Management and Budget's (OMB) Approval of Information Collection (Paperwork) Requirements

AGENCY: Occupational Safety and Health Administration (OSHA), Labor.

ACTION: Request for public comments.

SUMMARY: OSHA solicits public comments concerning the proposal to extend the Office of Management and Budget's (OMB) approval of the information collection requirements specified in the Fire Brigades Standard.

DATES: Comments must be submitted (postmarked, sent, or received) by January 22, 2024.

ADDRESSES:

Electronically: You may submit comments and attachments electronically at *https://www.regulations.gov,* which is the Federal eRulemaking Portal. Follow the instructions online for submitting comments.

Docket: To read or download comments or other material in the docket, go to *https://www.regulations.gov.* Documents in the docket are listed in the *https://www.regulations.gov* index; however, some information (*e.g.,* copyrighted material) is not publicly available to read or download through the website. All submissions, including copyrighted material, are available for inspection through the OSHA Docket Office. Contact the OSHA Docket Office at (202) 693–2350 (TTY (877) 889–5627) for assistance in locating docket submissions.

Instructions: All submissions must include the agency name and OSHA docket number (OSHA–2011–0009) for the Information Collection Request (ICR). OSHA will place all comments, including any personal information, in the public docket, which may be made available online. Therefore, OSHA cautions interested parties about submitting personal information such as social security numbers and birthdates.

For further information on submitting comments, see the ''Public Participation'' heading in the section of this notice titled **SUPPLEMENTARY INFORMATION**.

FOR FURTHER INFORMATION CONTACT: Seleda Perryman or Theda Kenney, Directorate of Standards and Guidance, OSHA, U.S. Department of Labor; telephone (202) 693–2222.

SUPPLEMENTARY INFORMATION:

I. Background

The Department of Labor, as part of the continuing effort to reduce paperwork and respondent (*i.e.,* employer) burden, conducts a preclearance consultation program to provide the public with an opportunity to comment on proposed and continuing information collection requirements in accordance with the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3506(c)(2)(A)). This program ensures that information is in the desired format, reporting burden (time and costs) is minimal, the collection instruments are clearly understood, and OSHA's estimate of the information collection burden is accurate. The Occupational Safety and Health Act of 1970 (OSH Act) (29 U.S.C. 651 *et seq.*) authorizes information collection by employers as necessary or appropriate for enforcement of the OSH Act or for developing information regarding the causes and prevention of occupational injuries, illnesses, and accidents (29 U.S.C. 657). The OSH Act also requires that OSHA obtain such information with minimum burden upon employers, especially those operating small businesses, and to reduce to the maximum extent feasible unnecessary duplication of effort in obtaining information (29 U.S.C. 657).

OSHA does not mandate that employers establish fire brigades; however, if they do so, they must comply with the provisions of the Fire Brigades Standard. The provisions of the standard, including the paperwork requirements, apply to fire brigades, industrial fire departments, and private or contract fire departments, but not to airport crash rescue units or forest firefighting operations. Paragraphs (b)(1), (b)(2), and (c)(4) contain the paperwork requirements of the standard.

Under paragraph (b)(1) of the standard, employers must develop and maintain an organizational statement that establishes the: existence of a fire brigade; the basic organizational structure of the brigade; type, amount, and frequency of training provided to brigade members; expected number of members in the brigade; and functions that the brigade is to perform. This paragraph also specifies that the organizational statement must be available for review by workers, their designated representatives, and OSHA compliance officers. The organizational statement describes the functions performed by the brigade members and, thereby, determines the level of training and type of personal protective equipment (PPE) necessary for these members to perform their assigned functions safely. Making the statement available to workers, their designated representatives, and OSHA compliance officers ensures that the elements of the statement are consistent with the functions performed by the brigade members and the occupational hazards they experience, and that employers are providing training and PPE appropriate to these functions and hazards.

To permit a worker with known heart disease, epilepsy, or emphysema to participate in fire brigade emergency activities, paragraph (b)(2) of the standard requires employers to obtain a physician's certificate of the worker's fitness. This provision provides employers with a direct and efficient means of ascertaining whether or not they can safely expose workers with these medical conditions to the hazards of firefighting operations.

Paragraph (c)(4) of the standard requires employers to inform fire brigade members of special hazards, such as the storage and use of flammable liquids and gases, toxic chemicals, radioactive sources, water-reactive substances that may be present during fires and other emergencies, and any changes in these special hazards. It also requires that employers develop written procedures describing the actions that brigade members are to take when special hazards are present, and to make these procedures available in the education and training program and for review by brigade members.

II. Special Issues for Comment

OSHA has a particular interest in comments on the following issues:

- Whether the proposed information collection requirements are necessary for the proper performance of the agency's functions to protect workers, including whether the information is useful;
- The accuracy of OSHA's estimate of the burden (time and costs) of the information collection requirements, including the validity of the methodology and assumptions used;
- The quality, utility, and clarity of the information collected; and
- Ways to minimize the burden on employers who must comply; for example, by using automated or other technological information collection, and transmission techniques.

III. Proposed Actions

OSHA is requesting that OMB extend the approval of the information collection requirements contained in the

Fire Brigades Standard (29 CFR 1910.156). The agency is requesting an adjustment decrease in burden hours from 2,767 to 2,695, a total decrease of 72 hours. The adjustment is due to a decrease in the number of manufacturing facilities with 100 or more workers from 25,546 to 24,885. Also, the number of responses decreased from 3,832 to 3,733.

OSHA will summarize the comments submitted in response to this notice and will include this summary in the request to OMB to extend the approval of the information collection requirements.

Type of Review: Extension of a currently approved collection.

Title: The Fire Brigades Standard (29 CFR 1910.156).

OMB Control Number: 1218–0075.

Affected Public: Business or other for-profits.

Number of Respondents: 24,885.

Number of Responses: 3,733.

Frequency of Responses: On occasion.

Average Time per Response: Varies.

Estimated Total Burden Hours: 2,695.

Estimated Cost (Operation and Maintenance): $0.

IV. Public Participation—Submission of Comments on This Notice and internet Access to Comments and Submissions

You may submit comments in response to this document as follows: (1) electronically at *https://www.regulations.gov,* which is the Federal eRulemaking Portal; (2) by facsimile (fax); if your comments, including attachments, are not longer than 10 pages you may fax them to the OSHA Docket Office at 202–693–1648; or (3) by hard copy. All comments, attachments, and other material must identify the agency name and the OSHA docket number for the ICR (Docket No. OSHA–2011–0009). You may supplement electronic submissions by uploading document files electronically.

Comments and submissions are posted without change at *https://www.regulations.gov.* Therefore, OSHA cautions commenters about submitting personal information such as social security numbers and dates of birth. Although all submissions are listed in the *https://www.regulations.gov* index, some information (*e.g.,* copyrighted material) is not publicly available to read or download from this website. All submissions, including copyrighted material, are available for inspection and copying at the OSHA Docket Office. Information on using the *https://www.regulations.gov* website to submit comments and access the docket is available at the website's ''User Tips'' link.

Contact the OSHA Docket Office at (202) 693–2350, (TTY (877) 889–5627) for information about materials not available from the website, and for assistance in using the internet to locate docket submissions.

V. Authority and Signature

James S. Frederick, Deputy Assistant Secretary of Labor for Occupational Safety and Health, directed the preparation of this notice. The authority for this notice is the Paperwork Reduction Act of 1995 (44 U.S.C. 3506 *et seq.*) and Secretary of Labor's Order No. 8–2020 (85 FR 58393).

Signed at Washington, DC.

James S. Frederick,

Deputy Assistant Secretary of Labor for Occupational Safety and Health.

[FR Doc. 2023–25800 Filed 11–21–23; 8:45 am]

BILLING CODE 4510–26–P

DEPARTMENT OF LABOR

Occupational Safety and Health Administration

[Docket No. OSHA–2007–0043]

TUV SUD America, Inc.: Applications for Expansion of Recognition

AGENCY: Occupational Safety and Health Administration (OSHA), Labor.

ACTION: Notice.

SUMMARY: In this notice, OSHA announces the applications of TUV SUD America, Inc. (TUVAM) for expansion of recognition as a Nationally Recognized Testing Laboratory (NRTL) and presents the agency's preliminary finding to grant the applications.

DATES: Submit comments, information, and documents in response to this notice, or requests for an extension of time to make a submission, on or before December 7, 2023.

ADDRESSES: Comments may be submitted as follows:

Electronically: You may submit comments, including attachments, electronically at *http://www.regulations.gov,* the Federal eRulemaking Portal. Follow the online instructions for submitting comments.

Instructions: All submissions must include the agency's name and the docket number for this rulemaking (Docket No. OSHA–2007–0043). All comments, including any personal information you provide, are placed in the public docket without change and may be made available online at *https://www.regulations.gov.* Therefore, OSHA cautions commenters about submitting information they do not want made available to the public, or submitting materials that contain personal information (either about themselves or others), such as Social Security numbers and birthdates.

Docket: To read or download comments or other material in the docket, go to *http://www.regulations.gov.* Documents in the docket (including this **Federal Register** notice) are listed in the *http://www.regulations.gov* index; however, some information (*e.g.,* copyrighted material) is not publicly available to read or download through the website. All submissions, including copyrighted material, are available for inspection through the OSHA Docket Office. Contact the OSHA Docket Office at (202) 693–2350 (TTY (877) 889–5627) for assistance in locating docket submissions.

Extension of comment period: Submit requests for an extension of the comment period on or before December 7, 2023 to the Office of Technical Programs and Coordination Activities, Directorate of Technical Support and Emergency Management, Occupational Safety and Health Administration, U.S. Department of Labor, 200 Constitution Avenue NW, Room N–3653, Washington, DC 20210, or by fax to (202) 693–1644.

FOR FURTHER INFORMATION CONTACT: Information regarding this notice is available from the following sources:

Press inquiries: Contact Mr. Frank Meilinger, Director, OSHA Office of Communications, U.S. Department of Labor by phone: (202) 693–1999 or email: *meilinger.francis2@dol.gov.*

General and technical information: Contact Mr. Kevin Robinson, Director, Office of Technical Programs and Coordination Activities, Directorate of Technical Support and Emergency Management, Occupational Safety and Health Administration, U.S. Department of Labor by phone: (202) 693–1911 or email: *robinson.kevin@dol.gov.*

SUPPLEMENTARY INFORMATION:

I. Notice of the Applications for Expansion

OSHA is providing notice that TUV SUD America, Inc. (TUVAM) is applying for expansion of the current recognition as a NRTL. TUVAM requests the addition of two recognized testing standards and one recognized testing site to the NRTL scope of recognition.

OSHA recognition of a NRTL signifies that the organization meets the requirements specified in 29 CFR 1910.7. Recognition is an acknowledgment that the organization

can perform independent safety testing and certification of the specific products covered within its scope of recognition. Each NRTL's scope of recognition includes (1) the type of products the NRTL may test, with each type specified by its applicable test standard; and (2) the recognized site(s) that has/have the technical capability to perform the product-testing and product-certification activities for test standards within the NRTL's scope. Recognition is not a delegation or grant of government authority; however, recognition enables employers to use products approved by the NRTL to meet OSHA standards that require product testing and certification.

The agency processes an application by a NRTL for initial recognition and for an expansion or renewal of this recognition, following requirements in Appendix A, 29 CFR 1910.7. This appendix requires that the agency publish two notices in the **Federal Register** in processing an application. In the first notice, OSHA announces the application and provides its preliminary finding. In the second notice, the agency provides the final decision on the application. These notices set forth the NRTL's scope of recognition or modifications of that scope. OSHA maintains an informational web page for each NRTL, including TUVAM, which details the NRTL's scope of recognition. These pages are available from the OSHA website at: *https://www.osha.gov/nationally-recognized-testing-laboratory-program.*

TUVAM currently has sixteen facilities (sites) recognized by OSHA for product testing and certification, with its headquarters located at: TUV SUD America, Inc., 401 Edgewater Place, Suite 500, Wakefield, MA 01880. A complete list of TUVAM's scope of recognition (including sites recognized by OSHA) is available at: *https://www.osha.gov/nationally-recognized-testing-laboratory-program.*

II. General Background on the Applications

TUVAM submitted two applications to OSHA for expansion of the NRTL scope of recognition. The first application, dated June 8, 2020 (OSHA–2007–0043–0051), requested the expansion of the NRTL scope of recognition to include one additional test site located at: Daimlerstr, 40 Frankfurt am Main, Hessen 60314 Germany. The second application dated July 12, 2021 (OSHA–2007–0043–0052), requested the expansion of the NRTL scope of recognition to include two additional test standards that were removed from another NRTL expansion application (see OSHA–2007–0043–0042). In that application, TUVAM originally requested the addition of five standards to their scope of recognition on July 12, 2021. That application was amended to remove two standards, and the final **Federal Register** notice announcing the expansion of the NRTL scope of recognition to include the other three standards was published on June 29, 2022 (see 87 FR 38784). This notice covers the remaining two standards from the July 12, 2021, expansion application and the requested testing site. OSHA staff performed an on-site review of TUVAM's testing facilities at TUVAM Frankfurt on June 14–15, 2023, in which assessors found some nonconformances with the requirements of 29 CFR 1910.7. TUVAM has addressed these issues sufficiently, and OSHA staff has preliminarily determined that OSHA should grant the applications.

Table 1 below lists the appropriate test standards found in TUVAM's applications for expansion for testing and certification of products under the NRTL Program.

TABLE 1—PROPOSED LIST OF APPROPRIATE TEST STANDARDS FOR INCLUSION IN TUVAM'S NRTL SCOPE OF RECOGNITION

Test standard	Test standard title
UL 61010–2–040 ..	Safety Requirements for Electrical Equipment for Measurement, Control and Laboratory Use—Part 2–040: Particular Requirements for Sterilizers and Washer-Disinfectors Used to Treat Medical Materials.
UL 61010–2–091 ..	Standard for Safety Requirements for Electrical Equipment for Measurement, Control and Laboratory Use—Part 2–091: Particular Requirements for Cabinet X-Ray Systems.

III. Preliminary Findings on the Applications

TUVAM submitted acceptable applications for expansion of the NRTL scope of recognition. OSHA's review of the application file, and pertinent documentation, indicate that TUVAM can meet the requirements prescribed by 29 CFR 1910.7 for expanding their recognition to include the addition of two additional testing standards and one additional testing site for NRTL testing and certification. This preliminary finding does not constitute an interim or temporary approval of TUVAM's applications. OSHA seeks comment on this preliminary determination.

IV. Public Participation

OSHA welcomes public comment as to whether TUVAM meets the requirements of 29 CFR 1910.7 for expansion of recognition as a NRTL. Comments should consist of pertinent written documents and exhibits.

Commenters needing more time to comment must submit a request in writing, stating the reasons for the request by the due date for comments. OSHA will limit any extension to 10 days unless the requester justifies a longer time period. OSHA may deny a request for an extension if it is not adequately justified.

To review copies of the exhibits identified in this notice, as well as comments submitted to the docket, contact the Docket Office, Occupational Safety and Health Administration, U.S. Department of Labor. These materials also are generally available online at *https://www.regulations.gov* under Docket No. OSHA–2007–0043 (for further information, see the ''*Docket*'' heading in the section of this notice titled **ADDRESSES**).

OSHA staff will review all comments to the docket submitted in a timely manner. After addressing the issues raised by these comments, staff will make a recommendation to the Assistant Secretary of Labor for Occupational Safety and Health on whether to grant TUVAM's applications for expansion of the scope of recognition. The Assistant Secretary will make the final decision on granting the applications. In making this decision, the Assistant Secretary may undertake other proceedings prescribed in Appendix A to 29 CFR 1910.7.

OSHA will publish a public notice of the final decision in the **Federal Register**.

V. Authority and Signature

James S. Frederick, Deputy Assistant Secretary of Labor for Occupational Safety and Health, 200 Constitution Avenue NW, Washington, DC 20210,

authorized the preparation of this notice. Accordingly, the agency is issuing this notice pursuant to Section 29 U.S.C. 657(g)(2), Secretary of Labor's Order No. 8–2020 (85 FR 58393; Sept. 18, 2020), and 29 CFR 1910.7.

Signed at Washington, DC.

James S. Frederick,

Deputy Assistant Secretary of Labor for Occupational Safety and Health.

[FR Doc. 2023–25758 Filed 11–21–23; 8:45 am]

BILLING CODE 4510–26–P

NATIONAL TRANSPORTATION SAFETY BOARD

[Docket No.: NTSB–2023–0005]

Information Collection: Generic Clearance for the Collection of Qualitative Feedback on Agency Service Delivery

AGENCY: National Transportation Safety Board (NTSB).

ACTION: Notice and request for comments for a new information collection.

SUMMARY: Under the Paperwork Reduction Act (PRA) of 1995, this notice announces that the NTSB's Information Collection Request (ICR) will be submitted to the Office of Management and Budget (OMB) for review and approval. On May 30, 2023, the NTSB published the requisite 60-Day Notice in the **Federal Register**, notifying the public that the NTSB seeks OMB approval on generic clearance for qualitative feedback on agency service delivery. To date, no comments have been received. However, the NTSB has since corrected a typographical error regarding the estimated average burden hours and has added to the list of the types of collections that this generic clearance covers. The NTSB is now issuing this 30-Day Notice, directing the public to submit all comments to OMB.

DATES: Submit written comments to OMB regarding this proposed collection of information by December 22, 2023.

ADDRESSES: Submit written comments to OMB at *www.reginfo.gov/public/do/PRAMain.* To find this IC, select ''Currently under Review—Open for Public Comments'' or use the search function.

FOR FURTHER INFORMATION CONTACT: William T. (Tom) McMurry, Jr., General Counsel, (202) 314–6080, *rulemaking@ntsb.gov.*

SUPPLEMENTARY INFORMATION: A **Federal Register** notice with a 60-day comment period was published on May 30, 2023, notifying the public of the agency's intent to seek OMB approval on generic clearance for qualitative feedback on agency service delivery; no comments were received as a result. However, the NTSB has since corrected a typographical error regarding the estimated average burden hours per respondent from 30 minutes to 5 minutes. This correction is consistent with the agency's total estimated annual burden hours of 1,250 for the 15,000 total estimated number of annual responses. Further, the NTSB has added to its list of the types of collections that this generic clearance covers. The NTSB is currently issuing this 30-Day notice, informing the public that the agency will now submit the following ICR to OMB and that all comments should be directed to OMB:

Title of Collection: Generic Clearance for the Collection of Qualitative Feedback on Agency Service Delivery.

Form Number: To be determined by specific collections.

Type of Request: New Collection.

Type of Review: Regular.

Type of Review Requested: 3 years from the date of approval.

Summary of the Collection of Information: With the goal of ensuring that the Federal Government provided the highest quality service as possible, Executive Order (E.O.) 12862 (Setting Customer Service Standards) was issued to set customer service standards to a level that either matched or exceeded the best service available in the private sector. Accordingly, E.O. 12862 directed Federal agencies to create customer surveys to obtain information on customer satisfaction. E.O. 14058 (Transforming Federal Customer Experience and Service Delivery to Rebuild Trust in Government) was later issued and reiterated the Federal Government's commitment to improve a customer's experience in an agency's service delivery. E.O. 14058 defined service delivery as an action related to a Federal benefit or service provided to a customer.

To ensure that the NTSB's service delivery is effective and meets its customer needs, the NTSB seeks OMB approval of a generic clearance to collect qualitative feedback on the agency's service delivery. This proposed IC provides a means to garner qualitative feedback in an efficient, timely manner in accordance with the commitment to improving service delivery.

Qualitative feedback is information that will provide insights into 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 and services. This feedback will allow for ongoing, collaborative, and actionable communications between the NTSB and its stakeholders. It will also allow for feedback to contribute directly to the improvement of program management.

The feedback solicited will target areas that include, but are not limited to: 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 is not collected, vital feedback from stakeholders on the agency's services will be unavailable.

The agency will only submit a collection for approval under this generic clearance if it meets the following conditions:

- The collection is voluntary;
- The collection is low-burden for respondents (based on considerations of total burden hours, total number of respondents, or burden-hours per respondent) and is low-cost for both the respondents and the Federal Government;
- The collection is non-controversial and does 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 only internally for general service improvement and program management purposes and is not intended for release outside of the agency (if released, the agency must indicate the qualitative nature of the information);
- 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 study. The types of collections that this generic clearance covers include, but are not limited to:
- Customer comment cards/complaint forms.
- Qualitative customer satisfaction surveys (*e.g.,* post-meeting surveys; web surveys).

• In-person observation testing (*e.g.,* website or software usability tests).
• Small discussion groups.
• Focus Groups of customers, potential customers, delivery partners, or other stakeholders.
• Cognitive laboratory studies, such as those used to refine questions or assess usability of a website.

Feedback collected under this generic clearance provides useful information, but it does not yield data that can be generalized to the overall population. 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. Such data uses 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. Depending on the degree of influence the results are likely to have, such as collections may still be eligible for submission for other generic mechanisms that are designed to yield quantitative results.

As a general matter, information collections under this request 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.

Current Actions: New collection of information.

Type of Review: New Collection.

Affected Public: Individuals and Households, Businesses and Organizations, and State, Local, or Tribal Government.

Total Estimated Annual Burden Hours: 1,250.

Estimated Average Burden Hours per Respondent: 5 minutes.

Frequency of Response: On occasion, per request.

Total Estimated No. of Annual Responses: 15,000.

The 1,250 annual burden hours requested are based on the number of collections the NTSB expects to conduct over the requested three-year period for this generic clearance.

Estimated Total Annual Burden Cost: $0.

Participation in this collection is voluntary, and there are no costs to respondents beyond the time spent participating in the surveys.

Request for Comments: OMB is interested in comments that include: (1) whether the proposed collection is necessary for the NTSB to perform its mission; (2) the accuracy of the estimated burden; (3) ways for the NTSB to enhance the quality, usefulness, and clarity of the IC; and (4) ways to minimize burden without reducing the quality of the IC.

William T. McMurry, Jr.,

General Counsel.

[FR Doc. 2023–25863 Filed 11–21–23; 8:45 am]

BILLING CODE 7533–01–P

NUCLEAR REGULATORY COMMISSION

[Docket Nos. 50–611 and 50–612; NRC–2023–0138]

Kairos Power, LLC; Hermes 2

AGENCY: Nuclear Regulatory Commission.

ACTION: Construction permit application; opportunity to request a hearing and petition for leave to intervene; order imposing procedures.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is providing notice that an uncontested hearing will be held on the Kairos Power, LLC (Kairos) construction permit application that proposes the construction of a test reactor facility, identified as 'Hermes 2', in Oak Ridge, Tennessee, at a time and place to be set in the future by the Commission or designated by the Atomic Safety and Licensing Board. This notice provides the public an opportunity to request a hearing and petition for leave to intervene (*i.e.,* contested hearing) with respect to that application. The NRC staff is currently conducting a detailed technical review of the construction permit application. If the NRC issues a construction permit, the applicant, Kairos, would be authorized to construct its proposed test reactor facility in accordance with the provisions of the construction permit. Because the application contains Sensitive Unclassified Non-Safeguards Information (SUNSI), an order imposes procedures to obtain access to this type of information for contention preparation.

DATES: A request for a hearing or petitions for leave to intervene must be filed by January 22, 2024. Any potential party as defined in section 2.4 of title 10 of the *Code of Federal Regulations* (10 CFR) who believes access to SUNSI is necessary to respond to this notice must request document access by December 4, 2023.

ADDRESSES: Please refer to Docket ID NRC–2023–0138 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–2023–0138. Address questions about Docket IDs in *Regulations.gov* to Stacy Schumann; telephone: 301–415–0624; email: *Stacy.Schumann@nrc.gov.* For technical questions, contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.

• *NRC's Agencywide Documents Access and Management System (ADAMS):* You may obtain publicly available documents online in the ADAMS Public Documents collection at *https://www.nrc.gov/reading-rm/adams.html.* To begin the search, select ''Begin Web-based ADAMS Search.'' For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1–800–397–4209, at 301–415–4737, or by email to *PDR.Resource@nrc.gov.* 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.

• *NRC's PDR:* The PDR, where you may examine and order copies of publicly available documents, is open by appointment. To make an appointment to visit the PDR, please send an email to *PDR.Resource@nrc.gov* or call 1–800–397–4209 or 301–415–4737, between 8 a.m. and 4 p.m. eastern time (ET), Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Michael Orenak, Office of Nuclear Reactor Regulation, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001; telephone: 301–415–3229; email: *Michael.Orenak@nrc.gov.*

SUPPLEMENTARY INFORMATION:

I. Introduction

On July 14, 2023, Kairos Power LLC (Kairos) submitted, pursuant to 10 CFR part 50, ''Domestic Licensing of Production and Utilization Facilities,'' an application (ADAMS Package Accession No. ML23195A121) for a construction permit for the 'Hermes 2' test reactor facility (a ''testing facility'' as defined in 10 CFR 50.2), that would consist of two fluoride salt-cooled test

reactor units at the East Tennessee Technology Park in Oak Ridge, Tennessee. A notice of receipt and availability was published in the **Federal Register** on August 4, 2023 (88 FR 51876). The NRC staff determined that Kairos submitted the application in accordance with 10 CFR 2.101(a)(5), and a notice of the acceptability of docketing of Kairos's application was published in the **Federal Register** on September 15, 2023 (88 FR 63632). The docket numbers established for this application are 50–611 and 50–612 for Units 1 and 2, respectively.

The NRC is considering issuance of a construction permit to Kairos that would authorize construction of the proposed Hermes 2 test reactor facility to be located in Oak Ridge, Tennessee. The Hermes 2 facility would contain two fluoride-salt cooled, high-temperature test reactors using solid tri-structural isotropic fuel in pebble form. Each test reactor would contain an intermediate heat transfer loop and share a common power generation system.

II. Hearing

Pursuant to the Atomic Energy Act of 1954, as amended, 10 CFR part 2, ''Agency Rules of Practice and Procedure,'' and part 50, notice is hereby given that an uncontested (*i.e.,* mandatory) hearing will be held, at a time and place to be set in the future by the Commission or designated by the Atomic Safety and Licensing Board (Board).

The hearing on the application for a construction permit filed by Kairos pursuant to 10 CFR part 50 will be conducted by a Board that will be designated by the Chief Judge of the Atomic Safety and Licensing Board Panel or will be conducted by the Commission. If the hearing is conducted by a Board, notice as to the membership of the Board will be published in the **Federal Register** at a later date. The NRC staff will complete a detailed technical review of the application and will document its findings in a safety evaluation. The Commission will refer a copy of the application to the Advisory Committee on Reactor Safeguards (ACRS) in accordance with 10 CFR 50.58, ''Hearings and Report of the Advisory Committee on Reactor Safeguards,'' and the ACRS will report on those portions of the application that concern safety. The NRC staff will also complete an environmental review of the application and will document its findings in accordance with the National Environmental Policy Act of 1969 (NEPA), as amended, and the Commission's regulations in 10 CFR part 51, ''Environmental Protection Regulations for Domestic Licensing and Related Regulatory Functions.'' The staff will prepare an environmental assessment that will be used to determine whether an environmental impact statement is necessary or a finding of no significant impact is warranted to satisfy the NRC's NEPA obligations.

III. Opportunity To Request a Hearing and Petition for Leave To Intervene

Within 60 days after the date of publication of this notice, any person (petitioner) whose interest may be affected by this action may file a request for a hearing and petition for leave to intervene (petition) with respect to the action. Petitions shall be filed in accordance with the Commission's ''Agency Rules of Practice and Procedure'' in 10 CFR part 2. Interested persons should consult 10 CFR 2.309. If a petition is filed, the presiding officer will rule on the petition and, if appropriate, a notice of a hearing will be issued.

Petitions must be filed no later than 60 days from the date of publication of this notice in accordance with the filing instructions in the ''Electronic Submissions (E-Filing)'' section of this document. Petitions and motions for leave to file new or amended contentions that are filed after the deadline will not be entertained absent a determination by the presiding officer that the filing demonstrates good cause by satisfying the three factors in 10 CFR 2.309(c)(1)(i) through (iii).

A State, local governmental body, Federally recognized Indian Tribe, or designated agency thereof, may submit a petition to the Commission to participate as a party under 10 CFR 2.309(h)(1) no later than 60 days from the date of publication of this notice. Alternatively, a State, local governmental body, Federally recognized Indian Tribe, or agency thereof may participate as a non-party under 10 CFR 2.315(c).

For information about filing a petition and about participation by a person not a party under 10 CFR 2.315(c), see ADAMS Accession No. ML20340A053 (*https://adamswebsearch2.nrc.gov/webSearch2/main.jsp?AccessionNumber=ML20340A053*) and on the NRC website at *https://www.nrc.gov/about-nrc/regulatory/adjudicatory/hearing.html#participate.*

IV. Electronic Submissions (E-Filing)

All documents filed in NRC adjudicatory proceedings, including documents filed by an interested State, local governmental body, Federally recognized Indian Tribe, or designated agency thereof that requests to participate under 10 CFR 2.315(c), must be filed in accordance with 10 CFR 2.302. The E-Filing process requires participants to submit and serve all adjudicatory documents over the internet, or in some cases, to mail copies on electronic storage media, unless an exemption permitting an alternative filing method, as further discussed, is granted. Detailed guidance on electronic submissions is located in the ''Guidance for Electronic Submissions to the NRC'' (ADAMS Accession No. ML13031A056) and on the NRC's public website at *https://www.nrc.gov/site-help/e-submittals.html.*

To comply with the procedural requirements of E-Filing, at least 10 days prior to the filing deadline, the participant should contact the Office of the Secretary by email at *Hearing.Docket@nrc.gov,* or by telephone at 301–415–1677, to (1) request a digital identification (ID) certificate, which allows the participant (or its counsel or representative) to digitally sign submissions and access the E-Filing system for any proceeding in which it is participating; and (2) advise the Secretary that the participant will be submitting a petition or other adjudicatory document (even in instances in which the participant, or its counsel or representative, already holds an NRC-issued digital ID certificate). Based upon this information, the Secretary will establish an electronic docket for the proceeding if the Secretary has not already established an electronic docket.

Information about applying for a digital ID certificate is available on the NRC's public website at *https://www.nrc.gov/site-help/e-submittals/getting-started.html.* After a digital ID certificate is obtained and a docket created, the participant must submit adjudicatory documents in Portable Document Format. Guidance on submissions is available on the NRC's public website at *https://www.nrc.gov/site-help/electronic-sub-ref-mat.html.* A filing is considered complete at the time the document is submitted through the NRC's E-Filing system. To be timely, an electronic filing must be submitted to the E-Filing system no later than 11:59 p.m. ET on the due date. Upon receipt of a transmission, the E-Filing system time-stamps the document and sends the submitter an email confirming receipt of the document. The E-Filing system also distributes an email that provides access to the document to the NRC's Office of the General Counsel and any others who have advised the Office of the Secretary that they wish to

participate in the proceeding, so that the filer need not serve the document on those participants separately. Therefore, applicants and other participants (or their counsel or representative) must apply for and receive a digital ID certificate before adjudicatory documents are filed to obtain access to the documents via the E-Filing system.

A person filing electronically using the NRC's adjudicatory E-Filing system may seek assistance by contacting the NRC's Electronic Filing Help Desk through the ''Contact Us'' link located on the NRC's public website at *https://www.nrc.gov/site-help/e-submittals.html,* by email to *MSHD.Resource@nrc.gov,* or by a toll-free call at 1–866–672–7640. The NRC Electronic Filing Help Desk is available between 9 a.m. and 6 p.m., ET, Monday through Friday, except Federal holidays.

Participants who believe that they have good cause for not submitting documents electronically must file an exemption request, in accordance with 10 CFR 2.302(g), with their initial paper filing stating why there is good cause for not filing electronically and requesting authorization to continue to submit documents in paper format. Such filings must be submitted in accordance with 10 CFR 2.302(b)–(d). Participants filing adjudicatory documents in this manner are responsible for serving their documents on all other participants. Participants granted an exemption under 10 CFR 2.302(g)(2) must still meet the electronic formatting requirement in 10 CFR 2.302(g)(1), unless the participant also seeks and is granted an exemption from 10 CFR 2.302(g)(1).

Documents submitted in adjudicatory proceedings will appear in the NRC's electronic hearing docket, which is publicly available at *https://adams.nrc.gov/ehd,* unless excluded pursuant to an order of the presiding officer. If you do not have an NRC-issued digital ID certificate as previously described, click ''cancel'' when the link requests certificates and you will be automatically directed to the NRC's electronic hearing dockets where you will be able to access any publicly available documents in a particular hearing docket. Participants are requested not to include personal privacy information such as social security numbers, home addresses, or personal phone numbers in their filings unless an NRC regulation or other law requires submission of such information. With respect to copyrighted works, except for limited excerpts that serve the purpose of the adjudicatory filings and would constitute a Fair Use application, participants should not include copyrighted materials in their submission.

Order Imposing Procedures for Access to Sensitive Unclassified Non-Safeguards Information for Contention Preparation

A. This Order contains instructions regarding how potential parties to this proceeding may request access to documents containing Sensitive Unclassified Non-Safeguards Information (SUNSI).

B. Within 10 days after publication of this notice of hearing or opportunity for hearing, any potential party who believes access to SUNSI is necessary to respond to this notice may request access to SUNSI. A ''potential party'' is any person who intends to participate as a party by demonstrating standing and filing an admissible contention under 10 CFR 2.309. Requests for access to SUNSI submitted later than 10 days after publication of this notice will not be considered absent a showing of good cause for the late filing, addressing why the request could not have been filed earlier.

C. The requestor shall submit a letter requesting permission to access SUNSI to the Office of the Secretary, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, Attention: Rulemakings and Adjudications Staff, and provide a copy to the Deputy General Counsel for Licensing, Hearings, and Enforcement, Office of the General Counsel, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001. The expedited delivery or courier mail address for both offices is: U.S. Nuclear Regulatory Commission, 11555 Rockville Pike, Rockville, Maryland 20852. The email addresses for the Office of the Secretary and the Office of the General Counsel are *Hearing.Docket@nrc.gov* and *RidsOgcMailCenter.Resource@nrc.gov,* respectively.[1] The request must include the following information:

(1) A description of the licensing action with a citation to this **Federal Register** notice;

(2) The name and address of the potential party and a description of the potential party's particularized interest that could be harmed by the action identified in C.(1); and

(3) The identity of the individual or entity requesting access to SUNSI and the requestor's basis for the need for the information in order to meaningfully participate in this adjudicatory proceeding. In particular, the request must explain why publicly available versions of the information requested would not be sufficient to provide the basis and specificity for a proffered contention.

D. Based on an evaluation of the information submitted under paragraph C, the NRC staff will determine within 10 days of receipt of the request whether:

(1) There is a reasonable basis to believe the petitioner is likely to establish standing to participate in this NRC proceeding; and

(2) The requestor has established a legitimate need for access to SUNSI.

E. If the NRC staff determines that the requestor satisfies both D.(1) and D.(2), the NRC staff will notify the requestor in writing that access to SUNSI has been granted. The written notification will contain instructions on how the requestor may obtain copies of the requested documents, and any other conditions that may apply to access to those documents. These conditions may include, but are not limited to, the signing of a Non-Disclosure Agreement or Affidavit, or Protective Order[2] setting forth terms and conditions to prevent the unauthorized or inadvertent disclosure of SUNSI by each individual who will be granted access to SUNSI.

F. Filing of Contentions. Any contentions in these proceedings that are based upon the information received as a result of the request made for SUNSI must be filed by the requestor no later than 25 days after receipt of (or access to) that information. However, if more than 25 days remain between the petitioner's receipt of (or access to) the information and the deadline for filing all other contentions (as established in the notice of hearing or opportunity for hearing), the petitioner may file its SUNSI contentions by that later deadline.

G. Review of Denials of Access.

(1) If the request for access to SUNSI is denied by the NRC staff after a determination on standing and requisite need, the NRC staff shall immediately notify the requestor in writing, briefly stating the reason or reasons for the denial.

(2) The requestor may challenge the NRC staff's adverse determination by filing a challenge within 5 days of receipt of that determination with: (a) the presiding officer designated in this

[1] While a request for hearing or petition to intervene in this proceeding must comply with the filing requirements of the NRC's ''E-Filing Rule,'' the initial request to access SUNSI under these procedures should be submitted as described in this paragraph.

[2] Any motion for Protective Order or draft Non-Disclosure Affidavit or Agreement for SUNSI must be filed with the presiding officer or the Chief Administrative Judge if the presiding officer has not yet been designated, within 30 days of the deadline for the receipt of the written access request.

proceeding; (b) if no presiding officer has been appointed, the Chief Administrative Judge, or if this individual is unavailable, another administrative judge, or an Administrative Law Judge with jurisdiction pursuant to 10 CFR 2.318(a); or (c) if another officer has been designated to rule on information access issues, with that officer.

(3) Further appeals of decisions under this paragraph must be made pursuant to 10 CFR 2.311.

H. Review of Grants of Access. A party other than the requestor may challenge an NRC staff determination granting access to SUNSI whose release would harm that party's interest independent of the proceeding. Such a challenge must be filed within 5 days of the notification by the NRC staff of its grant of access and must be filed with: (a) the presiding officer designated in this proceeding; (b) if no presiding officer has been appointed, the Chief Administrative Judge, or if this individual is unavailable, another administrative judge, or an Administrative Law Judge with jurisdiction pursuant to 10 CFR 2.318(a); or (c) if another officer has been designated to rule on information access issues, with that officer.

If challenges to the NRC staff determinations are filed, these procedures give way to the normal process for litigating disputes concerning access to information. The availability of interlocutory review by the Commission of orders ruling on such NRC staff determinations (whether granting or denying access) is governed by 10 CFR 2.311.[3]

I. The Commission expects that the NRC staff and presiding officers (and any other reviewing officers) will consider and resolve requests for access to SUNSI, and motions for protective orders, in a timely fashion in order to minimize any unnecessary delays in identifying those petitioners who have standing and who have propounded contentions meeting the specificity and basis requirements in 10 CFR part 2. The attachment to this Order summarizes the general target schedule for processing and resolving requests under these procedures.

It is so ordered.

Dated: November 17, 2023.

For the Nuclear Regulatory Commission.

Carrie M. Safford,

Secretary of the Commission.

ATTACHMENT 1—General Target Schedule for Processing and Resolving Requests for Access to Sensitive Unclassified Non-Safeguards Information in This Proceeding

Day	Event/Activity
0	Publication of **Federal Register** notice of hearing or opportunity for hearing, including order with instructions for access requests.
10	Deadline for submitting requests for access to Sensitive Unclassified Non-Safeguards Information (SUNSI) with information: supporting the standing of a potential party identified by name and address; describing the need for the information in order for the potential party to participate meaningfully in an adjudicatory proceeding.
60	Deadline for submitting petition for intervention containing: (i) demonstration of standing; and (ii) all contentions whose formulation does not require access to SUNSI (+25 Answers to petition for intervention; +7 petitioner/requestor reply).
20	U.S. Nuclear Regulatory Commission (NRC) staff informs the requestor of the staff's determination whether the request for access provides a reasonable basis to believe standing can be established and shows need for SUNSI. (NRC staff also informs any party to the proceeding whose interest independent of the proceeding would be harmed by the release of the information.) If NRC staff makes the finding of need for SUNSI and likelihood of standing, NRC staff begins document processing (preparation of redactions or review of redacted documents).
25	If NRC staff finds no ''need'' or no likelihood of standing, the deadline for petitioner/requestor to file a motion seeking a ruling to reverse the NRC staff's denial of access; NRC staff files copy of access determination with the presiding officer (or Chief Administrative Judge or other designated officer, as appropriate). If NRC staff finds ''need'' for SUNSI, the deadline for any party to the proceeding whose interest independent of the proceeding would be harmed by the release of the information to file a motion seeking a ruling to reverse the NRC staff's grant of access.
30	Deadline for NRC staff reply to motions to reverse NRC staff determination(s).
40	(Receipt +30) If NRC staff finds standing and need for SUNSI, deadline for NRC staff to complete information processing and file motion for Protective Order and draft Non-Disclosure Agreement or Affidavit. Deadline for applicant/licensee to file Non-Disclosure Agreement or Affidavit for SUNSI.
A	If access granted: issuance of presiding officer or other designated officer decision on motion for protective order for access to sensitive information (including schedule for providing access and submission of contentions) or decision reversing a final adverse determination by the NRC staff.
A + 3	Deadline for filing executed Non-Disclosure Agreements or Affidavits. Access provided to SUNSI consistent with decision issuing the protective order.
A + 28	Deadline for submission of contentions whose development depends upon access to SUNSI. However, if more than 25 days remain between the petitioner's receipt of (or access to) the information and the deadline for filing all other contentions (as established in the notice of hearing or notice of opportunity for hearing), the petitioner may file its SUNSI contentions by that later deadline.
A + 53	(Contention receipt +25) Answers to contentions whose development depends upon access to SUNSI.
A + 60	(Answer receipt +7) Petitioner/Intervenor reply to answers.
>A + 60	Decision on contention admission.

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BILLING CODE 7590–01–P

[3] Requestors should note that the filing requirements of the NRC's E-Filing Rule (72 FR 49139; August 28, 2007, as amended at 77 FR 46562; August 3, 2012, 78 FR 34247, June 7, 2013) apply to appeals of NRC staff determinations (because they must be served on a presiding officer or the Commission, as applicable), but not to the initial SUNSI request submitted to the NRC staff under these procedures.

NUCLEAR REGULATORY COMMISSION

[Docket No. 50–323; NRC–2023–0197]

Pacific Gas and Electric Company; Diablo Canyon Nuclear Power Plant, Unit 2

AGENCY: Nuclear Regulatory Commission.

ACTION: License amendment application; opportunity to comment, request a hearing, and petition for leave to intervene.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC, the Commission) is considering issuance of an amendment to Facility Operating License No. DPR–82, issued to Pacific Gas and Electric Company (PG&E, the licensee), for operation of the Diablo Canyon Nuclear Power Plant (Diablo Canyon), Unit 2. The proposed amendment would revise Technical Specification (TS) 3.7.8, ''Auxiliary Saltwater (ASW) System,'' Condition A note to allow a one-time Completion Time (CT) of 144 hours to replace the ASW Pump 2–2 motor during Cycle 24. The proposed amendment is being requested under exigent circumstances pursuant to NRC regulations.

DATES: Submit comments by December 6, 2023. Request for a hearing or petitions for leave to intervene must be filed by January 22, 2024.

ADDRESSES: You may submit comments by any of the following; however, the NRC encourages electronic comment submission through the Federal rulemaking website:

- *Federal rulemaking website:* Go to *https://www.regulations.gov* and search for Docket ID NRC–2023–0197. Address questions about Docket IDs in *Regulations.gov* to Stacy Schumann; telephone: 301–415–0624; email: *Stacy.Schumann@nrc.gov.* For technical questions, contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.
- *Mail comments to:* Office of Administration, Mail Stop: TWFN–7–A60M, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, ATTN: Program Management, Announcements and Editing Staff.

For additional direction on obtaining information and submitting comments, see ''Obtaining Information and Submitting Comments'' in the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT: Siva P. Lingam, Office of Nuclear Reactor Regulation, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, telephone: 301–415–1564; email: *Siva.Lingam@nrc.gov.*

SUPPLEMENTARY INFORMATION:

I. Obtaining Information and Submitting Comments

A. Obtaining Information

Please refer to Docket ID NRC–2023–0197 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–2023–0197.
- *NRC's Agencywide Documents Access and Management System (ADAMS):* You may obtain publicly available documents online in the ADAMS Public Documents collection at *https://www.nrc.gov/reading-rm/adams.html.* To begin the search, select ''Begin Web-based ADAMS Search.'' For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1–800–397–4209, at 301–415–4737, or by email to *PDR.Resource@nrc.gov.* The License Amendment Request 23–03, as supplemented, to revise Technical Specification (TS) 3.7.8, ''Auxiliary Saltwater (ASW) System,'' is available in ADAMS under Accession Nos. ML23319A204 and ML23320A312, respectively.
- *NRC's PDR:* The PDR, where you may examine and order copies of publicly available documents, is open by appointment. To make an appointment to visit the PDR, please send an email to *PDR.Resource@nrc.gov* or call 1–800–397–4209 or 301–415–4737, between 8 a.m. and 4 p.m. eastern time (ET), Monday through Friday, except Federal holidays.

B. Submitting Comments

The NRC encourages electronic comment submission through the Federal rulemaking website (*https://www.regulations.gov*). Please include Docket ID NRC–2023–0197 in your comment submission.

The NRC cautions you not to include identifying or contact information that you do not want to be publicly disclosed in your comment submission. The NRC will post all comment submissions at *https://www.regulations.gov* as well as enter the comment submissions into ADAMS. The NRC does not routinely edit comment submissions to remove identifying or contact information.

If you are requesting or aggregating comments from other persons for submission to the NRC, then you should inform those persons not to include identifying or contact information that they do not want to be publicly disclosed in their comment submission. Your request should state that the NRC does not routinely edit comment submissions to remove such information before making the comment submissions available to the public or entering the comment into ADAMS.

II. Introduction

The NRC is considering issuance of an amendment to Facility Operating License No. DPR–82, issued to PG&E, for operation of Diablo Canyon, Unit 2, located in San Luis Obispo County, California.

The proposed amendment would revise TS 3.7.8, ''Auxiliary Saltwater (ASW) System,'' to provide a revised TS 3.7.8 Condition A Note to allow a one-time completion time (CT) of 144 hours to replace the ASW System Pump 2–2 motor during Cycle 24 for Diablo Canyon, Unit 2.

Pursuant to the requirements of sections 50.91 and 50.92 of Title 10 of the *Code of Federal Regulations* (10 CFR), the licensee requested approval of the amendment under exigent circumstances. The need to replace the ASW Pump 2–2 motor occurred on an emergent basis due to indication of a potential degraded motor bearing. The ASW Pump 2–2 motor is currently OPERABLE but trends in bearing performance indicate that OPERABILITY could be impacted prior to the next scheduled Unit 2 refueling outage in April 2023. In order to maintain high plant safety, PG&E currently plans to begin replacement of the ASW Pump 2–2 motor the week of December 11, 2023. The circumstances requiring this exigent amendment request could not reasonably have been avoided. Oil samples collected from ASW pump 2–2 in January 2023 up until August 21, 2023, were within acceptance limits. On October 23, 2023, the ASW Pump 2–2 oil sample visually exhibited further discoloration compared to the sample collected on August 21, 2023, indicating that degradation had continued. As a result of the indication of a potential degraded ASW Pump 2–2 motor bearing on October 23, 2023, the associated analysis on October 27, 2023, indicating a further step change increase in particulate count, and as a prudent measure to maintain high reliability of the ASW pump, PG&E currently plans to begin replacement of the ASW Pump 2–2 motor on the week of December 11, 2023. The replacement of this motor will have no impact on the unit

electrical load or electrical distribution systems.

Before any issuance of the proposed license amendment, the NRC will need to make the findings required by the Atomic Energy Act of 1954, as amended (the Act), and NRC's regulations.

Pursuant to 10 CFR 50.91(a)(6) for amendments to be granted under exigent circumstances, the NRC has made a proposed determination that the license amendment request involves no significant hazards consideration (NSHC). Under the NRC's regulations in 10 CFR 50.92, this means that operation of the facility in accordance with the proposed amendment would not (1) involve a significant increase in the probability or consequences of an accident previously evaluated; or (2) create the possibility of a new or different kind of accident from any accident previously evaluated; or (3) involve a significant reduction in a margin of safety. As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of NSHC, which is presented as follows:

1. Does the proposed change involve a significant increase in the probability or consequences of an accident previously evaluated?

Response: No.

The proposed change to the requirements in TS 3.7.8, ''Auxiliary Saltwater (ASW) System'' Condition A will allow a one-time Completion Time of 144-hours during Unit 2 Cycle 24 for Auxiliary Saltwater System (ASW) Pump 2–2 to support the emergent replacement of the pump motor. The ASW system is not an initiator of any UFSAR Chapter 6 or 15 design basis accident or event, and therefore, the proposed change does not increase the probability of any accident previously evaluated. The ASW system is used to supply cooling water to respond to accidents that have been previously evaluated. The proposed change affects only the time allowed for an ASW system train to be inoperable and does not affect the design of the ASW system. With the change to TS 3.7.8, adequate ASW continues to be provided to perform the heat removal function for accidents previously evaluated and there is no significant impact on accident consequences. The proposed change does not significantly change how the plant would mitigate an accident previously evaluated.

Therefore, the proposed change does not involve a significant increase in the probability or consequences of an accident previously evaluated.

2. Does the proposed change create the possibility of a new or different kind of accident from any accident previously evaluated?

Response: No.

The proposed change does not result in a change in the manner in which the ASW system provides plant protection. The ASW system will continue to perform the function of heat removal while in the proposed revised TS 3.7.8 Condition A. The change does not involve a physical alteration of the plant that impacts the capability of the ASW system to perform its design function. Therefore, the proposed change does not create the possibility of a new or different accident from any accident previously evaluated.

3. Does the proposed change involve a significant reduction in a margin of safety?

Response: No.

The proposed change does not alter the manner in which safety limits, limiting safety system settings, or limiting conditions for operation are determined. The safety analysis acceptance criteria are not impacted by this change. The proposed change will not result in plant operation in a configuration outside the existing design basis since TS 3.7.8 Condition A already allows one train of the ASW system to be inoperable.

Therefore, the proposed change does not involve a significant reduction in a margin of safety.

The NRC staff has reviewed the licensee's analysis and, based on this review, the three standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the license amendment request involves a NSHC. In accordance with 10 CFR 50.91(a)(6), where the Commission finds that exigent circumstances exist, in that a licensee and the Commission must act quickly and that time does not permit the Commission to publish a **Federal Register** notice allowing 30 days for prior public comment, and it also determines that the amendment involves NSHCs, it can issue a **Federal Register** notice providing notice of an opportunity for hearing and allowing at least two weeks from the date of the notice for prior public comment. Therefore, in accordance with 10 CFR 50.91(a)(6)(i)(A), the NRC staff is providing a 14-day notice period for public comment.

The NRC is seeking public comments on this proposed determination that the license amendment request involves NSHC. Any comments received within 14 days after the date of publication of this notice will be considered in making any final determination.

Normally, the Commission will not issue the amendment until the expiration of the 14-day notice period. However, if circumstances change during the notice period, such that failure to act in a timely way would result, for example, in derating or shutdown of the facility, the Commission may issue the license amendment before the expiration of the 14-day notice period, provided that its final determination is that the amendment involves NSHC. The final determination will consider all public and State comments received. If the Commission takes this action, it will publish in the **Federal Register** a notice of issuance. The Commission expects that the need to take this action will occur very infrequently.

III. Opportunity to Request a Hearing and Petition for Leave to Intervene

Within 60 days after the date of publication of this notice, any person (petitioner) whose interest may be affected by this action may file a request for a hearing and petition for leave to intervene (petition) with respect to the action. Petitions shall be filed in accordance with the Commission's ''Agency Rules of Practice and Procedure'' in 10 CFR part 2. Interested persons should consult a current copy of 10 CFR 2.309. If a petition is filed, the Commission or a presiding officer will rule on the petition and, if appropriate, a notice of a hearing will be issued.

Petitions must be filed no later than 60 days from the date of publication of this notice in accordance with the filing instructions in the ''Electronic Submissions (E-Filing)'' section of this document. Petitions and motions for leave to file new or amended contentions that are filed after the deadline will not be entertained absent a determination by the presiding officer that the filing demonstrates good cause by satisfying the three factors in 10 CFR 2.309(c)(1)(i) through (iii).

If a hearing is requested and the Commission has not made a final determination on the issue of NHSC, the Commission will make a final determination on the issue of NSHC, which will serve to establish when the hearing is held. If the final determination is that the amendment request involves NHSC, the Commission may issue the amendment and make it immediately effective, notwithstanding the request for a hearing. Any hearing would take place after issuance of the amendment. If the final determination is that the amendment request involves a significant hazards consideration, then any hearing held would take place before the issuance of the amendment unless the Commission finds an imminent danger to the health or safety of the public, in which case it will issue an appropriate order or rule under 10 CFR part 2.

A State, local governmental body, Federally recognized Indian Tribe, or designated agency thereof, may submit a petition to the Commission to participate as a party under 10 CFR 2.309(h) no later than 60 days from the date of publication of this notice. Alternatively, a State, local governmental body, Federally recognized Indian Tribe, or agency

thereof may participate as a non-party under 10 CFR 2.315(c).

For information about filing a petition and about participation by a person not a party under 10 CFR 2.315, see ADAMS Accession No. ML20340A053 (*https://adamswebsearch2.nrc.gov/webSearch2/main.jsp?AccessionNumber=ML20340A053*) and on the NRC's public website at *https://www.nrc.gov/about-nrc/regulatory/adjudicatory/hearing.html#participate.*

IV. Electronic Submissions (E-Filing)

All documents filed in NRC adjudicatory proceedings, including documents filed by an interested State, local governmental body, Federally recognized Indian Tribe, or designated agency thereof that requests to participate under 10 CFR 2.315(c), must be filed in accordance with 10 CFR 2.302. The E-Filing process requires participants to submit and serve all adjudicatory documents over the internet, or in some cases, to mail copies on electronic storage media, unless an exemption permitting an alternative filing method, as further discussed, is granted. Detailed guidance on electronic submissions is located in the ''Guidance for Electronic Submissions to the NRC'' (ADAMS Accession No. ML13031A056) and on the NRC's public website at *https://www.nrc.gov/site-help/e-submittals.html.*

To comply with the procedural requirements of E-Filing, at least 10 days prior to the filing deadline, the participant should contact the Office of the Secretary by email at *Hearing.Docket@nrc.gov,* or by telephone at 301–415–1677, to (1) request a digital identification (ID) certificate, which allows the participant (or its counsel or representative) to digitally sign submissions and access the E-Filing system for any proceeding in which it is participating; and (2) advise the Secretary that the participant will be submitting a petition or other adjudicatory document (even in instances in which the participant, or its counsel or representative, already holds an NRC-issued digital ID certificate). Based upon this information, the Secretary will establish an electronic docket for the proceeding if the Secretary has not already established an electronic docket.

Information about applying for a digital ID certificate is available on the NRC's public website at *https://www.nrc.gov/site-help/e-submittals/getting-started.html.* After a digital ID certificate is obtained and a docket created, the participant must submit adjudicatory documents in Portable Document Format. Guidance on submissions is available on the NRC's public website at *https://www.nrc.gov/site-help/electronic-sub-ref-mat.html.* A filing is considered complete at the time the document is submitted through the NRC's E-Filing system. To be timely, an electronic filing must be submitted to the E-Filing system no later than 11:59 p.m. ET on the due date. Upon receipt of a transmission, the E-Filing system time-stamps the document and sends the submitter an email confirming receipt of the document. The E-Filing system also distributes an email that provides access to the document to the NRC's Office of the General Counsel and any others who have advised the Office of the Secretary that they wish to participate in the proceeding, so that the filer need not serve the document on those participants separately. Therefore, applicants and other participants (or their counsel or representative) must apply for and receive a digital ID certificate before adjudicatory documents are filed to obtain access to the documents via the E-Filing system.

A person filing electronically using the NRC's adjudicatory E-Filing system may seek assistance by contacting the NRC's Electronic Filing Help Desk through the ''Contact Us'' link located on the NRC's public website at *https://www.nrc.gov/site-help/e-submittals.html,* by email to *MSHD.Resource@nrc.gov,* or by a toll-free call at 1–866–672–7640. The NRC Electronic Filing Help Desk is available between 9 a.m. and 6 p.m., ET, Monday through Friday, except Federal holidays.

Participants who believe that they have good cause for not submitting documents electronically must file an exemption request, in accordance with 10 CFR 2.302(g), with their initial paper filing stating why there is good cause for not filing electronically and requesting authorization to continue to submit documents in paper format. Such filings must be submitted in accordance with 10 CFR 2.302(b)-(d). Participants filing adjudicatory documents in this manner are responsible for serving their documents on all other participants. Participants granted an exemption under 10 CFR 2.302(g)(2) must still meet the electronic formatting requirement in 10 CFR 2.302(g)(1), unless the participant also seeks and is granted an exemption from 10 CFR 2.302(g)(1).

Documents submitted in adjudicatory proceedings will appear in the NRC's electronic hearing docket, which is publicly available at *https://adams.nrc.gov/ehd,* unless excluded pursuant to an order of the presiding officer. If you do not have an NRC-issued digital ID certificate as previously described, click ''cancel'' when the link requests certificates and you will be automatically directed to the NRC's electronic hearing dockets where you will be able to access any publicly available documents in a particular hearing docket. Participants are requested not to include personal privacy information such as social security numbers, home addresses, or personal phone numbers in their filings unless an NRC regulation or other law requires submission of such information. With respect to copyrighted works, except for limited excerpts that serve the purpose of the adjudicatory filings and would constitute a Fair Use application, participants should not include copyrighted materials in their submission.

For further details with respect to this action, see the application for license amendment dated November 14, 2023, as supplemented by letter dated November 16, 2023 (ADAMS Accession Nos. ML23319A204 and ML23320A312, respectively).

Attorney for licensee: Jennifer Post, Esq. Pacific Gas & Electric Co., 77 Beale Street, Room 3065, Mail Code B30A, San Francisco, CA 94105.

NRC Branch Chief: Jennifer L. Dixon-Herrity.

Dated: November 17, 2023.

For the Nuclear Regulatory Commission.

Siva P. Lingam,

Project Manager, Plant Licensing Branch IV, Division of Operating Reactor Licensing, Office of Nuclear Reactor Regulation.

[FR Doc. 2023–25819 Filed 11–21–23; 8:45 am]

BILLING CODE 7590–01–P

POSTAL REGULATORY COMMISSION

[Docket Nos. MC2024–52 and CP2024–53]

New Postal Products

AGENCY: Postal Regulatory Commission.

ACTION: Notice.

SUMMARY: The Commission is noticing a recent Postal Service filing for the Commission's consideration concerning a negotiated service agreement. This notice informs the public of the filing, invites public comment, and takes other administrative steps.

DATES: *Comments are due:* November 27, 2023.

ADDRESSES: Submit comments electronically via the Commission's Filing Online system at *http://www.prc.gov.* Those who cannot submit comments electronically should contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section by

telephone for advice on filing alternatives.

FOR FURTHER INFORMATION CONTACT: David A. Trissell, General Counsel, at 202–789–6820.

SUPPLEMENTARY INFORMATION:

Table of Contents

I. Introduction

The Commission gives notice that the Postal Service filed request(s) for the Commission to consider matters related to negotiated service agreement(s). The request(s) may propose the addition or removal of a negotiated service agreement from the Market Dominant or the Competitive product list, or the modification of an existing product currently appearing on the Market Dominant or the Competitive product list.

Section II identifies the docket number(s) associated with each Postal Service request, the title of each Postal Service request, the request's acceptance date, and the authority cited by the Postal Service for each request. For each request, the Commission appoints an officer of the Commission to represent the interests of the general public in the proceeding, pursuant to 39 U.S.C. 505 (Public Representative). Section II also establishes comment deadline(s) pertaining to each request.

The public portions of the Postal Service's request(s) can be accessed via the Commission's website (*http://www.prc.gov*). Non-public portions of the Postal Service's request(s), if any, can be accessed through compliance with the requirements of 39 CFR 3011.301.[1]

The Commission invites comments on whether the Postal Service's request(s) in the captioned docket(s) are consistent with the policies of title 39. For request(s) that the Postal Service states concern Market Dominant product(s), applicable statutory and regulatory requirements include 39 U.S.C. 3622, 39 U.S.C. 3642, 39 CFR part 3030, and 39 CFR part 3040, subpart B. For request(s) that the Postal Service states concern Competitive product(s), applicable statutory and regulatory requirements include 39 U.S.C. 3632, 39 U.S.C. 3633, 39 U.S.C. 3642, 39 CFR part 3035, and 39 CFR part 3040, subpart B. Comment deadline(s) for each request appear in section II.

[1] *See* Docket No. RM2018–3, Order Adopting Final Rules Relating to Non-Public Information, June 27, 2018, Attachment A at 19–22 (Order No. 4679).

II. Docketed Proceeding(s)

1. *Docket No(s).:* MC2024–52 and CP2024–53; *Filing Title:* USPS Request to Add Priority Mail Express, Priority Mail & USPS Ground Advantage Contract 13 to Competitive Product List and Notice of Filing Materials Under Seal; *Filing Acceptance Date:* November 15, 2023; *Filing Authority:* 39 U.S.C. 3642, 39 CFR 3040.130 through 3040.135, and 39 CFR 3035.105; *Public Representative:* Jennaca D. Upperman; *Comments Due:* November 27, 2023.

This Notice will be published in the **Federal Register**.

Erica A. Barker,

Secretary.

[FR Doc. 2023–25757 Filed 11–21–23; 8:45 am]

BILLING CODE 7710–FW–P

POSTAL REGULATORY COMMISSION

[Docket Nos. MC2024–53 and CP2024–54; MC2024–54 and CP2024–55]

New Postal Products

AGENCY: Postal Regulatory Commission.

ACTION: Notice.

SUMMARY: The Commission is noticing a recent Postal Service filing for the Commission's consideration concerning a negotiated service agreement. This notice informs the public of the filing, invites public comment, and takes other administrative steps.

DATES: *Comments are due:* November 28, 2023.

ADDRESSES: Submit comments electronically via the Commission's Filing Online system at *http://www.prc.gov.* Those who cannot submit comments electronically should contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section by telephone for advice on filing alternatives.

FOR FURTHER INFORMATION CONTACT: David A. Trissell, General Counsel, at 202–789–6820.

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II. Docketed Proceeding(s)

1. *Docket No(s).:* MC2024–53 and CP2024–54; *Filing Title:* USPS Request to Add Priority Mail & USPS Ground Advantage Contract 106 to Competitive Product List and Notice of Filing Materials Under Seal; *Filing Acceptance Date:* November 16, 2023; *Filing Authority:* 39 U.S.C. 3642, 39 CFR 3040.130 through 3040.135, and 39 CFR 3035.105; *Public Representative:* Jennaca D. Upperman; *Comments Due:* November 28, 2023.

2. *Docket No(s).:* MC2024–54 and CP2024–55; *Filing Title:* USPS Request to Add Priority Mail & USPS Ground Advantage Contract 107 to Competitive Product List and Notice of Filing Materials Under Seal; *Filing Acceptance Date:* November 16, 2023; *Filing Authority:* 39 U.S.C. 3642, 39 CFR

[1] *See* Docket No. RM2018–3, Order Adopting Final Rules Relating to Non-Public Information, June 27, 2018, Attachment A at 19–22 (Order No. 4679).

3040.130 through 3040.135, and 39 CFR 3035.105; *Public Representative:* Jennaca D. Upperman; *Comments Due:* November 28, 2023.

This Notice will be published in the **Federal Register**.

Erica A. Barker,

Secretary.

[FR Doc. 2023–25865 Filed 11–21–23; 8:45 am]

BILLING CODE 7710–FW–P

POSTAL SERVICE

Change in Rates and Classes of General Applicability for Competitive Products

AGENCY: Postal Service™.

ACTION: Notice of a change in rates and classifications of general applicability for competitive products.

SUMMARY: This notice sets forth changes in rates and classifications of general applicability for competitive products.

DATES: *Applicable date:* January 21, 2024.

FOR FURTHER INFORMATION CONTACT: Elizabeth Reed, 202–268–3179.

SUPPLEMENTARY INFORMATION: On November 13, 2023, pursuant to their authority under 39 U.S.C. 3632, the Governors of the Postal Service established prices and classification changes for competitive products. The Governors' Decision and the record of proceedings in connection with such decision are reprinted below in accordance with section 3632(b)(2). Mail Classification Schedule language containing the new prices and classification changes can be found at *www.prc.gov.*

Sarah Sullivan,

Attorney, Ethics & Legal Compliance.

Decision of the Governors of the United States Postal Service on Changes in Rates and Classifications of General Applicability for Competitive Products (Governors' Decision No. 23–5)

November 13, 2023

Statement of Explanation and Justification

Pursuant to authority under section 3632 of title 39, as amended by the Postal Accountability and Enhancement Act of 2006 (''PAEA''), we establish prices and classifications of general applicability for the Postal Service's competitive products. The changes are described generally below, with a detailed description of the changes in the Postal Service's associated draft Mail Classification Schedule change document. That document contains the draft Mail Classification Schedule sections with classification changes in legislative format, and new prices displayed in the price charts.

As shown in the nonpublic annex being filed under seal herewith, the changes we establish should enable each competitive product to cover its attributable costs (39 U.S.C. 3633(a)(2)) and should result in competitive products as a whole complying with 39 U.S.C. 3633(a)(3), which, as implemented by 39 CFR 3035.107(c), requires competitive products collectively to contribute a minimum of 9.9 percent to the Postal Service's institutional costs. Accordingly, no issue of subsidization of competitive products by market dominant products should arise (39 U.S.C. 3633(a)(1)). We therefore find that the new prices and classification changes are in accordance with 39 U.S.C. 3632–3633 and 39 CFR 3035.102 and 104.

I. Domestic Products

A. Priority Mail Express

Overall, the Priority Mail Express price change represents a 5.9 percent increase. In 2023, we consolidated the Commercial Base and Commercial Plus price categories into one Commercial price category and differentiated the ''Local, 1, 2'' Zone prices. For January 2024, this new structure will be maintained. Dimensional weighting, which was introduced for all zones in 2019, will also continue in 2024.

Retail prices will increase an average of 5.9 percent. The price for the Retail Flat Rate Envelope, a significant portion of all Priority Mail Express volume, will increase to $30.45, with the Legal Size and Padded Flat Rate Envelopes priced at $30.65 and $31.20, respectively.

The Commercial price category will increase 5.9 percent on average. Commercial prices will, on average, reflect a 13.7 percent discount off of Retail prices. The eVS Unmanifested Fee will be renamed as ''Unmanifested Fee'' to accommodate the ongoing migration of customers from eVS to the USPS Ship platform. Finally, certain Nonstandard Fees (NSFs) applicable to Priority Mail Express will see a 20 percent increase in 2024.

B. Priority Mail

On average, the Priority Mail prices will be increased by 5.7 percent. Similar to Priority Mail Express, the Commercial Base and Commercial Plus price categories were consolidated into one Priority Mail Commercial price category and ''Local, 1, 2'' Zone prices were differentiated in 2023. For January 2024, this new structure will be maintained. Dimensional weighting, which was introduced for all zones in 2019, will also continue in 2024.

Retail prices will increase by an average of 5.6 percent. Retail Flat Rate Box prices will be: Small, $10.40; Medium, $18.40; Large, $24.75 and Large APO/FPO/DPO, $23.00. Thus, the Large APO/FPO/DPO Flat Rate Box will be $1.75 less than the Large Flat Rate Box. The regular Flat Rate Envelope will be priced at $9.85, with the Legal Size and Padded Flat Rate Envelopes priced at $10.15 and $10.60, respectively.

The Commercial price category will increase by 5.8 percent on average. Commercial prices will, on average, reflect a 20.5 percent discount off of Retail prices. The eVS Unmanifested Fee will be renamed as ''Unmanifested Fee'' to accommodate the ongoing migration of customers from eVS to the USPS Ship platform. Finally, certain Nonstandard Fees (NSFs) applicable to Priority Mail will see a 20 percent increase in 2024.

C. Parcel Select

On average, Parcel Select prices as a whole will increase 5.9 percent. New for 2024, we will be eliminating Parcel Select Lightweight as a separate price category; rather, ounce-based prices will be added under the destination-entered categories at 4-, 8-, and 12-ounce increments. With the elimination of Parcel Select Lightweight and prior structural changes made earlier in 2023, the prices for Parcel Select can now be expressed in a single price table, which further supports the Postal Service's product simplification efforts.

For destination delivery unit (DDU) entered parcels, the average price increase is 5.9 percent. For destination hub (Dhub) entered parcels, the average price increase is 5.9 percent. For destination sectional center facility (DSCF) destination entered parcels, the average price increase is 5.9 percent. For destination network distribution center (DNDC) parcels, the average price increase is 5.9 percent. Prices for USPS Connect Local, introduced in 2022, will remain unchanged for 2024. Dimensional weighting, which was introduced for all zones in 2019, will continue in 2024. The eVS Unmanifested Fee will be renamed as ''Unmanifested Fee'' to accommodate the ongoing migration of customers from eVS to the USPS Ship platform. Finally, certain Nonstandard Fees (NSFs) applicable to Parcel Select will see a 20 percent increase in 2024.

D. USPS Ground Advantage

USPS Ground Advantage, introduced in July 2023, is the Postal Service's flagship ground package product. The existing structure will be maintained for 2024. Overall, USPS Ground Advantage prices will increase 5.4 percent on average. Retail prices will increase 5.2 percent on average, while Commercial prices will increase 5.4 percent on average. The Alaska Limited Overland Routes (LOR) price category will see a 9.2 percent average increase for January 2024. The eVS Unmanifested Fee will be renamed as ''Unmanifested Fee'' to accommodate the ongoing migration of customers from eVS to the USPS Ship platform. Finally, certain Nonstandard Fees (NSFs) applicable to USPS Ground Advantage will see a 20 percent increase in 2024.

F. Domestic Extra Services

Premium Forwarding Service (PFS) prices will increase 3.0 percent on average in 2024. The retail counter enrollment fee will increase to $26.20. The online enrollment option, introduced in 2014, will increase to $24.10. The weekly reshipment fee will increase to $26.20. The reshipment fee for PFS Local, which was introduced in 2019 for P.O. Box customers, will increase to $26.20. Prices for Adult Signature service will increase to $9.35 for the basic service and $9.65 for the person-specific service. Address Enhancement Service prices will increase 3.0 percent on average in 2024. Competitive Post Office Box prices will be increasing 6.5 percent on average, within the existing price ranges. Package Intercept Service will increase to $17.50. The Pickup On Demand fee will remain unchanged for 2024, at $26.50. Premium Data Retention and Retrieval Service (USPS Tracking Plus), which was introduced in 2020, will not see a price change in 2024. The fee for Label Delivery Service, introduced in 2023 under the Competitive Ancillary Services product, will remain at $1.25 for 2024.

II. International Products

A. Expedited Services

International expedited services include Global Express Guaranteed (GXG) and Priority Mail Express International (PMEI). Overall, GXG prices will rise by 5.4 percent, and PMEI will be subject to an overall 5.4 percent increase. Commercial Plus prices will be equivalent to Commercial Base.

B. Priority Mail International

The overall increase for Priority Mail International (PMI) will be 5.4 percent. Commercial Plus prices will be equivalent to Commercial Base.

C. International Priority Airmail and International Surface Air Lift

Published prices for International Priority Airmail (IPA) and International Surface Air Lift (ISAL) will increase by 5.5 percent and 3.5 percent, respectively.

D. Airmail M-Bags

The published prices for Airmail M-Bags will increase by 5.4 percent.

E. First-Class Package International Service™

The overall increase for First-Class Package International Service (FCPIS) prices will be 6.4 percent. Commercial Plus prices will be equivalent to Commercial Base.

F. International Ancillary Services and Special Services

Prices for several international ancillary services will be increased, including a 2.5 percent increase for International Certificate of Mailing, a 3.0 percent increase for International Insurance, a 2.5 percent increase for International Registered Mail, a 2.7 percent increase for International Return Receipt, and a 3.0 percent increase for the Customs and Clearance Delivery Fee.

Order

The changes in prices and classes set forth herein shall be effective at 12:01 a.m. on January 21, 2024. We direct the Secretary to have this decision published in the **Federal Register** in accordance with 39 U.S.C. 3632(b)(2) and direct management to file with the Postal Regulatory Commission appropriate notice of these changes.

By the Governors.

/s/

Roman Martinez IV,

Chairman, Board of Governors.

United States Postal Service Office of the Board of Governors

Certification of Governors' Vote on Governors' Decision No. 23–5

Consistent with 39 U.S.C. 3632(a), I hereby certify that, on November 13, 2023, the Governors voted on adopting Governors' Decision No. 23–5, and that a majority of the Governors then holding office voted in favor of that Decision.

Date: November 13, 2023.

/s/

Michael J. Elston,

Secretary of the Board of Governors.

[FR Doc. 2023–25766 Filed 11–21–23; 8:45 am]

BILLING CODE 7710–12–P

OFFICE OF SCIENCE AND TECHNOLOGY POLICY

Notice of Request for Information; National Plan for Civil Earth Observations

AGENCY: Office of Science and Technology Policy (OSTP).

ACTION: Notice of Request for Information (RFI).

SUMMARY: The White House Office of Science and Technology Policy (OSTP) requests public inputs to inform the development of the congressionally mandated National Plan for Civil Earth Observations (hereinafter ''2023 National Plan''). This notice, which includes a draft of the 2023 National Plan, seeks information to achieve a future vision for continued United States global leadership in enabling and leveraging civil Earth Observations to increase access to Earth data, and address global changes. This notice serves as the follow-on Request for Information referenced in a **Federal Register** Notice titled ''Notice of Upcoming Request for Information; National Plan for Civil Earth Observations''.

DATES: Interested persons and organizations are invited to submit comments on or before 5 p.m. ET, December 31, 2023 to be considered.

ADDRESSES: Due to time constraints, mailed paper submissions will not be accepted, and electronic submissions received after the deadline may not be taken into consideration.

Interested individuals and organizations should submit comments electronically via regulations.gov (Docket #: OSTP–2023–XXXX). Due to time constraints, mailed paper submissions will not be accepted, and electronic submissions received after the deadline cannot be ensured to be incorporated or taken into consideration.

Instructions: Federal eRulemaking Portal: Go to *www.regulations.gov* to submit your comments electronically. Information on how to use *Regulations.gov,* including instructions for accessing agency documents, submitting comments, and viewing the docket, is available on the site under ''FAQ'' (*https://www.regulations.gov/faq*).

Privacy Note: OSTP's policy is to make all comments received from

members of the public available for public viewing in their entirety on the Federal eRulemaking Portal at *www.regulations.gov.* Therefore, commenters should be careful to include in their comments only information that they wish to make publicly available. OSTP requests that no proprietary information, copyrighted information, or personally identifiable information be submitted in response to this RFI.

Information obtained from this RFI may be used by the Government on a non-attribution basis for planning and strategy development. OSTP will not respond to individual submissions. A response to this RFI will not be viewed as a binding commitment to develop or pursue the project or ideas discussed. This RFI is not accepting applications for financial assistance or financial incentives.

Responses containing references, studies, research, and other empirical data that are not widely published should include copies of or electronic links to the referenced materials. Responses from minors, or responses containing profanity, vulgarity, threats, or other inappropriate language or content will not be considered.

Comments submitted in response to this notice are subject to the Freedom of Information Act (FOIA). Responses to this RFI may be posted without change online. Please note that the United States Government will not pay for response preparation, or for the use of any information contained in a response.

FOR FURTHER INFORMATION CONTACT: Ezinne Uzo-Okoro; tel: 202–456–4010.

SUPPLEMENTARY INFORMATION: Pursuant to 42 U.S.C. 6617, OSTP is soliciting public input through an RFI to obtain feedback from a wide variety of stakeholders, including individuals, industry, academia, research laboratories, nonprofits, and think tanks. OSTP is specifically interested in public input to inform the development and release of the 2023 National Plan to better leverage Earth Observations for addressing key societal challenges and trends of the coming decade. The first draft of the 2023 National Plan is included for public input.

Dated: November 16, 2023.

Stacy Murphy,

Deputy Chief Operations Officer/Security Officer.

[FR Doc. 2023–25798 Filed 11–21–23; 8:45 am]

BILLING CODE 3270–F1–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–98964; File No. SR–NYSEARCA–2023–79]

Self-Regulatory Organizations; NYSE Arca, Inc.; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend the Connectivity Fee Schedule

November 16, 2023.

Pursuant to Section 19(b)(1) [1] of the Securities Exchange Act of 1934 (''Act'') [2] and Rule 19b–4 thereunder,[3] notice is hereby given that on November 9, 2023, NYSE Arca, Inc. (''NYSE Arca'' or the ''Exchange'') filed with the Securities and Exchange Commission (the ''Commission'') the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend the Connectivity Fee Schedule regarding colocation services and fees to provide Users with wireless connectivity to CME Group market data. 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.

[1] 15 U.S.C. 78s(b)(1).

[2] 15 U.S.C. 78a.

[3] 17 CFR 240.19b–4.

A. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend the Connectivity Fee Schedule (''Fee Schedule'') regarding colocation services and fees to provide Users [4] with wireless connectivity to CME Group market data.[5]

The Exchange currently provides Users with wireless connections to eight market data feeds or combinations of feeds from third-party markets (the ''Existing Third Party Data''),[6] and wired connections to more than 45 market data feeds or combinations of feeds.[7] The Exchange proposes to add to the Fee Schedule wireless connections to CME Group, Inc. (''CME Group'') market data (''CME Group Data'' and, together with the Existing Third Party Data, the ''Third Party Data''). Users would be offered the proposed wireless connection to the CME Group Data through connections into the colocation center in the Mahwah, New Jersey data center (''MDC'').[8]

The Exchange expects that the proposed rule change would become

[4] For purposes of the Exchange's colocation services, a ''User'' means any market participant that requests to receive colocation services directly from the Exchange. *See* Securities Exchange Act Release No. 76010 (September 29, 2015), 80 FR 60197 (October 5, 2015) (SR–NYSEArca–2015–82). As specified in the Fee Schedule, a User that incurs colocation fees for a particular colocation service pursuant thereto would not be subject to colocation fees for the same colocation service charged by the Exchange's affiliates the New York Stock Exchange LLC, NYSE American LLC, NYSE Chicago, Inc., and NYSE National, Inc. (together, the ''Affiliate SROs''). Each Affiliate SRO has submitted substantially the same proposed rule change to propose the changes described herein. *See* SR–NYSE–2023–44, SR–NYSEAMER–2023–59, SR–NYSECHX–2023–22, and SR–NYSENAT–2023–26.

[5] The Exchange filed a similar proposal in 2021, which it subsequently withdrew. *See* Securities Exchange Act Release No. 93810 (December 17, 2021), 86 FR 73026 (December 23, 2021) (SR–NYSE–2021–67, SR–NYSEAMER–2021–43, SR–NYSEARCA–2021–97, SR–NYSECHX–2021–17, SR–NYSENAT–2021–23).

[6] *See* Securities Exchange Act Release Nos. 76749 (December 23, 2015), 80 FR 81640 (December 30, 2015) (SR–NYSEArca–2015–99); 78377 (July 21, 2016), 81 FR 49327 (July 27, 2016) (SR–NYSEARCA–2016–99); and 80116 (February 28, 2017), 82 FR 12663 (March 6, 2017) (SR–NYSEArca–2017–18).

[7] *See* Securities Exchange Act Release No. 80310 (March 24, 2017), 82 FR 15763 (March 30, 2017) (SR–NYSEArca–2016–89).

[8] Through its Fixed Income and Data Services (''FIDS'') (previously ICE Data Services) business, Intercontinental Exchange, Inc. (''ICE'') operates the MDC. The Exchange and the Affiliate SROs are indirect subsidiaries of ICE. The proposed service would be provided by FIDS pursuant to an agreement with a non-ICE entity. FIDS does not own the wireless network that would be used to provide the service.

operative in the fourth quarter of 2023, and in any event, no later than December 31, 2023. The Exchange will announce the date that the wireless connection to the CME Group Data will be available through a customer notice.

To receive CME Group Data, the User would enter into an agreement with a third party for permission to receive the data, if required. The User would pay this third party any fees for the data content.

The Exchange proposes to revise the Fee Schedule to reflect fees related to the wireless connection to CME Group Data. For each wireless connection to CME Group Data, a User would be charged a $5,000 non-recurring initial charge and a monthly recurring charge of $6,000. If a User were to purchase more than one wireless connection to CME Group Data, it would pay more than one non-recurring initial charge. Each proposed wireless connection would include the use of one port for connectivity to CME Group Data, and a User would not pay a separate fee for the use of such port.[9]

The Exchange's proposed wireless connectivity to CME Group market data would not include the entire CME Group market data feed, which includes market data for approximately 1,200 futures symbols. Wireless bandwidth capacity is a small fraction of the capacity required to transport the full CME Group feed. Accordingly, FIDS has consulted with customers about which of the CME Group symbols they would like to be available wirelessly and plans to offer connectivity to a subgroup of symbols based on this customer feedback. The Exchange understands that Quincy Data LLC (''Quincy''),[10] a third party that already provides wireless connectivity to CME Group market data in the MDC, similarly provides wireless connectivity to a subset of CME Group market data based on customer demand for particular symbols.[11]

Application and Impact of the Proposed Changes

The proposed changes would not apply differently to distinct types or sizes of market participants. Rather, they would apply to all Users equally.

As is currently the case, the purchase of any colocation service, including connectivity to Third Party Data, is completely voluntary and the Fee Schedule is applied uniformly to all Users.

Competitive Environment

The Exchange operates in a highly competitive market in which other vendors offer colocation services as a means to facilitate the trading and other market activities of those market participants who believe that colocation enhances the efficiency of their operations. The Commission has repeatedly expressed its preference for competition over regulatory intervention in determining prices, products, and services in the securities markets. Specifically, in Regulation NMS, the Commission highlighted the importance of market forces in determining prices and SRO revenues and, also, recognized that current regulation of the market system ''has been remarkably successful in promoting market competition in its broader forms that are most important to investors and listed companies.'' [12]

As explained below in this filing, the Exchange's proposed wireless connection to CME Group Data would compete with the wireless connection to CME Group market data provided by Quincy. Third-party vendors such as Quincy are not at any competitive disadvantage created by the Exchange.

The proposed change is not otherwise intended to address any other issues relating to colocation services or related fees, and the Exchange is not aware of any problems that Users would have in complying with the proposed change.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with Section 6(b) of the Act,[13] in general, and furthers the objectives of Section 6(b)(5) of the Act,[14] 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. The Exchange further believes that the proposed rule change is consistent with Section 6(b)(4) of the Act,[15] because it provides for the equitable allocation of reasonable dues, fees, and other charges among its members and issuers and other persons using its facilities and does not unfairly discriminate between customers, issuers, brokers, or dealers.

The Proposed Change Is Reasonable

The Exchange believes that the proposed rule change is reasonable. In considering the reasonableness of proposed services and fees, the Commission's market-based test considers ''whether the exchange was subject to significant competitive forces in setting the terms of its proposal . . . , including the level of any fees.'' [16] If the Exchange meets that burden, ''the Commission will find that its proposal is consistent with the Act unless 'there is a substantial countervailing basis to find that the terms' of the proposal violate the Act or the rules thereunder.'' [17] Here, the Exchange is subject to significant competitive forces in setting the terms on which it offers its proposal, in particular because substantially similar substitutes are available, and the Exchange has not placed the third party vendors at a competitive disadvantage created by the Exchange.

Substantially Similar Substitutes Are Available

The Exchange's proposed wireless connection to CME Group Data would compete with other methods by which both the Exchange and various third parties already provide connectivity to CME Group market data to Users.

Quincy already provides wireless connectivity to CME Group market data in the MDC. Like the Exchange's

[9] If a User also connects to Existing Third Party Data, it would not be able to connect to such Existing Third Party Data using the same port that it uses for connectivity to CME Group Data.

[10] The Exchange understands that Quincy is an affiliate of McKay Brothers LLC.

[11] The Exchange understands that the third parties that provide wireless connectivity to CME Group market data to the MDC and other data centers in New Jersey (as discussed later in this filing) follow a substantially similar model, offering wireless connectivity to a selection of market data rather than to entire feeds.

[12] *See* Securities Exchange Act Release No. 51808 (June 9, 2005), 70 FR 37496, 37499 (June 29, 2005).

[13] 15 U.S.C. 78f(b).

[14] 15 U.S.C. 78f(b)(5).

[15] 15 U.S.C. 78f(b)(4).

[16] *See* Securities Exchange Act Release No. 90209 (October 15, 2020), 85 FR 67044, 67049 (October 21, 2020) (Order Granting Accelerated Approval to Establish a Wireless Fee Schedule Setting Forth Available Wireless Bandwidth Connections and Wireless Market Data Connections) (SR–NYSE–2020–05, SR–NYSEAMER–2020–05, SR–NYSEArca–2020–08, SR–NYSECHX–2020–02, SR–NYSENAT–2020–03, SR–NYSE–2020–11, SR–NYSEAMER–2020–10, SR–NYSEArca–2020–15, SR–NYSECHX–2020–05, SR–NYSENAT–2020–08) (''Wireless Approval Order''), citing Securities Exchange Act Release No. 59039 (December 2, 2008), 73 FR 74770, 74781 (December 9, 2008) (''2008 ArcaBook Approval Order''). *See NetCoalition* v. *SEC,* 615 F.3d 525 (D.C. Cir. 2010).

[17] *See* Wireless Approval Order, *supra* note 16, at 67049, citing 2008 ArcaBook Approval Order, *supra* note 16, at 74781.

proposed wireless connectivity, Quincy's wireless connectivity to CME Group market data includes a similarly-sized subset of symbols that almost completely overlaps with the symbols for which the Exchange proposes to provide wireless connectivity—presumably because customers have requested the same symbols of each provider. Specifically, like the Quincy wireless connection, the Exchange's proposed wireless connection would include the main futures for equity indices, government bonds, foreign exchanges, oil, and precious metals.[18] In addition, the Exchange's proposed wireless connection would also include several additional symbols that proposed Users have specifically requested be included. The Exchange plans to continuously monitor Users' preferences and their views of the usefulness of the included symbols, and may adjust them accordingly. The Exchange believes that the Quincy wireless connection to CME Group market data is at a same or similar speed as the Exchange's proposed connection, and at a similar price.[19]

Accordingly, the Quincy wireless connection to CME Group market data would compete with the Exchange's proposed wireless connection, and would exert significant competitive forces on the Exchange in setting the terms of its proposal, including the level of the Exchange's proposed fees.[20] If the Exchange were to set its proposed fees too high, Users could respond by instead selecting Quincy's substantially similar wireless connectivity to CME Group data.[21]

[18] Quincy's symbol list for wireless connectivity to CME Group data is available at *https://www.quincy-data.com/product-page/* under the heading ''2023 Quincy Extreme Data Symbol Set/North America QED Symbol Set.'' The Exchange understands that the Quincy wireless connection to CME Group data currently includes 26 symbols. The Exchange's proposed wireless connection to CME Group data would contain a similar number of symbols, nearly all of which are included in the Quincy wireless connection.

[19] Because Quincy is not a regulated entity, it is not obligated to make its latency figures or fees publicly available or the same for all entities.

[20] *See* 2008 ArcaBook Approval Order, *supra* note 16, at 74789 and n.295 (recognizing that products need not be identical to be substitutable).

[21] In addition, the Exchange believes that at least two third-party market participants, in addition to FIDS, offer fiber connections to CME Group market data in colocation. *See* Securities Exchange Act Release No. 81013 (June 23, 2017), 82 FR 29604 (June 29, 2017) (SR–NYSEARCA–2017–62). Unlike the proposed wireless connectivity, FIDS' fiber connection to CME Group market data includes the entire CME Group data feed, instead of a subset of symbols.

Third Party Competitors Are Not at a Competitive Disadvantage Created by the Exchange

The Exchange does not believe that FIDS would have any competitive advantage over either the existing third-party provider or any future providers of wireless connectivity to CME Group market data. The Exchange's proposed service for connectivity to CME Group Data does not have any special access to or advantage within the MDC. The Exchange's proposed wireless connection would lead to a pole, from which a fiber connection would lead into the MDC. The pole is owned by a third party and is not on the grounds of the MDC, and the path into the MDC through a meet-me-room is available to any telecommunications provider. Within the MDC, the proposed connection would follow the same route as that of any User, connecting to equipment in colocation and then to any Users that are customers.

Further, all distances in the MDC are normalized and Exchange rules require that the distance from the Patch Panel Point to each User cabinet in colocation be the same.[22] Every provider of wireless connectivity to Users, including FIDS, is connected to the Patch Panel Point, and the length of the fiber path from the Patch Panel Point to each User cabinet in colocation is the same.

Nor does the Exchange have a competitive advantage over the third-party competitors offering wireless connectivity to CME Group market data by virtue of the fact that it owns and operates the MDC's meet-me-rooms. Users purchasing wireless connectivity to CME Group market data—like Users of any other colocation service—would require a circuit connecting out of the MDC, and in most cases, such circuits are provided by third-party telecommunications service providers that have installed their equipment in the MDC's two meet-me-rooms (''Telecoms'').[23] Currently, 16 Telecoms operate in the meet-me-rooms and provide a variety of circuit choices. It is in the Exchange's best interest to set the fees that Telecoms pay to operate in the meet-me-rooms at a reasonable level[24] so that market participants, including Telecoms, will maximize their use of the MDC. By setting the meet-me-room fees at a reasonable level, the Exchange encourages Telecoms to participate in the meet-me-rooms and to sell circuits to Users for connecting into and out of the MDC. These Telecoms then compete with each other by pricing such circuits at competitive rates. These competitive rates for circuits help draw in more Users and Hosted Customers to the MDC, which directly benefits the Exchange by increasing the customer base to whom the Exchange can sell its colocation services, which include cabinets, power, ports, and connectivity to many third-party data feeds, and because having more Users and Hosted Customers leads, in many cases, to greater participation on the Exchange. In this way, by setting the meet-me-room fees at a level attractive to telecommunications firms, the Exchange spurs demand for all of the services it sells at the MDC, while setting the meet-me-room fees too high would negatively affect the Exchange's ability to sell its services at the MDC.[25] Accordingly, there are real constraints on the meet-me-room fees the Exchange charges, such that the Exchange does not have an advantage in terms of costs when compared to third parties that enter the MDC through the meet-me-rooms to provide services to compete with the Exchange's services.

If anything, the Exchange is subject to a competitive disadvantage vis-à-vis third-party competitors offering wireless connectivity to CME Group market data. Third-party competitors are not subject to the Commission's filing requirements, and therefore can freely change their services and pricing in response to competitive forces. In contrast, the Exchange's service and pricing would be standardized as set out in this filing, and the Exchange would be unable to respond to pricing pressure from its competitors without seeking a formal fee change in a filing before the Commission.

In sum, because the Exchange is subject to significant competitive forces in setting the terms on which it offers its proposal, in particular because a substantially similar substitute is available, and the Exchange has not

[22] *See* NYSE Rule 3.13(c), NYSE American Rule 3.13E(c), NYSE Arca Rule 3.13(c), NYSE Chicago Rule 3.13(c), and NYSE National Rule 3.13(c) (Data Center Pole Restrictions—Connectivity to Co-Location Space). ''Patch Panel Point'' is defined as ''the patch panel where fiber connections for wireless services connect to the network row in the space used for co-location in the Data Center.'' *Id.* The proposed service would not use the MDC pole, so Rule 3.13(b) would not apply.

[23] Note that in the case of wireless connectivity, a User in colocation still requires a fiber circuit to transport data. If a Telecom is used, the data is transmitted wirelessly to the relevant pole, and then from the pole to the meet-me-room using a fiber circuit.

[24] *See* Securities Exchange Act Release No. 98000 (July 26, 2023), 88 FR 50244 (August 1, 2023) (SR–NYSEARCA–2023–47) (''MMR Notice'').

[25] *See id.* at 50247. Importantly, the Exchange is prevented from making any alteration to its meet-me-room services or fees without filing a proposal for such changes with the Commission.

placed the third-party vendors at a competitive disadvantage created by the Exchange, the proposed fees for the Exchange's wireless connectivity to CME Group Data are reasonable.[26] If the Exchange were to set its prices for wireless connectivity to CME Group Data at a level that Users found to be too high, Users could easily choose to connect to CME Group market data in colocation at the MDC through the competing Quincy wireless connection, as detailed above.

Additional Considerations

The Exchange believes that it is reasonable for the proposed wireless connection to CME Group Data not to transport information for all of the symbols included in CME Group data feeds to the MDC, but rather to transport a subset of that data. Wireless bandwidth capacity is a small fraction of the capacity required to transport the full CME Group feed. The Exchange believes it is reasonable for FIDS to select the symbols it will make available for wireless connectivity based on customer input and demand. The Exchange understands that Quincy similarly provides wireless connectivity to a subset of CME Group market data based on customer demand for particular symbols.

The Exchange believes that it is reasonable that a User that connects to both CME Group Data and Existing Third Party Data may not use the same port for connectivity to both, and so would have at least two ports, because the proposed wireless connection would include the use of one port for connectivity to CME Group Data, and the connectivity to the Existing Third Party Data includes the use of one port for connectivity to Existing Third Party Data. A User would not pay a separate fee for using such ports.

The Proposed Change Is an Equitable Allocation of Fees and Credits

The Exchange believes that its proposal equitably allocates its fees among Users. Without this proposed rule change, Users would have fewer options for connectivity to CME Group market data. The proposed change would provide Users with an additional choice with respect to the form and optimal latency of the connectivity they use to receive CME Group market data, allowing a User to select the connectivity that better suits its needs, helping it tailor its colocation operations to the requirements of its business operations. Users that do not opt to utilize the Exchange's proposed wireless connection would still be able to obtain CME Group market data wirelessly using Quincy's wireless connection.

The Exchange believes that the proposed change is equitable because it will result in fees being charged only to Users that voluntarily select to receive the corresponding services and because those services will be available to all Users. Furthermore, the Exchange believes that the services and fees proposed herein are equitably allocated because, in addition to the services being completely voluntary, they are available to all Users on an equal basis (*i.e.,* the same products and services are available to all Users). All Users that voluntarily select the Exchange's proposed wireless connections to CME Group Data would be charged the same amount for the same services.

The Proposed Change Is Not Unfairly Discriminatory

The Exchange believes that the proposed rule change is not unfairly discriminatory, for the following reasons. Without this proposed rule change, Users would have fewer options for connectivity to CME Group Data. The proposed change would provide Users with an additional choice with respect to the form and optimal latency of the connectivity they use to receive CME Group market data, allowing a User to select the connectivity that better suits its needs, helping it tailor its colocation operations to the requirements of its business operations. Users that do not opt to utilize the Exchange's proposed wireless connection would still be able to obtain CME Group market data wirelessly using Quincy's wireless connection.

The Exchange believes that it is not unfairly discriminatory to not transport information for all of the symbols included in CME Group data feeds to the MDC, but rather to transport a subset of that data. There is limited bandwidth available on the wireless network to colocation, and there are a number of CME Group data feeds. Limiting the feeds to the selection of CME Group market data regarding securities for which FIDS determines there is demand would allow Users to receive the relevant CME Group Data over a wireless network.

The Exchange believes that the proposed change is not unfairly discriminatory because it will result in fees being charged only to Users that voluntarily select to receive the corresponding services and because those services will be available to all Users. Furthermore, the Exchange believes that the services and fees proposed herein are not unfairly discriminatory because, in addition to the services being completely voluntary, they are available to all Users on an equal basis (*i.e.,* the same products and services are available to all Users). All Users that voluntarily select wireless connections to CME Group Data would be charged the same amount for the same services. Users that opt to use wireless connections to CME Group Data would receive the CME Group Data that is available to all Users, as all market participants that contract with CME Group or its affiliate for CME Group Data, as required, may receive it.

For the reasons above, the proposed changes do not unfairly discriminate between or among market participants that are otherwise capable of satisfying any applicable colocation fees, requirements, terms, and conditions established from time to time by the Exchange.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange believes that the proposal will not impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of Section 6(b)(8) of the Act.[27]

The proposed change would not affect competition among national securities exchanges or among members of the Exchange, but rather between FIDS and its commercial competitors. The proposed wireless connection would provide Users with an alternative means of connectivity to CME Group Data. The proposed change would provide Users with an additional choice with respect to the form and optimal latency of the connectivity they use to receive CME Group market data, allowing a User to select the connectivity that better suits its needs, helping it tailor its colocation operations to the requirements of its business operations.

Users that do not opt to utilize the Exchange's proposed wireless connection would still be able to obtain CME Group market data wirelessly using Quincy's wireless connection. The Exchange's proposed wireless connection and the existing Quincy wireless connection to CME Group market data are sufficiently similar substitutes and thus provide market participants with choices to meet their wireless connectivity needs.

In addition, the Exchange does not believe that FIDS would have any competitive advantage over either the existing third-party provider or any future providers of wireless connectivity to CME Group market data. The

[26] *See* Wireless Approval Order, *supra* note 16.

[27] 15 U.S.C. 78f(b)(8).

Exchange's proposed service for connectivity to CME Group Data does not have any special access to or advantage within the MDC. The Exchange's proposed wireless connection would lead to a pole, from which a fiber connection would lead into the MDC. The pole is owned by a third party and is not on the grounds of the MDC, and the path into the MDC through a meet-me-room is the same path followed by any Telecom. Within the MDC, the proposed connection would follow the same route as that of any User, connecting to equipment in colocation and then to any Users that are customers.

Further, all distances in the MDC are normalized and Exchange rules require that the distance from the Patch Panel Point to each User cabinet in colocation be the same.[28] Every provider of wireless connectivity to Users, including FIDS, is connected to the Patch Panel Point, and the length of the fiber path from the Patch Panel Point to each User cabinet in colocation is the same.

Nor does the Exchange have a competitive advantage over the third-party competitors offering wireless connectivity to CME Group market data by virtue of the fact that it owns and operates the MDC's meet-me-rooms. Users purchasing wireless connectivity to CME Group market data—like Users of any other colocation service—would require a circuit connecting out of the MDC, and in most cases, such circuits are provided by third-party Telecoms that have installed their equipment in the MDC's two meet-me-rooms.[29] Currently, 16 Telecoms operate in the meet-me-rooms and provide a variety of circuit choices. It is in the Exchange's best interest to set the fees that Telecoms pay to operate in the meet-me-rooms at a reasonable level [30] so that market participants, including Telecoms, will maximize their use of the MDC. By setting the meet-me-room fees at a reasonable level, the Exchange encourages Telecoms to participate in the meet-me-rooms and to sell circuits to Users for connecting into and out of the MDC. These Telecoms then compete with each other by pricing such circuits at competitive rates. These competitive rates for circuits help draw in more Users and Hosted Customers to the MDC, which directly benefits the Exchange by increasing the customer base to whom the Exchange can sell its colocation services, which include cabinets, power, ports, and connectivity to many third-party data feeds, and because having more Users and Hosted Customers leads, in many cases, to greater participation on the Exchange. In this way, by setting the meet-me-room fees at a level attractive to telecommunications firms, the Exchange spurs demand for all of the services it sells at the MDC, while setting the meet-me-room fees too high would negatively affect the Exchange's ability to sell its services at the MDC.[31] Accordingly, there are real constraints on the meet-me-room fees the Exchange charges, such that the Exchange does not have an advantage in terms of costs when compared to third parties that enter the MDC through the meet-me-rooms to provide services to compete with the Exchange's services.

If anything, the Exchange is subject to a competitive disadvantage vis-à-vis third party competitors offering wireless connectivity to CME Group market data. Third-party competitors are not subject to the Commission's filing requirements, and therefore can freely change their services and pricing in response to competitive forces. In contrast, the Exchange's service and pricing would be standardized as set out in this filing, and the Exchange would be unable to respond to pricing pressure from its competitors without seeking a formal fee change in a filing before the Commission.

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 Exchange has filed the proposed rule change pursuant to Section 19(b)(3)(A)(iii) of the Act [32] and Rule 19b–4(f)(6) thereunder.[33] Because the 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 prior to 30 days from the date on which it was filed, or such shorter time as the Commission may designate, if consistent with the protection of investors and the public interest, the proposed rule change has become effective pursuant to Section 19(b)(3)(A) of the Act and Rule 19b–4(f)(6)(iii) thereunder.

A proposed rule change filed under Rule 19b–4(f)(6) [34] normally does not become operative prior to 30 days after the date of the filing. However, pursuant to Rule 19b4(f)(6)(iii),[35] the Commission may designate a shorter time if such action is consistent with the protection of investors and the public interest.

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) [36] of the Act to determine whether the proposed rule change should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic comments

- Use the Commission's internet comment form (*https://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov*. Please include file number SR–NYSEARCA–2023–79 on the subject line.

Paper comments

- Send paper comments in triplicate to: Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to file number SR–NYSEARCA–2023–79. 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 (*https://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

[28] *See supra* note 22.

[29] *See supra* note 23.

[30] *See* MMR Notice, *supra* note 24.

[31] *See supra* note 25.

[32] 15 U.S.C. 78s(b)(3)(A)(iii).

[33] 17 CFR 240.19b–4(f)(6).

[34] 17 CFR 240.19b–4(f)(6).

[35] 17 CFR 240.19b–4(f)(6)(iii).

[36] 15 U.S.C. 78s(b)(2)(B).

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 a.m. and 3 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. Do not include personal identifiable information in submissions; you should submit only information that you wish to make available publicly. We may redact in part or withhold entirely from publication submitted material that is obscene or subject to copyright protection. All submissions should refer to file number SR–NYSEARCA–2023–79 and should be submitted on or before December 13, 2023.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[37]

Sherry R. Haywood,

Assistant Secretary.

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SECURITIES AND EXCHANGE COMMISSION

[Investment Company Act Release No. 35050; File No. 812–15458]

John Hancock GA Mortgage Trust, et al.

November 16, 2023.

AGENCY: Securities and Exchange Commission (''Commission'' or ''SEC'').

ACTION: Notice.

Notice of application for an order (''Order'') under sections 17(d) and 57(i) of the Investment Company Act of 1940 (the ''Act'') and rule 17d–1 under the Act to permit certain joint transactions otherwise prohibited by sections 17(d) and 57(a)(4) of the Act and rule 17d–1 under the Act.

Summary of Application: Applicants request an order to amend a previous order granted by the Commission that permits certain business development companies (''BDCs'') and closed-end management investment companies to co-invest in portfolio companies with each other and with certain affiliated investment entities.

Applicants: John Hancock GA Mortgage Trust, John Hancock GA Senior Loan Trust, Manulife Investment Management Private Markets (US) LLC, John Hancock Life Insurance Company (U.S.A.), John Hancock Life & Health Insurance Company, John Hancock Life Insurance Company of New York, John Hancock Funding Company, LLC, Manulife SDF SPV—OH, LLC, MDLF Holdings Onshore LLC, Manulife Direct Lending Fund (Unlevered) L.P., and Manulife Direct Lending Fund, L.P.

Filing Dates: The application was filed on April 25, 2023, and amended on May 10, 2023, August 16, 2023, and October 4, 2023.

Hearing or Notification of Hearing: An order granting the requested relief will be issued unless the Commission orders a hearing. Interested persons may request a hearing on any application by emailing the SEC's Secretary at *Secretarys-Office@sec.gov* and serving the Applicants with a copy of the request by email, if an email address is listed for the relevant Applicant below, or personally or by mail, if a physical address is listed for the relevant Applicant below. Hearing requests should be received by the Commission by 5:30 p.m. on, December 11, 2023, and should be accompanied by proof of service on applicants, in the form of an affidavit or, for lawyers, a certificate of service. Pursuant to rule 0–5 under the Act, hearing requests should state the nature of the writer's interest, any facts bearing upon the desirability of a hearing on the matter, the reason for the request, and the issues contested. Persons who wish to be notified of a hearing may request notification by emailing the Commission's Secretary at *Secretarys-Office@sec.gov*.

ADDRESSES: The Commission: *Secretarys-Office@sec.gov*. Applicants: E. David Pemstein, John Hancock GA Mortgage Trust, John Hancock GA Senior Loan Trust, c/o John Hancock Life Insurance Company (U.S.A.), at *DPemstein@jhancock.com;* and George J. Zornada, Esq., K&L Gates LLP, at *George.Zornada@klgates.com*.

FOR FURTHER INFORMATION CONTACT: Kieran G. Brown, Senior Counsel, or Terri Jordan, Branch Chief, at (202) 551–6825 (Division of Investment Management, Chief Counsel's Office).

SUPPLEMENTARY INFORMATION: For Applicants' representations, legal analysis, and conditions, please refer to Applicants' third amended and restated application, dated October 4, 2023, which may be obtained via the Commission's website by searching for the file number at the top of this document, or for an Applicant using the Company name search field, on the SEC's EDGAR system. The SEC's EDGAR system may be searched at *http://www.sec.gov/edgar/searchedgar/legacy/companysearch.html.* You may also call the SEC's Public Reference Room at (202) 551–8090.

For the Commission, by the Division of Investment Management, under delegated authority.

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2023–25782 Filed 11–21–23; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–98975; File No. SR–NYSEAMER–2023–57]

Self-Regulatory Organizations; NYSE American LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Expand the Application of the per User Access Fee for Use of Certain Market Data Products by Redistributors

November 16, 2023.

Pursuant to Section 19(b)(1)[1] of the Securities Exchange Act of 1934 (''Act'')[2] and Rule 19b–4 thereunder,[3] notice is hereby given that on November 1, 2023, 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 and II 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 fees for NYSE American BBO and NYSE American Trades by expanding the application of the Per User Access Fee. The Exchange proposes to implement the proposed fee change on November 1, 2023. 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,

[37] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 15 U.S.C. 78a.

[3] 17 CFR 240.19b–4.

and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of those statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant parts of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to expand the application of the Per User Access Fee [4] for certain NYSE American market data products, as set forth on the NYSE American Proprietary Market Data Fee Schedule (''Fee Schedule''). Specifically, the Exchange proposes to expand the application of the Per User Access Fee, which is currently available for Redistributors [5] of NYSE American BBO and NYSE American Trades that subscribe to only such data feeds and do not subscribe to any other market data product listed on the Fee Schedule and use such market data product for external distribution only. The Exchange proposes to make the Per User Access Fee available to Redistributors of NYSE American OpenBook as well.

The proposed fee change, taken together with similar fee changes filed by the Exchange's affiliated exchanges, New York Stock Exchange LLC (''NYSE'') and NYSE Arca, Inc. (''NYSE Arca''),[6] will reduce the fees associated with the NYSE BQT proprietary data product for Redistributors of NYSE American OpenBook. As described below, NYSE BQT competes directly with similar products offered by both the Nasdaq and Cboe families of U.S. equity exchanges. Collectively, the proposed fee changes are intended to respond to the competition posed by similar products offered by the other exchange groups.

The Exchange proposes to implement the proposed fee change on November 1, 2023.

Background

The Securities and Exchange Commission (''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.'' [7]

While Regulation NMS has enhanced competition, it has also fostered a ''fragmented'' market structure where trading in a single stock can occur across multiple trading centers. When multiple trading centers compete for order flow in the same stock, the Commission has recognized that ''such competition can lead to the fragmentation of order flow in that stock.'' [8] Indeed, equity trading is currently dispersed across 16 exchanges,[9] numerous alternative trading systems,[10] and broker-dealer internalizers and wholesalers, all competing for order flow. Based on publicly-available information, no single exchange currently has more than 17% market share (whether including or excluding auction volume).[11]

With the NYSE BQT market data product, NYSE American and its affiliates compete head to head with the Nasdaq Basic [12] and Cboe One Feed [13] market data products. Similar to those market data products, NYSE BQT, which was established in 2014,[14] consists of certain elements from the NYSE American BBO and NYSE American Trades market data products as well as from market data products from the Exchange's affiliates, NYSE, NYSE Arca, NYSE Chicago, Inc. (''NYSE Chicago''),[15] and NYSE National, Inc. (''NYSE National'').[16] Similar to both Nasdaq Basic and the Cboe One Feed, NYSE BQT provides investors with a unified view of comprehensive last sale and BBO data in all Tape A, B, and C securities that trade on the Exchange, NYSE, NYSE Arca, NYSE Chicago, and NYSE National. Also similar to Nasdaq Basic and the Cboe One Feed, NYSE BQT is not intended to be used for purposes of making order-routing or trading decisions, but rather provides indicative prices for Tape A, B, and C securities.[17]

Together with NYSE and NYSE Arca, the Exchange proposes to compete for subscribers to NYSE BQT by designing the proposed fee change to be attractive to Redistributors of NYSE American OpenBook that intend to subscribe to and externally redistribute NYSE BQT. Currently, Redistributors of NYSE American OpenBook that want to subscribe to and redistribute NYSE BQT must pay the General Access Fee. Redistributors of NYSE American OpenBook who have data recipient customers interested in NYSE BQT may

[4] The Per User Access Fee is a lower access fee that currently applies for subscribers of NYSE American BBO and NYSE American Trades that receive a data feed and use those market data products in a display-only format. *See* Fee Schedule. *See also* Securities Exchange Act Release Nos. 87801 (December 19, 2019), 84 FR 71491 (December 27, 2019) (SR–NYSEAMER–2019–55) (Notice of Filing and Immediate Effectiveness of Proposed Rule Change, as Modified by Partial Amendment No. 1, To Amend the Fees for NYSE American BBO and NYSE American Trades) (''BQT Fee Reduction Filing''); and 90408 (November 12, 2020), 85 FR 73556 (November 18, 2020) (SR–NYSEAMER–2020–79) (Notice of Filing and Immediate Effectiveness of Proposed Rule Change Amending the Fees for NYSE American BBO and NYSE American Trades by Modifying the Application of the Access Fee and Amending the Fees for NYSE American Trades by Adopting a Waiver Applicable to the Redistribution Fee) (''Second BQT Fee Reduction Filing'').

[5] A Redistributor is a vendor or any other person that provides a NYSE data product to a data recipient or to any system that a data recipient uses, irrespective of the means of transmission or access.

[6] *See* SR–NYSE–2023–42 and SR–NYSEArca–2023–78.

[7] *See* Securities Exchange Act Release No. 51808 (June 9, 2005), 70 FR 37495, 37499 (June 29, 2005) (S7–10–04) (Final Rule) (''Regulation NMS Adopting Release'').

[8] *See* Securities Exchange Act Release No. 61358, 75 3594, 3597 (January 21, 2010) (File No. S7–02–10) (Concept Release on Equity Market Structure).

[9] *See* Cboe U.S. Equities Market Volume Summary, available at *http://markets.cboe.com/us/equities/market_share/.*

[10] *See* FINRA ATS Transparency Data, *available at https://otctransparency.finra.org/otctransparency/AtsIssueData.* A list of alternative trading systems registered with the Commission is *available at https://www.sec.gov/foia/docs/atslist.htm.*

[11] *See* Cboe U.S. Equities Market Volume Summary, available at *http://markets.cboe.com/us/equities/market_share/.*

[12] As described on the Nasdaq website, available here: *http://www.nasdaqtrader.com/Trader.aspx?id=nasdaqbasic,* Nasdaq Basic is a ''low cost alternative'' that provides ''Best Bid and Offer and Last Sale information for all U.S. exchange-listed securities based on liquidity within the Nasdaq market center, as well as trades reported to the FINRA Trade Reporting Facility (''TRF'').''

[13] As described on the Cboe website, available here: *https://markets.cboe.com/us/equities/market_data_services/cboe_one/,* the Cboe One Feed is a ''market data product that provides cost-effective, high-quality reference quotes and trade data for market participants looking for comprehensive, real-time market data'' and provides a ''unified view of the market from all four Cboe equity exchanges: BZX Exchange, BYX Exchange, EDGX Exchange, and EDGA Exchange.''

[14] *See* Securities Exchange Act Release Nos. 72750 (August 4, 2014), 79 FR 46494 (August 8, 2014) (notice—NYSE BQT); and 73553 (November 6, 2014), 79 FR 67491 (November 13, 2014) (approval order—NYSE BQT) (SR–NYSE–2014–40) (''NYSE BQT Filing'').

[15] In 2019, NYSE BQT was amended to include NYSE Chicago BBO and NYSE Chicago Trades. *See* Securities Exchange Act Release No. 87511 (November 12, 2019), 84 FR 63689 (November 18, 2019) (SR–NYSE–2019–60).

[16] In 2018, NYSE BQT was amended to include NYSE National BBO and NYSE National Trades. *See* Securities Exchange Act Release No. 83359 (June 1, 2018), 83 FR 26507 (June 7, 2018) (SR–NYSE–2018–22).

[17] *See* NYSE BQT Filing, *supra* note 14.

not be inclined to subscribe to NYSE BQT. When Redistributors do not subscribe to NYSE BQT, the prospective data recipients that are the customers of such Redistributors are unable to subscribe to NYSE BQT. The proposed fee change is designed to provide a financial incentive for such Redistributors to subscribe to NYSE BQT so that their customers, which have expressed an interest in subscribing to NYSE BQT, would be able to access the product via such Redistributors.

Currently, subscribers of each of the NYSE American BBO and NYSE American Trades products that receive a data feed pay a General Access Fee of $750 per month. In February 2020, the Exchange added the Per User Access Fee, which is a reduced fee of $100 per month available at that time only for subscribers of NYSE American BBO and NYSE American Trades that use those products in a display-only format, including for internal use for Professional Users and external distribution to both Professional and Non-Professional Users.[18]

In November 2020, the Exchange expanded the application of the reduced Per User Access Fee to Redistributors of NYSE American BBO and NYSE American Trades data feeds that do not subscribe to any other market data product listed on the Fee Schedule and use such market data products for external distribution only.[19]

As noted above, the Exchange now proposes to further expand the applicability of the reduced Per User Access Fee. Specifically, the Exchange proposes that Redistributors of NYSE American BBO and NYSE American Trades that do not subscribe to any other market data product listed on the Fee Schedule other than NYSE American OpenBook and use such market data products for external distribution only, would be eligible for the reduced Per User Access Fee. A Redistributor that receives such data feeds and uses the market data products for any other purpose (such as internal use) would continue to pay the $1,500 per month General Access Fee. And, as currently set forth in footnote 3 to the Fee Schedule, a subscriber would be charged only one access fee for each of the NYSE American BBO and NYSE American Trades products, depending on the use of that product.

To effect this change, the Exchange proposes to modify footnote 3 to the Fee Schedule as follows (proposed text italicized, proposed deletions bracketed):

> The Per User Access Fee is charged to: (i) a subscriber that receives a data feed and uses the market data product only for Professional Users and Non-Professional Users in a display-only format, including for internal use and external redistribution in a display-only format, and (ii) a Redistributor that subscribes [only] to the NYSE American BBO and NYSE American Trades data feeds, and does not subscribe to any other Products listed on this Fee Schedule *other than the NYSE American OpenBook data feed,* and uses these market data products for external distribution only. A subscriber that receives a data feed and uses the market data product for any other purpose, including if combined with Per User use, will be charged the General Access Fee. A subscriber will be charged only one access fee for each of the NYSE American BBO and NYSE American Trades products, depending on the use of that product.

The proposed rule change would result in lower fees for Redistributors that receive NYSE American BBO, NYSE American Trades, and NYSE American OpenBook data feeds, and use such market data products for external distribution only.[20] The Exchange believes that the proposed expansion of the reduced Per User Access Fee would provide an incentive for Redistributors that currently subscribe to NYSE American OpenBook to also subscribe to the NYSE BQT data feeds so that such product would be available to their customers, which have expressed an interest in subscribing to NYSE BQT.

The proposed rule change is intended to encourage greater use of NYSE BQT by making it more affordable for Redistributors that subscribe to NYSE American OpenBook and also have customers interested in subscribing to NYSE BQT. The proposed fee change would allow the Exchange to compete more effectively with Nasdaq Basic and Cboe One Feed by expanding the number of Redistributors that would subscribe to NYSE BQT, and therefore make the product more widely available to data subscribers interested in NYSE BQT.

Applicability of Proposed Rule Change

As noted above, the proposed rule change is designed to reduce the overall cost for Redistributors of NYSE BQT that also redistribute NYSE American OpenBook by expanding the applicability of the reduced Per User Access Fee. Today, the Exchange has thirty-one data feed subscribers, two of whom became Redistributors as a direct result of the Second BQT Fee Reduction Filing and currently pay the reduced Per User Access Fee. The Exchange believes that the proposed rule change would provide a further incentive for Redistributors that already subscribe to NYSE American OpenBook to subscribe to NYSE BQT for purposes of providing external distribution of NYSE BQT to potential data recipients interested in the product.

Because the proposed rule change is targeted to potential Redistributors of NYSE BQT that also subscribe to NYSE American OpenBook, the proposed change to the availability of the NYSE American BBO and NYSE American Trades Per User Access Fees, together with the proposed changes on NYSE and NYSE Arca, are narrowly tailored with that purpose in mind. Accordingly, this proposed fee change is not designed for Redistributors that are existing customers of NYSE American market data products (other than NYSE American OpenBook) or that engage in internal use of NYSE BQT. This proposed rule change would not result in any changes to the market data fees for NYSE American BBO and NYSE American Trades for such data subscribers.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with the provisions of Section 6 of the Act,[21] in general, and Sections 6(b)(4) and 6(b)(5) of the Act,[22] in particular, in that it provides an equitable allocation of reasonable fees among users and recipients of the data and is not designed to permit unfair discrimination among customers, issuers, and brokers.

The Proposed Rule Change Is Reasonable

In adopting Regulation NMS, the Commission granted SROs and broker-dealers increased authority and flexibility to offer new and unique market data to the public. The Commission has repeatedly expressed its preference for competition over regulatory intervention in determining prices, products, and services in the securities markets. Specifically, in Regulation NMS, the Commission highlighted the importance of market forces in determining prices and SRO revenues, and also recognized that

[18] *See* BQT Fee Reduction Filing, *supra,* note 4.

[19] *See* Second BQT Fee Reduction Filing, *supra,* note 4.

[20] The Per User Access Fee is 93% lower than the General Access Fee. Together with the corresponding proposed rule changes by NYSE and NYSE Arca to similarly reduce the access fees to their BBO and Trades products for Redistributors, such Redistributors would be eligible for significantly lower access fees for NYSE BQT, from $6,250 per month to $850 per month ($250 + $200 + $200 +$200), a reduction of more than 86%.

[21] 15 U.S.C. 78f(b).

[22] 15 U.S.C. 78f(b)(4), (5).

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.'' [23]

With respect to market data, the decision of the United States Court of Appeals for the District of Columbia Circuit in *NetCoalition* v. *SEC* upheld the Commission's reliance on the existence of competitive market mechanisms to evaluate the reasonableness and fairness of fees for proprietary market data:

> In fact, the legislative history indicates that the Congress intended that the market system ''evolve through the interplay of competitive forces as unnecessary regulatory restrictions are removed'' and that the SEC wield its regulatory power ''in those situations where competition may not be sufficient,'' such as in the creation of a ''consolidated transactional reporting system.'' [24]

The court agreed with the Commission's conclusion that ''Congress intended that 'competitive forces should dictate the services and practices that constitute the U.S. national market system for trading equity securities.' '' [25]

More recently, the Commission confirmed that it applies a ''market-based'' test in its assessment of market data fees, and that under that test:

> the Commission considers whether the exchange was subject to significant competitive forces in setting the terms of its proposal for [market data], including the level of any fees. If an exchange meets this burden, the Commission will find that its fee rule is consistent with the Act unless there is a substantial countervailing basis to find that the terms of the rule violate the Act or the rules thereunder.[26]

1. The Proposed Fees Are Constrained by Significant Competitive Forces

An exchange may demonstrate that its fees are constrained by competitive forces by showing that platform competition applies.

As the United States Supreme Court recognized in *Ohio* v. *American Express,* platforms are firms that act as intermediaries between two or more sets of agents, and typically the choices made on one side of the platform affect the results on the other side of the platform via externalities, or ''indirect network effects.'' [27] Externalities are linkages between the different ''sides'' of a platform such that one cannot understand pricing and competition for goods or services on one side of the platform in isolation; one must also account for the influence of the other side. As the Supreme Court explained:

> To ensure sufficient participation, two-sided platforms must be sensitive to the prices that they charge each side. . . . Raising the price on side A risks losing participation on that side, which decreases the value of the platform to side B. If the participants on side B leave due to this loss in value, then the platform has even less value to side A—risking a feedback loop of declining demand. . . . Two-sided platforms therefore must take these indirect network effects into account before making a change in price on either side.[28]

The Exchange and its affiliated exchanges have long maintained that they function as platforms between consumers of market data and consumers of trading services. Proving the existence of linkages between the two sides of this platform requires an in-depth economic analysis of both public data and confidential Exchange data about particular customers' trading activities and market data purchases. Exchanges, however, are prohibited from sharing details about these specific customer activities and purchases. For example, pursuant to Exchange Rule 7.41E, transactions executed on the Exchange are processed anonymously.

Exchanges function as platforms for market data and transaction services mean that exchanges do not set fees for market data products without considering, and being constrained by, the effect the fees will have on the order-flow side of the platform. And as the D.C. Circuit recognized in *NetCoalition I,* ''[n]o one disputes that competition for order flow is fierce.'' [29] The court further noted that ''no exchange possesses a monopoly, regulatory or otherwise, in the execution of order flow from broker dealers,'' and that an exchange ''must compete vigorously for order flow to maintain its share of trading volume.'' [30]

As noted above, while Regulation NMS has enhanced competition, it has also fostered a ''fragmented'' market structure where trading in a single stock can occur across multiple trading centers. When multiple trading centers compete for order flow in the same stock, the Commission has recognized that ''such competition can lead to the fragmentation of order flow in that stock.'' [31] The Commission's Division of Trading and Markets has also recognized that with so many ''operating equities exchanges and dozens of ATSs, there is vigorous price competition among the U.S. equity markets and, as a result, [transaction] fees are tailored and frequently modified to attract particular types of order flow, some of which is highly fluid and price sensitive.'' [32] Indeed, today, equity trading is currently dispersed across 16 exchanges,[33] numerous alternative trading systems,[34] broker-dealer internalizers and wholesalers, all competing for order flow. Based on publicly-available information, no single exchange currently has more than 17% market share.[35]

Further, low barriers to entry mean that new exchanges may, and do, rapidly and inexpensively enter the market and offer additional substitute platforms to compete with the Exchange. For example, since 2020, three new exchanges have entered the market: Long Term Stock Exchange (LTSE), which began operations as an exchange on August 28, 2020; [36] Members Exchange (MEMX), which began operations as an exchange on

[23] *See* Regulation NMS Adopting Release, 70 FR 37495, at 37499.

[24] *NetCoalition* v. *SEC,* 615 F.3d 525, 535 (D.C. Cir. 2010) (''*NetCoalition I*'') (quoting H.R. Rep. No. 94–229 at 92 (1975), *as reprinted in* 1975 U.S.C.C.A.N. 323).

[25] *Id.* at 535.

[26] *See* Securities Exchange Act Release No. 34–90217 (October 16, 2020), 85 FR 67392 (October 22, 2020) (SR–NYSENAT–2020–05) (''National IF Approval Order'') (internal quotation marks omitted), quoting Securities Exchange Act Release No. 59039 (December 2, 2008), 73 FR 74770, 74781 (December 9, 2008) (''2008 ArcaBook Approval Order'').

[27] *Ohio* v. *American Express,* 138 S. Ct. 2274, 2280–81 (2018).

[28] *Id.* at 2281.

[29] *NetCoalition I,* 615 F.3d at 544 (internal quotation omitted).

[30] *Id.*

[31] *See* Securities Exchange Act Release No. 61358, 75 3594, 3597 (January 21, 2010) (File No. S7–02–10) (Concept Release on Equity Market Structure).

[32] Commission Division of Trading and Markets, Memorandum to EMSAC, dated October 20, 2015, available here: *https://www.sec.gov/spotlight/emsac/memo-maker-taker-fees-on-equities-exchanges.pdf.*

[33] *See* Cboe Global Markets, U.S. Equities Market Volume Summary, available at *http://markets.cboe.com/us/equities/market_share/.*

[34] *See* FINRA ATS Transparency Data, *available at https://otctransparency.finra.org/otctransparency/AtsIssueData.* A list of alternative trading systems registered with the Commission is *available at https://www.sec.gov/foia/docs/atslist.htm.*

[35] *See* Cboe Global Markets, U.S. Equities Market Volume Summary, available at *http://markets.cboe.com/us/equities/market_share/.*

[36] *See* LTSE Market Announcement: MA–2020–020, dated August 14, 2020, announcing LTSE production securities phase-in planned for August 28, available here: *https://assets-global.website-files.com/6462417e8db99f8baa06952c/6462417e8db99f8baa0698e7_MA-2020-020__Production_Securities_Launching_August_28_-_Google_Docs.pdf* and LTSE Market Announcement: MA–2020–025, available here: *https://assets-global.website-files.com/6462417e8db99f8baa06952c/6462417e8db99f8baa069873_MA-2020-025.pdf.*

September 29, 2020;[37] and Miami International Holdings (MIAX), which began operations of its first equities exchange on September 29, 2020.[38]

These low barriers enable existing exchange customers to disintermediate and start their own exchanges if they think the prices charged for exchange proprietary market data products are too high. This is precisely the rationale behind the creation of MEMX, which was formed by some of the largest and most well capitalized financial firms that are also Exchange customers (including Bank of America, BlackRock, Charles Schwab, Citadel, Citi, E*Trade, Fidelity, Goldman Sachs, J.P. Morgan, Jane Street, Morgan Stanley, TD Ameritrade, and others).[39]

For example, one of MEMX's founding principles is that exchange proprietary market data prices are too high, and that MEMX will benefit its members by offering ''[l]ower pricing on market data.'' [40] Nor is this a new phenomenon: exchange customers formed BATS to compete with incumbent exchanges and once registered as an exchange in 2008, BATS did not initially charge for market data. The BATS venture was a financial success for its founders, first through recouping their investment in its initial public offering and then in the subsequent sale of BATS to Cboe, which now charges for market data from those exchanges. Notably, MEMX has some of the same founding broker-dealer customers, leading some to dub MEMX ''BATS 2.0.'' [41]

The fact that this cycle is viable and repeatable by entities that both trade on and compete with existing exchanges confirms that barriers to entry are low and that these markets are competitive and contestable.[42] And low barriers to entry act as a market check on high prices.[43]

In sum, the fierce competition for order flow thus constrains any exchange from pricing its market data at a supracompetitive price, and constrains the Exchange in setting its fees at issue here.

The proposed expansion of the Per User Access Fee is therefore reasonable because in setting it, the Exchange is constrained by the availability of numerous substitute platforms offering market data products and trading. Such substitutes need not be identical, but only substantially similar to the product at hand.

More specifically, in expanding the applicability of the Per user Access Fee to Redistributors of NYSE American OpenBook, the Exchange is constrained by the fact that, if its pricing across the platform is unattractive to customers, customers have their pick of an increasing number of alternative platforms to use instead of the Exchange. The Exchange believes that it has considered all relevant factors and has not considered irrelevant factors in order to establish reasonable fees. The existence of numerous alternative platforms to the Exchange's platform ensures that the Exchange cannot set unreasonable market data fees without suffering the negative effects of that decision in the fiercely competitive market for trading order flow.

Even putting aside the facts that exchanges are platforms and that pricing decisions on the two sides of the platform are intertwined, the Exchange is constrained in setting the proposed market data fees by the availability of numerous substitute market data products. The Commission has been clear that substitute products need not be identical, but only substantially similar to the product at hand.[44]

The NYSE BQT market data product is subject to significant competitive forces that constrain its pricing. Specifically, as described above, NYSE BQT competes head-to-head with the Nasdaq Basic product and the Cboe One Feed. These products each serve as reasonable substitutes for one another as they are each designed to provide investors with a unified view of real-time quotes and last-sale prices in all Tape A, B, and C securities. Each product provides subscribers with consolidated top-of-book quotes and trades from multiple U.S. equities markets. In the case of NYSE BQT, this product provides top-of-book quotes and trades data from five NYSE-affiliated U.S. equities exchanges, which together account for approximately 20% of consolidated U.S. equities trading volume as of October 2023.[45] Cboe One Feed similarly provides top-of-book quotes and trades data from Cboe's four U.S. equities exchanges. NYSE BQT, Nasdaq Basic, and Cboe One Feed are all intended to provide indicative pricing and are not intended to be used for order routing or trading decisions.

In addition to competing with proprietary data products from Nasdaq and Cboe, NYSE BQT also competes with the consolidated data feed. However, the Exchange does not claim that NYSE BQT is a substitute for consolidated data with respect to requirements under the Vendor Display Rule, which is Regulation NMS Rule 603(c).

The fact that this filing is proposing to further expand the application of the reduced Per User Access Fee is itself confirmation of the inherently competitive nature of the market for the sale of proprietary market data. For example, in August 2019, Cboe filed proposed rule changes to reduce certain of its Cboe One Feed fees and noted that it attracted two additional customers because of the reduced fees.[46] More

[37] As of October 29, 2020, MEMX is trading all NMS symbols. *See https://info.memxtrading.com/trader-alert-20-10-memx-trading-symbols-update/.*

[38] *See* MIAX Pearl Press release, dated September 29, 2020, available here: *https://www.miaxoptions.com/sites/default/files/alert-files/MIAX_Press_Release_09292020.pdf.*

[39] MEMX Home Page (''Founded by members and investors, MEMX aims to drive simplicity, efficiency, and competition in equity markets.''), available at *https://memx.com/.*

[40] MEMX home page, available at *https://memx.com/.*

[41] *See* ''MEMX turns up the heat on US stock exchanges,'' Financial Times, January 9, 2019, available at *https://www.ft.com/content/4908c8b0-1418-11e9-a581-4ff78404524e; see also* ''US equities exchanges: If you can't beat them, join them,'' Euromoney, February 13, 2019, available at *https://www.euromoney.com/article/b1d3tfby4p3y4v/us-equities-exchanges-if-you-cant-beat-them-join-them.*

[42] *United States* v. *SunGard Data Sys.,* 172 F. Supp. 2d 172, 186 (D.D.C. 2001) (recognizing that ''[a]s a matter of law, courts have generally recognized that when a customer can replace the services of an external product with an internally-created system, this captive output (*i.e.* the self-production of all or part of the relevant product) should be included in the same market.''). In *SunGard,* the court rejected the Antitrust Division's attempt to block SunGuard's acquisition of the disaster recovery assets of Comdisco on the basis that the acquisition would ''substantially lessen competition in the market for shared hotsite disaster recovery services,'' when the evidence showed that ''internal hotsites'' created by customers competed with the ''external shared hotsite business'' engaged in by the merging parties. *Id.* at 173–74, 187.

[43] *United States* v. *Baker Hughes,* 908 F.2d 981, 987 (1990) (''In the absence of significant barriers [to entry], a company probably cannot maintain supracompetitive pricing for any length of time.''); *see also* David S. Evans and Richard Schmalensee, Markets with Two-Sided Platforms, in 1 Issues In Competition Law And Policy 667, 685 (ABA Section of Antitrust Law 2008) (noting that exchange mergers in 2005 and 2006 were approved by competition authorities in part in reliance on planned and likely entry of other firms).

[44] For example, in the National IF Approval Order, the Commission recognized that for some customers, the best bid and offer information from consolidated data feeds may function as a substitute for the NYSE National Integrated Feed product, which contains order by order information. *See* National IF Approval Order, *supra* note 26, at 67397 [release p. 21] (''[I]nformation provided by NYSE National demonstrates that a number of executing broker-dealers do not subscribe to the NYSE National Integrated Feed and executing broker-dealers can otherwise obtain NYSE National best bid and offer information from the consolidated data feeds.'' (internal quotations omitted)).

[45] *See* Cboe Global Markets U.S. Equities Market Volume Summary, available at *https://www.cboe.com/us/equities/market_share/.*

[46] *See* Securities Exchange Act Release Nos. 86667 (August 14, 2019) (SR–CboeBZX–2019–069);

recently, Nasdaq filed a proposed rule change to lower the enterprise license fee for broker-dealers distributing Nasdaq Basic to internal Professional subscribers and the enterprise license fee for broker-dealers distributing Nasdaq Last Sale to Professional subscribers.[47]

The Exchange notes that NYSE American proprietary market data products are entirely optional. The Exchange is not required to make the proprietary data products that are the subject of this proposed rule change available or to offer any specific pricing alternatives to any customers, nor is any firm or investor required to purchase the Exchange's data products. Unlike some other data products (*e.g.,* the consolidated quotation and last-sale information feeds) that firms are required to purchase in order to fulfil regulatory obligations,[48] a customer's decision whether to purchase any of the Exchange's proprietary market data feeds is entirely discretionary. Most firms that choose to subscribe to proprietary market data feeds from the Exchange and its affiliates do so for the primary goals of using them to increase their revenues, reduce their expenses, and in some instances compete directly with the Exchange's trading services. Such firms are able to determine for themselves whether or not the products in question or any other similar products are attractively priced. If market data feeds from the Exchange and its affiliates do not provide sufficient value to firms based on the uses those firms may have for it, such firms may simply choose to conduct their business operations in ways that do not use the products.

In addition, in the case of products that are also redistributed through market data vendors, such as Bloomberg and Refinitiv, the vendors themselves provide additional price discipline for proprietary data products because they control the primary means of access to certain end users. These vendors impose price discipline based upon their business models. For example, vendors that assess a surcharge on data they sell are able to refuse to offer proprietary products that their end users do not or will not purchase in sufficient numbers. This competitive constraint is precisely what is driving the proposed fee changes here, which are designed to attract new market data vendors, and through them new subscribers, to the NYSE BQT product. Currently, only seven data feed vendors subscribe to NYSE BQT, and each vendor has limited redistribution of NYSE BQT. No other vendors currently subscribe to NYSE BQT and likely will not unless their customers request it, and customers will not elect to pay the proposed fees unless such product can provide value by sufficiently increasing revenues or reducing costs in the customer's business in a manner that will offset the fees. All of these factors operate as constraints on pricing proprietary data products.

Because of the availability of substitutes, an exchange that overprices its market data products stands a high risk that users may substitute another source of market data information for its own. Those competitive pressures imposed by available alternatives are evident in the Exchange's proposed pricing.

In setting the proposed fees, the Exchange considered the competitiveness of the market for proprietary data and all of the implications of that competition. The Exchange believes that it has considered all relevant factors and has not considered irrelevant factors in order to establish reasonable fees. The existence of numerous alternatives to the Exchange's platform and, more specifically, alternatives to the market data products, including proprietary data from other sources, ensures that the Exchange cannot set unreasonable fees when vendors and subscribers can elect these alternatives or choose not to purchase a specific proprietary data product if the attendant fees are not justified by the returns that any particular vendor or data recipient would achieve through the purchase.

The proposed expansion of the Per User Access Fee is reasonable, for the following additional reasons.

Overall. This proposed fee change is a result of the competitive environment, as the Exchange seeks to decrease certain of its fees to attract Redistributors that do not currently subscribe to the NYSE BQT market data product. The Exchange is proposing the fee reduction at issue to make the Exchange's fees more competitive for a specific segment of market participants, thereby increasing the availability of the Exchange's data products, and

86670 (August 14, 2019) (SR–CboeBYX–2019–012); 86676 (August 14, 2019) (SR–CboeEDGA–2019–013); and 86678 (August 14, 2019) (SR–CboeEDGX–2019–048) (Notices of filing and Immediate effectiveness of proposed rule change to reduce fees for the Cboe One Feed) (collectively ''Cboe One Fee Filings''). The Cboe One Fee Filings were in effect from August 1, 2019 until September 30, 2019, when the Commission suspended them and instituted proceedings to determine whether to approve or disapprove those proposals. *See, e.g.,* Securities Exchange Act Release No. 87164 (September 30, 2019), 84 FR 53208 (October 4, 2019) (SR–CboeBZX–2019–069). On October 1, 2019, the Cboe equities exchanges refiled the Cboe One Fee Filings on the basis that they had new customers subscribe as a result of the Cboe One Fee Filings, and therefore its fee proposal had increased competition for top-of-book market data. *See* Securities Exchange Act Release Nos. 87312 (October 15, 2019), 84 FR 56235 (October 21, 2019) (SR–CboeBZX–2019–086); 87305 (October 14, 2019), 84 FR 56210 (October 21, 2019) (SR–CboeBYX–2019–015); 87295 (October 11, 2019), 84 FR 55624 (October 17, 2019) (SR–CboeEDGX–2019–059); and 87294 (October 11, 2019), 84 FR 55638 (October 17, 2019) (SR–CboeEDGA–2019–015) (Notices of filing and immediate effectiveness of proposed rule changes to re-file the Small Retail Broker Distribution Program) (''Cboe One Fee Re-Filings''). On November 26, 2019, the Commission suspended the Cboe One Fee Re-Filings and instituted proceedings to determine whether to approve or disapprove those proposals. *See, e.g.,* Securities Exchange Act Release No. 87629 (November 26, 2019), 84 FR 66245 (December 3, 2019) (SR–CboeBZX–2019–086). On November 27, 2019, the Cboe equities exchanges refiled the Cboe One Fee Filings with one revision to the requirements for participating in the Small Retail Broker Distribution Program and additional information about the basis for the proposed fee changes. *See* Securities Exchange Act Release Nos. 87712 (December 10, 2019), 84 FR 68508 (December 16, 2019) (SR–CboeBZX–2019–101); 88713 (December 10, 2019), 84 FR 68530 (December 16, 2019) (SR–CboeBYX–2019–023); 87709 (December 10, 2019), 84 FR 68523 (December 16, 2019) (SR–CboeEDGA–2019–021); and 87711 (December 10, 2019), 84 FR 68501 (December 16, 2019) (SR–Cboe–EDGX–2019–071) (Notices of filing and immediate effectiveness of proposed rule changes to introduce a Small Retail Broker Distribution Program) (''Cboe One Third Fee Re-Filings''). On February 4, 2020, the Cboe equities exchanges withdrew the Cboe One Third Fee Re-Filings and, on the same date, refiled the Cboe One Fee Filings. *See* Securities Exchange Act Release Nos. 88221 (February 14, 2020), 85 FR 9904 (February 20, 2020) (SR–CboeBYX–2020–007); 88218 (February 14, 2020), 85 FR 9827 (February 20, 2020) (SR–CboeBZX–2020–014); 88220 (February 14, 2020), 85 FR 9912 (February 20, 2020) (SR–CboeEDGA–2020–004); and 88219 (February 14, 2020), 85 FR 9872 (February 20, 2020) (SR–CboeEDGX–2020–008) (Notices of filing and immediate effectiveness of proposed rule changes to introduce a Small Retail Broker Distribution Program) (''Cboe One Fourth Fee Re-Filings''). On April 15, 2020, the Cboe equities exchanges withdrew the Cboe One Fee Filings and the Cboe One Fee Re-Filings. Pursuant to the Cboe One Fourth Fee Re-Filings, the Small Retail Broker Distribution Program is currently in effect at the Cboe equities exchanges.

[47] *See* Securities Exchange Act Release No. 90177 (October 14, 2020), 85 FR 66620 (October 20, 2020) (SR–NASDAQ–2020–065) (Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Lower the Enterprise License Fee for Broker-Dealers Distributing Nasdaq Basic to Internal Professional Subscribers as Set Forth in the Equity 7 Pricing Schedule, Section 147, and the Enterprise License Fee for Broker-Dealers Distributing Nasdaq Last Sale to Professional Subscribers at Equity 7, Section 139).

[48] The Exchange notes that broker-dealers are not required to purchase proprietary market data to comply with their best execution obligations. *See In the Matter of the Application of Securities Industry and Financial Markets Association for Review of Actions Taken by Self-Regulatory Organizations,* Release Nos. 34–72182; AP–3–15350; AP–3–15351 (May 16, 2014). Similarly, there is no requirement in Regulation NMS or any other rule that proprietary data be utilized for order routing decisions, and some broker-dealers and ATSs have chosen not to do so.

expanding the options available to firms making data purchasing decisions based on their business needs. The Exchange believes that this is consistent with the principles contained in Regulation NMS to ''promote the wide availability of market data and to allocate revenues to SROs that produce the most useful data for investors.'' [49]

Access Fee. By making the reduced Per User Access Fee available to Redistributors of NYSE American OpenBook for external distribution who do not subscribe to any other products listed on the Fee Schedule other than NYSE American BBO and NYSE American Trades, the Exchange believes that more Redistributors may choose to subscribe to these products, thereby expanding the distribution of this market data for the benefit of investors that participate in the national market system and increasing competition generally. The Exchange also believes that offering the Per User Access Fee to these Redistributors would expand the availability of NYSE BQT to potential data recipients that are interested in subscribing to NYSE BQT but do not have access to a Redistributor who subscribes to the data feeds.

The Exchange determined to make the reduced Per User Access Fee available to these Redistributors because it constitutes a substantial reduction of the current fee, with the intended purpose of increasing use of NYSE BQT by Redistributors. NYSE BQT has been in place since 2014 but has a very small number of subscribers. The Exchange believes that in order to compete with other indicative pricing products such as Nasdaq Basic and Cboe One Feed, it needs to provide a meaningful financial incentive for more Redistributors to choose to subscribe to NYSE BQT so that they can make it available to their customers. Accordingly, the proposed expansion of the Per User Access Fee, together with the proposed expansion of the Per User Access Fee by the Exchange's affiliates, is reasonable because the reductions will make NYSE BQT a more attractive offering for Redistributors that do not currently subscribe to any NYSE American market data products other than NYSE American OpenBook and make it more competitive with Nasdaq Basic and Cboe One Feed.

Evidence of the competition among exchange groups for these products has previously been demonstrated via fee changes. For example, following the introduction of the Cboe One Feed, Nasdaq responded by reducing its fees for the Nasdaq Basic product.[50] With the proposed changes by the Exchange, NYSE, and NYSE Arca, the Exchange is similarly seeking to compete by decreasing the total access fees for NYSE BQT from $6,250 to $850 for Redistributors that do not currently subscribe to any NYSE American market data products other than NYSE American OpenBook and have customers that are interested in subscribing to NYSE BQT but cannot do so until their Redistributor also subscribes. This proposed rule change therefore demonstrates the existence of an effective, competitive market because this proposal resulted from a need to generate innovative approaches in response to competition from other exchanges that offer market data for a specific segment of market participants.

For all of the foregoing reasons, the Exchange believes that the proposed fees are reasonable.

The Proposed Fees Are Equitably Allocated

The Exchange believes the proposed expansion of the Per User Access Fee is allocated fairly and equitably among the various categories of users of the Exchange's market data feed, and any differences among categories of users are justified.

Overall. As noted above, this proposed fee change is a result of the competitive environment for market data products that provide indicative pricing information across a family of exchanges. To respond to this competitive environment, the Exchange seeks to expand the application of the Per User Access Fee for Redistributors that would be subscribing to the NYSE American BBO, NYSE American Trades and NYSE American OpenBook data feeds and would use these market data products for external distribution only, which the Exchange hopes will attract new Redistributor subscribers for the NYSE BQT market data product so that the product can be made available to prospective market data recipients. The Exchange is proposing to expand the application of the reduced Per User Access Fee to make the Exchange's fees more competitive for a specific segment of market participants, thereby increasing the availability of the Exchange's data products, expanding the options available to firms making data purchasing decisions based on their business needs, and generally increasing competition.

Access Fee. The Exchange believes that making the Per User Access Fee available to Redistributors that would be subscribing to the NYSE American BBO, NYSE American Trades and NYSE American OpenBook data feeds and would use these market data products for external distribution only is equitable as the reduced fee would apply equally to all data recipients that choose to subscribe to NYSE American BBO, NYSE American Trades and NYSE American OpenBook for external distribution only. Because NYSE American BBO, NYSE American Trades and NYSE American OpenBook are optional products, any data recipient could choose to subscribe to such data feeds to distribute externally and be eligible for the Per User Access Fee. The Exchange does not believe that it is inequitable that the Per User Access Fee would be available only to data recipients that subscribe to NYSE American BBO, NYSE American Trades and NYSE American OpenBook and only for external distribution. Internal use of data represents a different set of use cases than a Redistributor that is engaged only in external distribution of data. For example, non-display data can be used by data recipients for a wide variety of profit-generating purposes, including proprietary and agency trading and smart order routing, as well as by data recipients that operate order matching and execution platforms that compete directly with the Exchange for order flow. The data also can be used for a variety of non-trading purposes that indirectly support trading, such as risk management and compliance. Although some of these non-trading uses do not directly generate revenues, they can nonetheless substantially reduce the recipient's costs by automating such functions so that they can be carried out in a more efficient and accurate manner and reduce errors and labor costs, thereby benefiting end users. The Exchange believes that charging a different access fee for a Redistributor that is engaged solely in external distribution of only the NYSE American BBO, NYSE American Trades and NYSE American OpenBook products is equitable because it would make NYSE BQT available to more data recipients that are customers of such Redistributors and who would not otherwise be able to access NYSE BQT

[49] *See* Regulation NMS Adopting Release, 70 FR 37495, at 37503.

[50] *See e.g.,* Securities Exchange Act Release No. 83751 (July 31, 2018), 83 FR 38428 (August 6, 2018) (SR–NASDAQ–2018–058) (Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Lower Fees and Administrative Costs for Distributors of Nasdaq Basic, Nasdaq Last Sale, NLS Plus and the Nasdaq Depth-of-Book Products Through a Consolidated Enterprise License). Nasdaq filed the proposed fee change to lower the Enterprise Fee for Nasdaq Basic and other market data products in response to the Enterprise Fee for the Cboe One Feed adopted by Cboe family of exchanges.

if their Redistributor did not subscribe to and redistribute NYSE BQT.

For all of the foregoing reasons, the Exchange believes that the proposed fees for the NYSE American market data products are equitably allocated.

The Proposed Fees Are Not Unfairly Discriminatory

The Exchange believes the proposed fees are not unfairly discriminatory because any differences in the application of the fees are based on meaningful distinctions between customers, and those meaningful distinctions are not unfairly discriminatory between customers.

Overall. As noted above, this proposed fee change is a result of the competitive environment for market data products that provide indicative pricing information across a family of exchanges. To respond to this competitive environment, the Exchange seeks to amend its fees to provide a financial incentive for Redistributors of NYSE American OpenBook that do not currently subscribe to any NYSE American market data products that decide to subscribe to NYSE BQT, which the Exchange hopes will attract more subscribers for the NYSE BQT market data product. The Exchange is proposing to expand the application of the Per User Access Fee to make the Exchange's fees more competitive for a specific segment of market participants, thereby increasing the availability of the Exchange's data products, expanding the options available to firms making data purchasing decisions based on their business needs, and generally increasing competition.

Access Fee. The Exchange believes that making the Per User Access Fee available to Redistributors that would be subscribing to the NYSE American BBO, NYSE American Trades and NYSE American OpenBook data feeds and would use these market data products for external distribution only is not unfairly discriminatory as the reduced fee would apply equally to all Redistributors that choose to subscribe to NYSE American BBO, NYSE American Trades and NYSE American OpenBook for external distribution only. Because NYSE American BBO, NYSE American Trades and NYSE American OpenBook are optional products, any data recipient could choose to subscribe to such data feeds to distribute externally and be eligible for the Per User Access Fee. The Exchange does not believe that it is unfairly discriminatory that the Per User Access Fee would be available only to data recipients that subscribe to NYSE American BBO, NYSE American Trades and NYSE American OpenBook and only for external distribution. Internal use of data represents a different set of use cases than a Redistributor that is engaged only in external distribution of data. For example, non-display data can be used by data recipients for a wide variety of profit-generating purposes, including proprietary and agency trading and smart order routing, as well as by data recipients that operate order matching and execution platforms that compete directly with the Exchange for order flow. The data also can be used for a variety of non-trading purposes that indirectly support trading, such as risk management and compliance. While some of these non-trading uses do not directly generate revenues, they can nonetheless substantially reduce the recipient's costs by automating such functions so that they can be carried out in a more efficient and accurate manner and reduce errors and labor costs, thereby benefiting end users. The Exchange therefore believes that there is a meaningful distinction between internal use and redistribution of market data and that charging a different access fee to a Redistributor that is engaged solely in external distribution of only the NYSE American BBO, NYSE American Trades and NYSE American OpenBook products is not unfairly discriminatory because it would make NYSE BQT available to more data recipients that are customers of such Redistributors and who would not otherwise be able to access NYSE BQT if their Redistributor did not subscribe to and redistribute NYSE BQT.

Moreover, the Exchange does not believe that it is unfairly discriminatory to offer the Per User Access Fee only to those Redistributors that would subscribe to the NYSE American BBO, NYSE American Trades and NYSE American OpenBook data feeds, and only for external distribution. This proposed rule change is designed to provide an incentive for Redistributors that currently subscribe to NYSE American OpenBook, but do not subscribe to NYSE BQT, and may have customers that are interested in subscribing to NYSE BQT, to subscribe to the NYSE American BBO and NYSE American Trades data feeds so that they can make NYSE BQT available to their customers. This fee incentive is not necessary for Redistributors that currently subscribe to the NYSE American BBO and NYSE American Trades data feeds because such Redistributors could already subscribe to NYSE BQT, but have chosen not to, and a reduction in their existing access fees would likely not result in such Redistributors choosing to subscribe to NYSE BQT.

For all of the foregoing reasons, the Exchange believes that the proposed fees are not unfairly discriminatory.

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. Indeed, as demonstrated above, the Exchange believes the proposed rule changes are pro-competitive.

Intramarket Competition. The Exchange believes that the proposed fees do not put any market participants at a relative disadvantage compared to other market participants. As noted above, the proposed fee schedule would apply to all subscribers of NYSE American market data products, and customers may not only choose whether to subscribe to the products at all, but also may tailor their subscriptions to include only the products and uses that they deem suitable for their business needs. The Exchange also believes that the proposed fees neither favor nor penalize one or more categories of market participants in a manner that would impose an undue market on competition. As shown above, to the extent that particular proposed fees apply to only a subset of subscribers, those distinctions are not unfairly discriminatory and do unfairly burden one set of customers over another.

Intermarket Competition. The Exchange believes that the proposed fees do not impose a burden on competition on other exchanges that is not necessary or appropriate; indeed, the Exchange believes the proposed fee changes would have the effect of increasing competition. As described above, exchanges are platforms for market data and trading. In setting the proposed fees, the Exchange is constrained by the availability of substitute platforms also offering market data products and trading, and low barriers to entry mean new exchange platforms are frequently introduced. The fact that exchanges are platforms ensures that no exchange can make pricing decisions for one side of its platform without considering, and being constrained by, the effects that price will have on the other side of the platform. In setting fees at issue here, the Exchange is constrained by the fact that, if its pricing across the platform is unattractive to customers, customers will have its pick of an increasing number of alternative platforms to use instead of the Exchange. Given this

intense competition between platforms, no one exchange's market data fees can impose an unnecessary burden on competition, and the Exchange's proposed fees do not do so here.

In addition, the Exchange believes that the proposed fees do not impose a burden on competition or on other exchanges that is not necessary or appropriate because of the availability of numerous substitute market data products. Specifically, as described above, NYSE BQT competes head-to-head with the Nasdaq Basic product and the Cboe One Feed. These products each serve as reasonable substitutes for one another as they are each designed to provide investors with a unified view of real-time quotes and last-sale prices in all Tape A, B, and C securities. Each product provides subscribers with consolidated top-of-book quotes and trades from multiple U.S. equities markets. NYSE BQT provides top-of-book quotes and trades data from five NYSE-affiliated U.S. equities exchanges, while Cboe One Feed similarly provides top-of-book quotes and trades data from Cboe's four U.S. equities exchanges. NYSE BQT, Nasdaq Basic, and Cboe One Feed are all intended to provide indicative pricing and therefore, are reasonable substitutes for one another. Additionally, market data vendors are also able to offer close substitutes to NYSE BQT. Because market data users can find suitable substitute feeds, an exchange that overprices its market data products stands a high risk that users may substitute another source of market data information for its own. These competitive pressures ensure that no one exchange's market data fees can impose an unnecessary burden on competition, and the Exchange's proposed fees do not do so here.

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 has become effective upon filing pursuant to Section 19(b)(3)(A)[51] of the Act and paragraph (f) of Rule 19b–4 thereunder.[52] 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.

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 (*https://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include file number SR–NYSEAMER–2023–57 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–2023–57. 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 (*https://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 a.m. and 3 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. Do not include personal identifiable information in submissions; you should submit only information that you wish to make available publicly. We may redact in part or withhold entirely from publication submitted material that is obscene or subject to copyright protection. All submissions should refer to file number SR–NYSEAMER–2023–57 and should be submitted on or before December 13, 2023.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[53]

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2023–25787 Filed 11–21–23; 8:45 am]

BILLING CODE 8011–01–P

[51] 15 U.S.C. 78s(b)(3)(A).

[52] 17 CFR 240.19b–4(f).

[53] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–98967; File No. SR–NYSE–2023–34]

Self-Regulatory Organizations; New York Stock Exchange LLC; Notice of Designation of Longer Period for Commission Action on a Proposed Rule Change To Amend Section 312.03(b) of the NYSE Listed Company Manual To Modify the Circumstances Under Which a Listed Company Must Obtain Shareholder Approval of a Sale of Securities Below the Minimum Price to a Substantial Security Holder of the Company

November 16, 2023.

On September 26, 2023, New York Stock Exchange LLC (the ''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 Section 312.03(b) of the NYSE Listed Company Manual (''Manual'') to modify the circumstances under which a listed company must obtain shareholder approval of a sale of securities below the Minimum Price[3] to a substantial security holder of the listed company. The proposed rule change was published for comment in the **Federal Register** on October 4, 2023.[4] The Commission received no comments on the proposed rule change.

Section 19(b)(2) of the Act[5] provides that, within 45 days of the publication of notice of the filing of a proposed rule change, or within such longer period up to 90 days as the Commission may designate if it finds such longer period to be appropriate and publishes its reasons for so finding, or as to which the self-regulatory organization consents, the Commission shall either approve the proposed rule change, disapprove the

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] Minimum Price is defined in Section 312.04(h) of the Manual.

[4] *See* Securities Exchange Act Release No. No. 98662 (September 29, 2023), 88 FR 68675 (October 4, 2023).

[5] 15 U.S.C. 78s(b)(2).

proposed rule change, or institute proceedings to determine whether the proposed rule change should be disapproved. The 45th day after publication of the notice for this proposed rule change is November 18, 2023. The Commission is extending this 45-day time period.

The Commission finds that it is appropriate to designate a longer period within which to take action on the proposed rule change so that it has sufficient time to consider the proposed rule change. Accordingly, the Commission, pursuant to Section 19(b)(2) of the Act,[6] designates January 2, 2024, as the date by which the Commission shall either approve or disapprove, or institute proceedings to determine whether to disapprove, the proposed rule change (File No. SR–NYSE–2023–34).

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[7]

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2023–25776 Filed 11–21–23; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Investment Company Act Release No. 35051; 812–15511]

Jackson Credit Opportunities Fund and Jackson National Asset Management, LLC

November 16, 2023.

AGENCY: Securities and Exchange Commission (''Commission'' or ''SEC'').

ACTION: Notice.

Notice of an application under section 6(c) of the Investment Company Act of 1940 (the ''Act'') for an exemption from sections 18(a)(2), 18(c) and 18(i) of the Act, under sections 6(c) and 23(c) of the Act for an exemption from rule 23c–3 under the Act, and for an order pursuant to section 17(d) of the Act and rule 17d–1 under the Act.

Summary of Application: Applicants request an order to permit certain registered closed-end investment companies to issue multiple classes of shares and to impose asset-based distribution and/or service fees and early withdrawal charges.

Applicants: Jackson Credit Opportunities Fund and Jackson National Asset Management, LLC.

Filing Dates: The application was filed on October 2, 2023.

Hearing or Notification of Hearing: An order granting the requested relief will be issued unless the Commission orders a hearing. Interested persons may request a hearing on any application by emailing the SEC's Secretary at *Secretarys-Office@sec.gov* and serving the Applicants with a copy of the request by email, if an email address is listed for the relevant Applicant below, or personally or by mail, if a physical address is listed for the relevant Applicant below. Hearing requests should be received by the Commission by 5:30 p.m. on December 11, 2023, and should be accompanied by proof of service on the Applicants, in the form of an affidavit, or, for lawyers, a certificate of service. Pursuant to rule 0–5 under the Act, hearing requests should state the nature of the writer's interest, any facts bearing upon the desirability of a hearing on the matter, the reason for the request, and the issues contested. Persons who wish to be notified of a hearing may request notification by emailing the Commission's Secretary.

ADDRESSES: The Commission: *Secretarys-Office@sec.gov.* Applicants: Emily J. Bennett, Esq., Jackson National Asset Management, LLC, *emily.bennett@jackson.com;* with a copy to Paulita A. Pike, Esq., Ropes & Gray LLP, *paulita.pike@ropesgray.com.*

FOR FURTHER INFORMATION CONTACT: Trace W. Rakestraw, Senior Special Counsel, at (202) 551–6825 (Division of Investment Management, Chief Counsel's Office).

SUPPLEMENTARY INFORMATION: For Applicants' representations, legal analysis, and conditions, please refer to Applicants' application, dated October 2, 2023, which may be obtained via the Commission's website by searching for the file number at the top of this document, or for an Applicant using the Company name search field on the SEC's EDGAR system. The SEC's EDGAR system may be searched at *https://www.sec.gov/edgar/searchedgar/legacy/companysearch.html.* You may also call the SEC's Public Reference Room at (202) 551–8090.

For the Commission, by the Division of Investment Management, under delegated authority.

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2023–25785 Filed 11–21–23; 8:45 am]

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SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–98970; File No. SR–CboeBZX–2023–093]

Self-Regulatory Organizations; Cboe BZX Exchange, Inc.; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Amend Its Rules To Adopt Monthly Options Series

November 16, 2023.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on November 15, 2023, Cboe BZX Exchange, Inc. (''BZX Options'' or ''Exchange'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I and II below, which Items have been prepared by the Exchange. The 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 Options'') proposes to amend its Rules to adopt Monthly Options Series. 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

[6] *Id.*

[7] 17 CFR 200.30–3(a)(31).

[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 amend its Rules to accommodate the listing of option series that would expire at the close of business on the last business day of a calendar month (''Monthly Options Series''). Pursuant to proposed Rules 19.6, Interpretation and Policy .08(a) and 29.11(k)(1),[5] the Exchange may list Monthly Options Series for up to five currently listed option classes that are either index options or options on exchange-traded funds (''ETFs'').[6] In addition, the Exchange may also list Monthly Options Series on any options classes that are selected by other securities exchanges that employ a similar program under their respective rules.[7] The Exchange may list 12 expirations for Monthly Options Series. Monthly Options Series need not be for consecutive months; however, the expiration date of a nonconsecutive expiration may not be beyond what would be considered the last expiration date if the maximum number of expirations were listed consecutively.[8] Other expirations in the same class are not counted as part of the maximum numbers of Monthly Options Series expirations for a class.[9] Monthly Options Series will be P.M.-settled.[10]

The strike price of each Monthly Options Series will be fixed at a price per share, with at least two, but no more than five, strike prices above and at least two, but no more than five, strike prices below the value of the underlying index or price of the underlying security at about the time that a Monthly Options Series is opened for trading on the Exchange. The Exchange will list strike prices for Monthly Options Series that are reasonably related to the current price of the underlying security or current index value of the underlying index to which such series relates at about the time such series of options is first opened for trading on the Exchange. The term ''reasonably related to the current price of the underlying security or index value of the underlying index'' means that the exercise price is within 30% of the current underlying security price or index value.[11] Additional Monthly Options Series of the same class may be open for trading on the Exchange when the Exchange deems it necessary to maintain an orderly market, to meet customer demand, or when the market price of the underlying security moves substantially from the initial exercise price or prices. To the extent that any additional strike prices are listed by the Exchange, such additional strike prices will be within 30% above or below the closing price of the underlying index or security on the preceding day. The Exchange may also open additional strike prices of Monthly Options Series that are more than 30% above or below the current price of the underlying security, provided that demonstrated customer interest exists for such series, as expressed by institutional, corporate, or individual customers or their brokers. Market-Makers trading for their own account will not be considered when determining customer interest under this provision. The opening of the new Monthly Options Series will not affect the series of options of the same class previously opened.[12] The interval between strike prices on Monthly Options Series will be the same as the interval for strike prices for series in that same options class that expire in accordance with the normal monthly expiration cycle.[13]

By definition, Monthly Options Series can never expire in the same week as a standard expiration series (which expire on the third Friday of a month) in the same class expires. The same, however, is not the case with regards to Short Term Option Series [14] or Quarterly Options Series. Therefore, to avoid any confusion in the marketplace, the Exchange proposes to amend Rules 19.6, Interpretation and Policy .05 (introductory paragraph), (b), and (h) and 22.11(h) (introductory paragraph) and (2) to provide the Exchange will not list a Short Term Option Series in a class on a date on which a Monthly Options Series or Quarterly Options

[5] The proposed rule change defines the term ''Monthly Options series'' in Rule 29.2(k) (and reletters current paragraphs (k) through (o) to be (l) through (p)) as a series in an options class that is approved for listing and trading on the Exchange in which the series is opened for trading on any business day and that expires at the close of business on the last business day of a calendar month.

[6] The Exchange proposes to amend Rule 19.6(a) and (b) to provide that proposed Rule 19.6, Interpretation and Policy .08 will describe how the Exchange will fix a specific expiration date and exercise price for Monthly Options Series and will govern the procedures for opening Monthly Options Series, respectively. The proposed change to Rule 19.6(a) is consistent with language in current Rule 19.6(a) for other Short Term Option Series and Quarterly Options Series. The proposed rule change also makes a nonsubstantive correction to pluralize the term ''policy'' (to become ''policies'') to be consistent with the terminology in the Rules. Additionally, the proposed rule change adds to Rule 19.6(b) that Interpretation and Policies .04 and .05 will govern the procedures for opening Quarterly Options Series and Short Term Option Series, respectively (as well as adding exception language to the beginning of that paragraph). This is merely a clarification, as Rule 19.6, Interpretations and Policies .04 and .05 clearly govern the opening procedures for those options listing programs. This proposed change is also consistent with Cboe Exchange, Inc. (''Cboe Options'') Rule 4.5(b), which has similar options listing programs.

[7] The Securities and Exchange Commission (the ''Commission'') recently approved a Cboe Options proposed rule change to adopt a substantively identical Monthly Options Series program. *See* Securities Exchange Act Release No. 98915 (November 13, 2023) (SR–CBOE–2023–049) (''Cboe Options Approval Order'').

[8] The Exchange notes this provision considers consecutive monthly listings. In other words, as other expirations (such as Quarterly Options Series) are not counted as part of the maximum, those expirations would not be considered when considering when the last expiration date would be if the maximum number were listed consecutively. For example, if it is January 2024 and the Exchange lists Quarterly Options Series in class ABC with expirations in March, June, September, December, and the following March, the Exchange could also list Monthly Options Series in class ABC with expirations in January, February, April, May, July, August, October, and November 2024 and January and February of 2025. This is because, if Quarterly Options Series, for example, were counted, the Exchange would otherwise never be able to list the maximum number of Monthly Options Series. This is consistent with the listing provisions for Quarterly Options Series, which permit calendar quarter expirations. The need to list series with the same expiration in the current calendar year and the following calendar year (whether Monthly or Quarterly expiration) is to allow market participants to execute one-year strategies pursuant to which they may roll their exposures in the longer-dated options (*e.g.* January 2025) prior to the expiration of the nearer-dated option (*e.g.* January 2024).

[9] *See* proposed Rules 19.6, Interpretation and Policy .08(b) and 29.11(k)(2).

[10] *See* proposed Rules 19.6, Interpretation and Policy .08(c) and 29.11(k)(3).

[11] *See* proposed Rules 19.6, Interpretation and Policy .08(d) and 29.11(k)(4). The Exchange notes these proposed provisions are consistent with the initial series provision for the Quarterly Options Series program in Rule 29.11(g)(3). While different than the initial strike listing provision for the Quarterly Options Series program in current Rule 19.6, Interpretation and Policy .04(b), the Exchange believes the proposed provision is appropriate, as it contemplates classes that may have strike intervals of $5 or greater. For consistency, the Exchange also proposes to amend Rule 19.6, Interpretation and Policy .04(b) to incorporate the same provision for initial series.

[12] *See* proposed Rules 19.6, Interpretation and Policy .08(e) and 29.11(k)(5).

[13] *See* proposed Rules 19.6, Interpretation and Policy .08(f) and 29.11(k)(6); *see also* Rule 19.6(d), (f), (g) and Interpretations and Policies .01–.03 and .06 (permissible strike prices for ETF classes) and Rule 29.11(c) (permissible strike prices for index options).

[14] The proposed rule change clarifies in Rule 29.11(a)(3) that index options have expiration months and weeks, which expirations may occur in consecutive weeks as specified in Rule 29.11(h). This is merely a clarification, as Rule 29.11(h) currently permits weekly expirations. This language is consistent with Cboe Options Rule 4.13(a)(2). Additionally, the proposed rule change adds to rule 29.11(a)(3) that index options may expire more than 12 months out as specified elsewhere in the Rule. This is consistent with current Rule 29.11(b), which permits long term index options to expire between 12 and 180 months after issuance, as well as proposed Rule 29.11(k)(2), as discussed above.

Series expires.[15] Similarly, proposed Rules 19.6, Interpretation and Policy .08(b) and 22.11(k)(2) provide that no Monthly Options Series may expire on a date that coincides with an expiration date of a Quarterly Options Series in the same index or ETF class. In other words, the Exchange will not list a Short Term Option Series on an index or ETF if a Monthly Options Series on that index or ETF were to expire on the same date, nor will the Exchange list a Monthly Options Series on an ETF or index if a Quarterly Options Series on that index or ETF were to expire on the same date to prevent the listing of series with concurrent expirations.[16]

With respect to Monthly Options Series added pursuant to proposed Rules 19.6, Interpretation and Policy .08(a) through (f) and 22.11(k)(1) through (6), the Exchange will, on a monthly basis, review series that are outside a range of five strikes above and five strikes below the current price of the underlying index or security, and delist series with no open interest in both the put and the call series having a: (i) strike higher than the highest strike price with open interest in the put and/or call series for a given expiration month; and (ii) strike lower than the lowest strike price with open interest in the put and/or call series for a given expiration month. Notwithstanding this delisting policy, customer requests to add strikes and/or maintain strikes in Monthly Options Series in series eligible for delisting will be granted. In connection with this delisting policy, if the Exchange identifies series for delisting, the Exchange will notify other options exchanges with similar delisting policies regarding eligible series for delisting and will work with such other exchanges to develop a uniform list of series to be delisted, so as to ensure uniform series delisting of multiply listed Monthly Options Series.[17]

The Exchange believes that Monthly Options Series will provide investors with another flexible and valuable tool to manage risk exposure, minimize capital outlays, and be more responsive to the timing of events affecting the securities that underlie option contracts. The Exchange believes limiting Monthly Options Series to five classes will ensure the addition of these new series will have a negligible impact on the Exchange's and the Options Price Reporting Authority's (''OPRA's'') quoting capacity. The Exchange represents it has the necessary systems capacity to support new options series that will result from the introduction of Monthly Options Series.

The Exchange notes that Rules 18.7 and 29.5 through 29.7 regarding position limits will apply to Monthly Options Series. These Rules provide that the position limits fixed by Cboe Options apply to options contracts traded on BZX Options, which would include Monthly Options Series. As noted above, Cboe Options recently received Commission approval to adopt a substantively identical Monthly Options Series Program as the one proposed in this rule filing.[18] Pursuant to those recently approved Cboe Options rules, Monthly Options Series will be aggregated with positions in options contracts on the same underlying security or index.[19] This is consistent with how position (and exercise) limits are currently imposed on series with other expirations (Short Term Option Series and Quarterly Options Series). Therefore, positions in options within class of index or ETF options, regardless of their expirations, would continue to be subject to existing position (and exercise) limits. The Exchange believes this will address potential manipulative schemes and adverse market impacts surrounding the use of options.

The Exchange also represents its current surveillance programs will apply to Monthly Options Series and will properly monitor trading in the proposed Monthly Options Series. The Exchange currently lists Quarterly Options Series in certain ETF classes, which expire at the close of business at the end of four calendar months (*i.e.,* the end of each calendar quarter), and has not experienced any market disruptions nor issues with capacity. The Exchange's surveillance programs currently in place to support and properly monitor trading in these Quarterly Options Series, as well as Short Term Option Series and standard expiration series, will apply to the proposed Monthly Options Series. The Exchange believes its surveillances continue to be designed to deter and detect violations of its Rules, including position and exercise limits and possible manipulative behavior, and these surveillances will apply to Monthly Options Series that the Exchange determines to list for trading. Ultimately, the Exchange does not believe the proposed rule change raises any unique regulatory concerns because existing safeguards—such as position and exercise limits (and the aggregation of options overlying the same index or ETF) and reporting requirements—would continue to apply.

2. Statutory Basis

The Exchange believes the proposed rule change is consistent with the Securities Exchange Act of 1934 (the ''Act'') and the rules and regulations thereunder applicable to the Exchange and, in particular, the requirements of Section 6(b) of the Act.[20] Specifically, the Exchange believes the proposed rule change is consistent with the Section 6(b)(5)[21] requirements that the rules of an exchange be 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. Additionally, the Exchange believes the proposed rule change is consistent with

[15] The Exchange also proposes to make a nonsubstantive change to Rules 19.6, Interpretation and Policy .05 and 22.11(h) to change current references to ''monthly options series'' to ''standard expiration options series'' (*i.e.,* series that expire on the third Friday of a month), to eliminate potential confusion. The current references to ''monthly options series'' are intended to refer to those series that expire on the third Friday of a month, which are generally referred to in the industry as standard expirations. The proposed rule change also adds a heading to Rule 19.6, Interpretation and Policy .05 for consistency with other Interpretations and Policies in that Rule.

[16] The Exchange notes this would not prevent the Exchange from listing a P.M.-settled Monthly Options Series on an index with the same expiration date as an A.M.-settled Short Term Option Series on the same index, both of which may expire on a Friday. In other words, the Exchange may list a P.M-settled Monthly Options Series on an index concurrent with an A.M.-settled Short Term Option Series on that index and both of which expire on a Friday. The Exchange believes this concurrent listing would provide investors with yet another hedging mechanism and is reasonable given these series would not be identical (unlike if they were both P.M-settled). This could not occur with respect to ETFs, as all Short Term Option Series on ETFs are P.M.-settled.

[17] *See* proposed Rules 19.6, Interpretation and Policy .08(g) and 22.11(k)(7).

[18] *See* Cboe Options Approval Order.

[19] *See id.; see also* Cboe Options Rules 8.30, Interpretation and Policy .09 (regarding position limits for options on stocks and ETFs), 8.31(e) (regarding position limits for broad-based index options), 8.32(f) (regarding position limits for industry index options), 8.33(c) (regarding position limits for micro narrow-based indexes), and 8.34(c) (regarding position limits for individual stock or ETF based volatility index options). Pursuant to Cboe Options Rule 8.42 (and Exchange Rules 18.9 and 29.9), exercise limits for impacted index and ETF classes would be equal to the applicable position limits.

[20] 15 U.S.C. 78f(b).

[21] 15 U.S.C. 78f(b)(5).

the Section 6(b)(5)[22] requirement that the rules of an exchange not be designed to permit unfair discrimination between customers, issuers, brokers, or dealers.

In particular, the Exchange believes the introduction of Monthly Options Series will remove impediments to and perfect the mechanism of a free and open market and a national market system by expanding hedging tools available to market participants. The Exchange believes the proposed monthly expirations will allow market participants to transact in the index and ETF options listed pursuant to the proposed rule change based on their timing as needed and allow them to tailor their investment and hedging needs more effectively. Further, the Exchange believes the availability of Monthly Options Series would protect investors and the public interest by providing investors with more flexibility to closely tailor their investment and hedging decisions in these options, thus allowing them to better manage their risk exposure.

The Exchange believes the Quarterly Options Series Program has been successful to date and the proposed Monthly Options Series program simply expands the ability of investors to hedge risk against market movements stemming from economic releases or market events that occur at months' ends in the same way the Quarterly Options Series Program has expanded the landscape of hedging for quarter-end news. Monthly Options Series will also complement Short Term Option Series, which allow investors to hedge risk against events that occur throughout a month. The Exchange believes the availability of additional expirations should create greater trading and hedging opportunities for investors, as well as provide investors with the ability to tailor their investment objectives more effectively.

The Exchange notes the proposed terms of Monthly Options Series, including the limitation to five index and ETF option classes, are substantively the same as the current terms of Quarterly Options Series.[23] Quarterly Options Series expire on the last business day of a calendar quarter, which is the last business day of every third month. The proposed Monthly Options Series would fill the gaps between Quarterly Options Series expirations by permitting series to expire on the last business day of every month, rather than every third month. The proposed Monthly Options Series may be listed in accordance with the same terms as Quarterly Options Series, including permissible strikes.[24] As is the case with Quarterly Options Series, no Short Term Option Series may expire on the same day as a Monthly Options Series. Similarly, as proposed, no Monthly Options Series may expire on the same day as a Quarterly Options Series. The Exchange believes preventing listing series with concurrent expirations in a class will eliminate potential investors confusion and thus protect investors and the public interest. Given that Quarterly Options Series the Exchange currently lists are essentially Monthly Options Series that can expire at the end of only certain calendar months, the Exchange believes it is reasonable to list Monthly Options Series in accordance with the same terms, as it will promote just and equitable principles of trade. The Exchange believes limiting Monthly Options Series to five classes will ensure the addition of these new series will have a negligible impact on the Exchange's and OPRA's quoting capacity. The Exchange represents it has the necessary systems capacity to support new options series that will result from the introduction of Monthly Options Series.

The Exchange further believes the proposed rule change regarding the treatment of Monthly Options Series with respect to determining compliance with position and exercise limits is designed to prevent fraudulent and manipulative acts and practices and promote just and equitable principles of trade. Monthly Options Series will be aggregated with options overlying the same ETF or index for purposes of compliance with position (and exercise) limits, which is consistent with how position (and exercise) limits are currently imposed on series with other expirations (Short Term Option Series, Quarterly Options Series, and Delayed Start Options Series).[25] Therefore, options positions within ETF or index option classes for which Monthly Options Series are listed, regardless of their expirations, would continue to be subject to existing position (and exercise) limits. The Exchange believes this will address potential manipulative schemes and adverse market impacts surrounding the use of options. The Exchange also represents its current surveillance programs will apply to Monthly Options Series and will properly monitor trading in the proposed Monthly Options Series. The Exchange currently trades Quarterly Options Series in certain index and ETF classes, which expire at the close of business at the end of four calendar months (*i.e.,* the end of each calendar quarter), and has not experienced any market disruptions nor issues with capacity. The Exchange's surveillance programs currently in place to support and properly monitor trading in these Quarterly Options Series, as well as Short Term Option Series and standard expiration series, will apply to the proposed Monthly Options Series. The Exchange believes its surveillances continue to be designed to deter and detect violations of its Rules, including position and exercise limits and possible manipulative behavior, and these surveillances will apply to Monthly Options Series that the Exchange determines to list for trading. Ultimately, the Exchange does not believe the proposed rule change raises any unique regulatory concerns because existing safeguards—such as position and exercise limits (and the aggregation of options overlying the same ETF or index) and reporting requirements—would continue to apply.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. The Exchange does not believe the proposed rule change to list Monthly Options Series will impose any burden on intramarket competition that is not necessary or appropriate in furtherance of the purposes of the Act, as any Monthly Options Series the Exchange lists for trading will be available in the same manner for all market participants who wish to trade such options. The Exchange notes the proposed terms of Monthly Options Series, including the limitation to five index and ETF option

[22] *Id.*

[23] *Compare* proposed Rules 19.6, Interpretation and Policy .08 and 29.11(k) *to* Rules 19.6, Interpretation and Policy .04 and 29.11(g), respectively.

[24] The Exchange notes the proposed maximum number of expirations is consistent with the maximum number of expirations permitted for end-of-month series in index classes. *See* Rule 29.11(j)(2) (which references Rule 29.11(a)(3), which permits up to 12 standard monthly expirations on the majority of index options currently listed on the Exchange).

[25] *See* Cboe Options Approval Order; *see also* Cboe Options Rules 8.30, Interpretation and Policy .09 (regarding position limits for options on stocks and ETFs), 8.31(e) (regarding position limits for broad-based index options), 8.32(f) (regarding position limits for industry index options), 8.33(c) (regarding position limits for micro narrow-based indexes), and 8.34(c) (regarding position limits for individual stock or ETF based volatility index options). Pursuant to Cboe Options Rule 8.42 (and Exchange Rules 18.9 and 29.9), exercise limits for impacted index and ETF classes would be equal to the applicable position limits.

classes, are substantively the same as the current terms of Quarterly Options Series.[26] Quarterly Options Series expire on the last business day of a calendar quarter, which is the last business day of every third month, making the concept of Monthly Options Series in a limited number of index and ETF options not novel. The proposed Monthly Options Series will fill the gaps between Quarterly Options Series expirations by permitting series to expire on the last business day of every month, rather than every third month. The proposed Monthly Options Series may be listed in accordance with the same terms as Quarterly Options Series, including permissible strikes.[27] Monthly Options Series will trade on the Exchange in the same manner as other options in the same class.

The Exchange does not believe the proposed rule change to list Monthly Options Series will impose any burden on intermarket competition that is not necessary or appropriate in furtherance of the purposes of the Act, as nothing prevents other options exchanges from proposing similar rules.[28] As discussed above, the proposed rule change would permit listing of Monthly Options Series in five index or ETF options, as well as any other classes that other exchanges may list under similar programs. To the extent that the availability of Monthly Options Series makes the Exchange a more attractive marketplace to market participants at other exchanges, market participants are free to elect to become market participants on the Exchange.

The Exchange believes that the proposed rule change may relieve any burden on, or otherwise promote, competition. Similar to Short Term Option Series and Quarterly Options Series, the Exchange believes the introduction of Monthly Options Series will not impose an undue burden on competition. The Exchange believes that it will, among other things, expand hedging tools available to market participants. The Exchange believes Monthly Options Series will allow market participants to purchase options based on their timing as needed and allow them to tailor their investment and hedging needs more effectively.

The Exchange does not believe the proposed rule change regarding aggregation of positions for purposes of determining compliance with position (and exercise) limits will impose any burden on intramarket competition that is not necessary or appropriate in furtherance of the purposes of the Act, because it will apply in the same manner to all market participants. The Exchange proposes to apply position (and exercise) limits to Monthly Options Series in the same manner it applies position limits to series with other expirations (Short Term Option Series and Quarterly Options Series). Therefore, positions in options in a class of ETF or index options, regardless of their expirations, would continue to be subject to existing position (and exercise) limits. Additionally, the Exchange does not believe this proposed rule change will impose any burden on intermarket competition that is not necessary or appropriate in furtherance of the purposes of the Act, because it will address potential manipulative schemes and adverse market impacts surrounding the use of options.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

The Exchange neither solicited nor received comments on the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The Exchange has filed the proposed rule change pursuant to Section 19(b)(3)(A)(iii) of the Act[29] and Rule 19b–4(f)(6) thereunder.[30] Because the foregoing proposed rule change does not: (i) significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative for 30 days from the date on which it was filed, or such shorter time as the Commission may designate, it has become effective pursuant to Section 19(b)(3)(A)(iii) of the Act[31] and subparagraph (f)(6) of Rule 19b–4 thereunder.[32]

A proposed rule change filed pursuant to Rule 19b–4(f)(6) under the Act[33] normally does not become operative for 30 days after the date of its filing. However, Rule 19b–4(f)(6)(iii)[34] permits the Commission to designate a shorter time if such action is consistent with the protection of investors and the public interest. The Exchange has requested that the Commission waive the 30-day operative delay so that the Exchange may list Monthly Options Series at the same time as Cboe Options, which the Exchange believes will benefit investors by promoting competition in Monthly Options Series. The Commission believes that the proposed rule change presents no novel issues and that waiver of the 30-day operative delay is consistent with the protection of investors and the public interest. Accordingly, the Commission hereby waives the operative delay and designates the proposed rule change operative upon filing.[35]

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 (*https://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include file number SR–CboeBZX–2023–093 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.

[26] *See* Rules 19.6, Interpretation and Policy .04 and 29.11(g).

[27] The Exchange notes the proposed maximum number of expirations is consistent with the maximum number of expirations permitted for end-of-month series in index classes. *See* Rule 29.11(j)(2) (which references Rule 29.11(a)(3), which permits up to 12 standard monthly expirations on the majority of index options currently listed on the Exchange).

[28] As noted above, at least one other options exchange recently adopted a substantively identical Monthly Options Series program. *See* Cboe Options Approval Order.

[29] 15 U.S.C. 78s(b)(3)(A)(iii).

[30] 17 CFR 240.19b–4(f)(6).

[31] 15 U.S.C. 78s(b)(3)(A)(iii).

[32] 17 CFR 240.19b–4(f)(6). In addition, Rule 19b–4(f)(6)(iii) requires a self-regulatory organization to give the Commission written notice of its intent to file the proposed rule change, along with a brief description and text of the proposed rule change, at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.

[33] 17 CFR 240.19b–4(f)(6).

[34] 17 CFR 240.19b–4(f)(6)(iii).

[35] For purposes only of waiving the 30-day operative delay, the Commission has also considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

All submissions should refer to file number SR–CboeBZX–2023–093. 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 (*https://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 a.m. and 3 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. Do not include personal identifiable information in submissions; you should submit only information that you wish to make available publicly. We may redact in part or withhold entirely from publication submitted material that is obscene or subject to copyright protection. All submissions should refer to file number SR–CboeBZX–2023–093 and should be submitted on or before December 13, 2023.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[36]

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2023–25777 Filed 11–21–23; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

Sunshine Act Meetings

TIME AND DATE: 2:15 p.m. on Thursday, November 30, 2023.

PLACE: The meeting will be held via remote means and/or at the Commission's headquarters, 100 F Street NE, Washington, DC 20549.

STATUS: This meeting will be closed to the public.

MATTERS TO BE CONSIDERED: Commissioners, Counsel to the Commissioners, the Secretary to the Commission, and recording secretaries will attend the closed meeting. Certain staff members who have an interest in the matters also may be present.

In the event that the time, date, or location of this meeting changes, an announcement of the change, along with the new time, date, and/or place of the meeting will be posted on the Commission's website at *https://www.sec.gov.*

The General Counsel of the Commission, or her designee, has certified that, in her opinion, one or more of the exemptions set forth in 5 U.S.C. 552b(c)(3), (5), (6), (7), (8), 9(B) and (10) and 17 CFR 200.402(a)(3), (a)(5), (a)(6), (a)(7), (a)(8), (a)(9)(ii) and (a)(10), permit consideration of the scheduled matters at the closed meeting.

The subject matter of the closed meeting will consist of the following topics:

Institution and settlement of injunctive actions;

Institution and settlement of administrative proceedings;

Resolution of litigation claims;

Matters related to litigation; and

Other matters relating to examinations and enforcement proceedings.

At times, changes in Commission priorities require alterations in the scheduling of meeting agenda items that may consist of adjudicatory, examination, litigation, or regulatory matters.

CONTACT PERSON FOR MORE INFORMATION: For further information; please contact Vanessa A. Countryman from the Office of the Secretary at (202) 551–5400.

Authority: 5 U.S.C. 552b.

Dated: November 17, 2023.

Vanessa A. Countryman,

Secretary.

[FR Doc. 2023–25864 Filed 11–17–23; 4:15 pm]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–98974; File No. SR–NYSEARCA–2023–78]

Self-Regulatory Organizations; NYSE Arca, Inc.; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend the Fees for NYSE Arca BBO and NYSE Arca Trades

November 16, 2023.

Pursuant to Section 19(b)(1)[1] of the Securities Exchange Act of 1934 (''Act'')[2] and Rule 19b–4 thereunder,[3] notice is hereby given that, on November 1, 2023, NYSE Arca, Inc. (''NYSE Arca'' or the ''Exchange'') filed with the Securities and Exchange Commission (the ''Commission'') the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend the fees for NYSE Arca BBO and NYSE Arca Trades by expanding the application of the Per User Access Fee. The Exchange proposes to implement the proposed fee change on November 1, 2023. The proposed rule change is available on the Exchange's website at *www.nyse.com,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of those statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant parts of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to expand the application of the Per User Access Fee[4]

[36] 17 CFR 200.30–3(a)(12), (59).

[1] 15 U.S.C. 78s(b)(1).

[2] 15 U.S.C. 78a.

[3] 17 CFR 240.19b–4.

[4] The Per User Access Fee is a lower access fee that currently applies for subscribers of NYSE Arca BBO and NYSE Arca Trades that receive a data feed and use those market data products in a display-only format. *See* Fee Schedule. *See also* Securities Exchange Act Release Nos. 87795 (December 18, 2019), 84 FR 71043 (December 26, 2019) (SR–NYSEArca-2019–88) (Notice of Filing and Immediate Effectiveness of Proposed Rule Change, as Modified by Partial Amendment No. 1, To Amend the Fees for NYSE Arca BBO and NYSE Arca Trades) (''BQT Fee Reduction Filing''); and 90409 (November 12, 2020), 85 FR 73522 (November 18, 2020) (SR–NYSEArca–2020–95) (Notice of Filing and Immediate Effectiveness of Proposed Rule Change Amending the Fees for NYSE Arca BBO and NYSE Arca Trades by Modifying the Application of the Access Fee and Amending the Fees for NYSE Arca Trades by

for certain NYSE Arca market data products, as set forth on the NYSE Arca Proprietary Market Data Fee Schedule (''Fee Schedule''). Specifically, the Exchange proposes to expand the application of the Per User Access Fee, which is currently available for Redistributors [5] of NYSE Arca BBO and NYSE Arca Trades that subscribe to only such data feeds and do not subscribe to any other market data product listed on the Fee Schedule and use such market data product for external distribution only. The Exchange proposes to make the Per User Access Fee available to Redistributors of NYSE ArcaBook as well.

The proposed fee change, taken together with similar fee changes filed by the Exchange's affiliated exchanges, New York Stock Exchange LLC (''NYSE'') and NYSE American LLC (''NYSE American''),[6] will reduce the fees associated with the NYSE BQT proprietary data product for Redistributors of NYSE ArcaBook. As described below, NYSE BQT competes directly with similar products offered by both the Nasdaq and Cboe families of U.S. equity exchanges. Collectively, the proposed fee changes are intended to respond to the competition posed by similar products offered by the other exchange groups.

The Exchange proposes to implement the proposed fee change on November 1, 2023.

Background

The Securities and Exchange Commission (''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.'' [7]

While Regulation NMS has enhanced competition, it has also fostered a ''fragmented'' market structure where trading in a single stock can occur across multiple trading centers. When multiple trading centers compete for order flow in the same stock, the Commission has recognized that ''such competition can lead to the fragmentation of order flow in that stock.'' [8] Indeed, equity trading is currently dispersed across 16 exchanges,[9] numerous alternative trading systems,[10] and broker-dealer internalizers and wholesalers, all competing for order flow. Based on publicly-available information, no single exchange currently has more than 17% market share (whether including or excluding auction volume).[11]

With the NYSE BQT market data product, NYSE Arca and its affiliates compete head to head with the Nasdaq Basic [12] and Cboe One Feed [13] market data products. Similar to those market data products, NYSE BQT, which was established in 2014,[14] consists of certain elements from the NYSE Arca BBO and NYSE Arca Trades market data products as well as from market data products from the Exchange's affiliates, NYSE, NYSE American, NYSE Chicago, Inc. (''NYSE Chicago''),[15] and NYSE National, Inc. (''NYSE National'').[16] Similar to both Nasdaq Basic and the Cboe One Feed, NYSE BQT provides investors with a unified view of comprehensive last sale and BBO data in all Tape A, B, and C securities that trade on the Exchange, NYSE, NYSE American, NYSE Chicago, and NYSE National. Also similar to Nasdaq Basic and the Cboe One Feed, NYSE BQT is not intended to be used for purposes of making order-routing or trading decisions, but rather provides indicative prices for Tape A, B, and C securities.[17]

Together with NYSE and NYSE American, the Exchange proposes to compete for subscribers to NYSE BQT by designing the proposed fee change to be attractive to Redistributors of NYSE ArcaBook that intend to subscribe to and externally redistribute NYSE BQT. Currently, Redistributors of NYSE ArcaBook that want to subscribe to and redistribute NYSE BQT must pay the General Access Fee. Redistributors of NYSE ArcaBook who have data recipient customers interested in NYSE BQT may not be inclined to subscribe to NYSE BQT. When Redistributors do not subscribe to NYSE BQT, the prospective data recipients that are the customers of such Redistributors are unable to subscribe to NYSE BQT. The proposed fee change is designed to provide a financial incentive for such Redistributors to subscribe to NYSE BQT so that their customers, which have expressed an interest in subscribing to NYSE BQT, would be able to access the product via such Redistributors.

Currently, subscribers of each of the NYSE Arca BBO and NYSE Arca Trades products that receive a data feed pay a General Access Fee of $750 per month. In February 2020, the Exchange added the Per User Access Fee, which is a reduced fee of $100 per month available at that time only for subscribers of NYSE Arca BBO and NYSE Arca Trades that use those products in a display-only format, including for internal use for Professional Users and external distribution to both Professional and Non-Professional Users.[18]

In November 2020, the Exchange expanded the application of the reduced Per User Access Fee to Redistributors of NYSE Arca BBO and NYSE Arca Trades data feeds that do not subscribe to any other market data product listed on the Fee Schedule and use such market data

Adopting a Waiver Applicable to the Redistribution Fee) (''Second BQT Fee Reduction Filing'').

[5] A Redistributor is a vendor or any other person that provides a NYSE data product to a data recipient or to any system that a data recipient uses, irrespective of the means of transmission or access.

[6] *See* SR–NYSE–2023–42 and SR–NYSEAMER–2023–57.

[7] *See* Securities Exchange Act Release No. 51808 (June 9, 2005), 70 FR 37495, 37499 (June 29, 2005) (S7–10–04) (Final Rule) (''Regulation NMS Adopting Release'').

[8] *See* Securities Exchange Act Release No. 61358, 75 3594, 3597 (January 21, 2010) (File No. S7–02–10) (Concept Release on Equity Market Structure).

[9] *See* Cboe U.S. Equities Market Volume Summary, available at *http://markets.cboe.com/us/equities/market_share/.*

[10] *See* FINRA ATS Transparency Data, *available at https://otctransparency.finra.org/otctransparency/AtsIssueData.* A list of alternative trading systems registered with the Commission is *available at https://www.sec.gov/foia/docs/atslist.htm.*

[11] *See* Cboe U.S. Equities Market Volume Summary, available at *http://markets.cboe.com/us/equities/market_share/.*

[12] As described on the Nasdaq website, available here: *http://www.nasdaqtrader.com/Trader.aspx?id=nasdaqbasic,* Nasdaq Basic is a ''low cost alternative'' that provides ''Best Bid and Offer and Last Sale information for all U.S. exchange-listed securities based on liquidity within the Nasdaq market center, as well as trades reported to the FINRA Trade Reporting Facility (''TRF'').''

[13] As described on the Cboe website, available here: *https://markets.cboe.com/us/equities/market_data_services/cboe_one/,* the Cboe One Feed is a ''market data product that provides cost-effective, high-quality reference quotes and trade data for market participants looking for comprehensive, real-time market data'' and provides a ''unified view of the market from all four Cboe equity exchanges: BZX Exchange, BYX Exchange, EDGX Exchange, and EDGA Exchange.''

[14] *See* Securities Exchange Act Release Nos. 72750 (August 4, 2014), 79 FR 46494 (August 8, 2014) (notice—NYSE BQT); and 73553 (November 6, 2014), 79 FR 67491 (November 13, 2014) (approval order—NYSE BQT) (SR–NYSE–2014–40) (''NYSE BQT Filing'').

[15] In 2019, NYSE BQT was amended to include NYSE Chicago BBO and NYSE Chicago Trades. *See* Securities Exchange Act Release No. 87511 (November 12, 2019), 84 FR 63689 (November 18, 2019) (SR–NYSE–2019–60).

[16] In 2018, NYSE BQT was amended to include NYSE National BBO and NYSE National Trades. *See* Securities Exchange Act Release No. 83359 (June 1, 2018), 83 FR 26507 (June 7, 2018) (SR–NYSE–2018–22).

[17] *See* NYSE BQT Filing, *supra* note 14.

[18] *See* BQT Fee Reduction Filing, *supra,* note 4.

products for external distribution only.[19]

As noted above, the Exchange now proposes to further expand the applicability of the reduced Per User Access Fee. Specifically, the Exchange proposes that Redistributors of NYSE Arca BBOand NYSE Arca Trades that do not subscribe to any other market data product listed on the Fee Schedule other than NYSE ArcaBook and use such market data products for external distribution only, would be eligible for the reduced Per User Access Fee. A Redistributor that receives such data feeds and uses the market data products for any other purpose (such as internal use) would continue to pay the $1,500 per month General Access Fee. And, as currently set forth in footnote 3 to the Fee Schedule, a subscriber would be charged only one access fee for each of the NYSE Arca BBO and NYSE Arca Trades products, depending on the use of that product.

To effect this change, the Exchange proposes to modify footnote 3 to the Fee Schedule as follows (proposed text italicized, proposed deletions bracketed):

> The Per User Access Fee is charged to: (i) a subscriber that receives a data feed and uses the market data product only for Professional Users and Non-Professional Users in a display-only format, including for internal use and external redistribution in a display-only format, and (ii) a Redistributor that subscribes [only] to the NYSE Arca BBO and NYSE Arca Trades data feeds, and does not subscribe to any other Products listed on this Fee Schedule *other than the NYSE ArcaBook data feed,* and uses these market data products for external distribution only. A subscriber that receives a data feed and uses the market data product for any other purpose, including if combined with Per User use, will be charged the General Access Fee. A subscriber will be charged only one access fee for each of the NYSE Arca BBO and NYSE Arca Trades products, depending on the use of that product.

The proposed rule change would result in lower fees for Redistributors that receive NYSE Arca BBO, NYSE Arca Trades, and NYSE ArcaBook data feeds, and use such market data products for external distribution only.[20] The Exchange believes that the proposed expansion of the reduced Per User Access Fee would provide an incentive for Redistributors that currently subscribe to NYSE ArcaBook to also subscribe to the NYSE BQT data feeds so that such product would be available to their customers, which have expressed an interest in subscribing to NYSE BQT.

The proposed rule change is intended to encourage greater use of NYSE BQT by making it more affordable for Redistributors that subscribe to NYSE ArcaBook and also have customers interested in subscribing to NYSE BQT. The proposed fee change would allow the Exchange to compete more effectively with Nasdaq Basic and Cboe One Feed by expanding the number of Redistributors that would subscribe to NYSE BQT, and therefore make the product more widely available to data subscribers interested in NYSE BQT.

Applicability of Proposed Rule Change

As noted above, the proposed rule change is designed to reduce the overall cost for Redistributors of NYSE BQT that also redistribute NYSE ArcaBook by expanding the applicability of the Per User Access Fee. Today, the Exchange has thirty-one data feed subscribers, two of whom became Redistributors as a direct result of the Second BQT Fee Reduction Filing and currently pay the reduced Per User Access Fee. The Exchange believes that the proposed rule change would provide a further incentive for Redistributors that already subscribe to NYSE ArcaBook to subscribe to NYSE BQT for purposes of providing external distribution of NYSE BQT to potential data recipients interested in the product.

Because the proposed rule change is targeted to potential Redistributors of NYSE BQT that also subscribe to NYSE ArcaBook, the proposed change to the availability of the NYSE Arca BBO and NYSE Arca Trades Per User Access Fees, together with the proposed changes on NYSE and NYSE American, are narrowly tailored with that purpose in mind. Accordingly, this proposed fee change is not designed for Redistributors that are existing customers of NYSE Arca market data products (other than NYSE ArcaBook) or that engage in internal use of NYSE BQT. This proposed rule change would not result in any changes to the market data fees for NYSE Arca BBO and NYSE Arca Trades for such data subscribers.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with the provisions of Section 6 of the Act,[21] in general, and Sections 6(b)(4) and 6(b)(5) of the Act,[22] in particular, in that it provides an equitable allocation of reasonable fees among users and recipients of the data and is not designed to permit unfair discrimination among customers, issuers, and brokers.

The Proposed Rule Change Is Reasonable

In adopting Regulation NMS, the Commission granted SROs and broker-dealers increased authority and flexibility to offer new and unique market data to the public. The Commission has repeatedly expressed its preference for competition over regulatory intervention in determining prices, products, and services in the securities markets. Specifically, in Regulation NMS, the Commission highlighted the importance of market forces in determining prices and SRO revenues, and also recognized that current regulation of the market system ''has been remarkably successful in promoting market competition in its broader forms that are most important to investors and listed companies.'' [23]

With respect to market data, the decision of the United States Court of Appeals for the District of Columbia Circuit in *NetCoalition* v. *SEC* upheld the Commission's reliance on the existence of competitive market mechanisms to evaluate the reasonableness and fairness of fees for proprietary market data:

> In fact, the legislative history indicates that the Congress intended that the market system ''evolve through the interplay of competitive forces as unnecessary regulatory restrictions are removed'' and that the SEC wield its regulatory power ''in those situations where competition may not be sufficient,'' such as in the creation of a ''consolidated transactional reporting system.'' [24]

The court agreed with the Commission's conclusion that ''Congress intended that 'competitive forces should dictate the services and practices that constitute the U.S. national market system for trading equity securities.' '' [25]

More recently, the Commission confirmed that it applies a ''market-based'' test in its assessment of market data fees, and that under that test:

> the Commission considers whether the exchange was subject to significant

[19] *See* Second BQT Fee Reduction Filing, *supra,* note 4.

[20] The Per User Access Fee is 93% lower than the General Access Fee. Together with the corresponding proposed rule changes by NYSE and NYSE American to similarly reduce the access fees to their BBO and Trades products for Redistributors, such Redistributors would be eligible for significantly lower access fees for NYSE BQT, from $6,250 per month to $850 per month ($250 + $200 + $200 +$200), a reduction of more than 86%.

[21] 15 U.S.C. 78f(b).

[22] 15 U.S.C. 78f(b)(4), (5).

[23] *See* Regulation NMS Adopting Release, 70 FR 37495, at 37499.

[24] *NetCoalition* v. *SEC,* 615 F.3d 525, 535 (D.C. Cir. 2010) (''*NetCoalition I*'') (quoting H.R. Rep. No. 94–229 at 92 (1975), *as reprinted in* 1975 U.S.C.C.A.N. 323).

[25] *Id.* at 535.

competitive forces in setting the terms of its proposal for [market data], including the level of any fees. If an exchange meets this burden, the Commission will find that its fee rule is consistent with the Act unless there is a substantial countervailing basis to find that the terms of the rule violate the Act or the rules thereunder.[26]

1. The Proposed Fees Are Constrained by Significant Competitive Forces

An exchange may demonstrate that its fees are constrained by competitive forces by showing that platform competition applies.

As the United States Supreme Court recognized in *Ohio* v. *American Express,* platforms are firms that act as intermediaries between two or more sets of agents, and typically the choices made on one side of the platform affect the results on the other side of the platform via externalities, or ''indirect network effects.'' [27] Externalities are linkages between the different ''sides'' of a platform such that one cannot understand pricing and competition for goods or services on one side of the platform in isolation; one must also account for the influence of the other side. As the Supreme Court explained:

> To ensure sufficient participation, two-sided platforms must be sensitive to the prices that they charge each side. . . . Raising the price on side A risks losing participation on that side, which decreases the value of the platform to side B. If the participants on side B leave due to this loss in value, then the platform has even less value to side A—risking a feedback loop of declining demand. . . . Two-sided platforms therefore must take these indirect network effects into account before making a change in price on either side.[28]

The Exchange and its affiliated exchanges have long maintained that they function as platforms between consumers of market data and consumers of trading services. Proving the existence of linkages between the two sides of this platform requires an in-depth economic analysis of both public data and confidential Exchange data about particular customers' trading activities and market data purchases. Exchanges, however, are prohibited from sharing details about these specific customer activities and purchases. For example, pursuant to Exchange Rule 7.41–E, transactions executed on the Exchange are processed anonymously.

Exchanges function as platforms for market data and transaction services mean that exchanges do not set fees for market data products without considering, and being constrained by, the effect the fees will have on the order-flow side of the platform. And as the D.C. Circuit recognized in *NetCoalition I,* ''[n]o one disputes that competition for order flow is fierce.'' [29] The court further noted that ''no exchange possesses a monopoly, regulatory or otherwise, in the execution of order flow from broker dealers,'' and that an exchange ''must compete vigorously for order flow to maintain its share of trading volume.'' [30]

As noted above, while Regulation NMS has enhanced competition, it has also fostered a ''fragmented'' market structure where trading in a single stock can occur across multiple trading centers. When multiple trading centers compete for order flow in the same stock, the Commission has recognized that ''such competition can lead to the fragmentation of order flow in that stock.'' [31] The Commission's Division of Trading and Markets has also recognized that with so many ''operating equities exchanges and dozens of ATSs, there is vigorous price competition among the U.S. equity markets and, as a result, [transaction] fees are tailored and frequently modified to attract particular types of order flow, some of which is highly fluid and price sensitive.'' [32] Indeed, today, equity trading is currently dispersed across 16 exchanges,[33] numerous alternative trading systems,[34] broker-dealer internalizers and wholesalers, all competing for order flow. Based on publicly-available information, no single exchange currently has more than 17% market share.[35]

Further, low barriers to entry mean that new exchanges may, and do, rapidly and inexpensively enter the market and offer additional substitute platforms to compete with the Exchange. For example, since 2020, three new exchanges have entered the market: Long Term Stock Exchange (LTSE), which began operations as an exchange on August 28, 2020; [36] Members Exchange (MEMX), which began operations as an exchange on September 29, 2020; [37] and Miami International Holdings (MIAX), which began operations of its first equities exchange on September 29, 2020.[38]

These low barriers enable existing exchange customers to disintermediate and start their own exchanges if they think the prices charged for exchange proprietary market data products are too high. This is precisely the rationale behind the creation of MEMX, which was formed by some of the largest and most well capitalized financial firms that are also Exchange customers (including Bank of America, BlackRock, Charles Schwab, Citadel, Citi, E*Trade, Fidelity, Goldman Sachs, J.P. Morgan, Jane Street, Morgan Stanley, TD Ameritrade, and others).[39]

For example, one of MEMX's founding principles is that exchange proprietary market data prices are too high, and that MEMX will benefit its members by offering ''[l]ower pricing on market data.'' [40] Nor is this a new phenomenon: exchange customers formed BATS to compete with incumbent exchanges and once registered as an exchange in 2008, BATS did not initially charge for market data. The BATS venture was a financial success for its founders, first through recouping their investment in its initial public offering and then in the subsequent sale of BATS to Cboe, which

[26] *See* Securities Exchange Act Release No. 34–90217 (October 16, 2020), 85 FR 67392 (October 22, 2020) (SR–NYSENAT–2020–05) (''National IF Approval Order'') (internal quotation marks omitted), quoting Securities Exchange Act Release No. 59039 (December 2, 2008), 73 FR 74770, 74781 (December 9, 2008) (''2008 ArcaBook Approval Order'').

[27] *Ohio* v. *American Express,* 138 S. Ct. 2274, 2280–81 (2018).

[28] *Id.* at 2281.

[29] *NetCoalition I,* 615 F.3d at 544 (internal quotation omitted).

[30] *Id.*

[31] *See* Securities Exchange Act Release No. 61358, 75 3594, 3597 (January 21, 2010) (File No. S7–02–10) (Concept Release on Equity Market Structure).

[32] Commission Division of Trading and Markets, Memorandum to EMSAC, dated October 20, 2015, available here: *https://www.sec.gov/spotlight/emsac/memo-maker-taker-fees-on-equities-exchanges.pdf.*

[33] *See* Cboe Global Markets, U.S. Equities Market Volume Summary, available at *http://markets.cboe.com/us/equities/market_share/.*

[34] *See* FINRA ATS Transparency Data, *available at https://otctransparency.finra.org/otctransparency/AtsIssueData.* A list of alternative trading systems registered with the Commission is *available at https://www.sec.gov/foia/docs/atslist.htm.*

[35] *See* Cboe Global Markets, U.S. Equities Market Volume Summary, available at *http://markets.cboe.com/us/equities/market_share/.*

[36] *See* LTSE Market Announcement: MA–2020–020, dated August 14, 2020, announcing LTSE production securities phase-in planned for August 28, available here: *https://assets-global.website-files.com/6462417e8db99f8baa06952c/6462417e8db99f8baa0698e7_MA-2020-020__Production_Securities_Launching_August_28_-_Google_Docs.pdf* and LTSE Market Announcement: MA–2020–025, available here: *https://assets-global.website-files.com/6462417e8db99f8baa06952c/6462417e8db99f8baa069873_MA-2020-025.pdf.*

[37] As of October 29, 2020, MEMX is trading all NMS symbols. *See https://info.memxtrading.com/trader-alert-20-10-memx-trading-symbols-update/.*

[38] *See* MIAX Pearl Press release, dated September 29, 2020, available here: *https://www.miaxoptions.com/sites/default/files/alert-files/MIAX_Press_Release_09292020.pdf.*

[39] MEMX Home Page (''Founded by members and investors, MEMX aims to drive simplicity, efficiency, and competition in equity markets.''), available at *https://memx.com/.*

[40] MEMX home page, available at *https://memx.com/.*

now charges for market data from those exchanges. Notably, MEMX has some of the same founding broker-dealer customers, leading some to dub MEMX ''BATS 2.0.'' [41]

The fact that this cycle is viable and repeatable by entities that both trade on and compete with existing exchanges confirms that barriers to entry are low and that these markets are competitive and contestable.[42] And low barriers to entry act as a market check on high prices.[43]

In sum, the fierce competition for order flow thus constrains any exchange from pricing its market data at a supracompetitive price, and constrains the Exchange in setting its fees at issue here.

The proposed expansion of Per User Access Fee is therefore reasonable because in setting it, the Exchange is constrained by the availability of numerous substitute platforms offering market data products and trading. Such substitutes need not be identical, but only substantially similar to the product at hand.

More specifically, in expanding the applicability of the Per User Access Fee to Redistributors of NYSE ArcaBook, the Exchange is constrained by the fact that, if its pricing across the platform is unattractive to customers, customers have their pick of an increasing number of alternative platforms to use instead of the Exchange. The Exchange believes that it has considered all relevant factors and has not considered irrelevant factors in order to establish reasonable fees. The existence of numerous alternative platforms to the Exchange's platform ensures that the Exchange cannot set unreasonable market data fees without suffering the negative effects of that decision in the fiercely competitive market for trading order flow.

Even putting aside the facts that exchanges are platforms and that pricing decisions on the two sides of the platform are intertwined, the Exchange is constrained in setting the proposed market data fees by the availability of numerous substitute market data products. The Commission has been clear that substitute products need not be identical, but only substantially similar to the product at hand.[44]

The NYSE BQT market data product is subject to significant competitive forces that constrain its pricing. Specifically, as described above, NYSE BQT competes head-to-head with the Nasdaq Basic product and the Cboe One Feed. These products each serve as reasonable substitutes for one another as they are each designed to provide investors with a unified view of real-time quotes and last-sale prices in all Tape A, B, and C securities. Each product provides subscribers with consolidated top-of-book quotes and trades from multiple U.S. equities markets. In the case of NYSE BQT, this product provides top-of-book quotes and trades data from five NYSE-affiliated U.S. equities exchanges, which together account for approximately 20% of consolidated U.S. equities trading volume as of October 2023.[45] Cboe One Feed similarly provides top-of-book quotes and trades data from Cboe's four U.S. equities exchanges. NYSE BQT, Nasdaq Basic, and Cboe One Feed are all intended to provide indicative pricing and are not intended to be used for order routing or trading decisions.

In addition to competing with proprietary data products from Nasdaq and Cboe, NYSE BQT also competes with the consolidated data feed. However, the Exchange does not claim that NYSE BQT is a substitute for consolidated data with respect to requirements under the Vendor Display Rule, which is Regulation NMS Rule 603(c).

The fact that this filing is proposing to further expand the application of the reduced Per User Access Fee is itself confirmation of the inherently competitive nature of the market for the sale of proprietary market data. For example, in August 2019, Cboe filed proposed rule changes to reduce certain of its Cboe One Feed fees and noted that it attracted two additional customers because of the reduced fees.[46] More

[41] *See* ''MEMX turns up the heat on US stock exchanges,'' Financial Times, January 9, 2019, available at *https://www.ft.com/content/4908c8b0-1418-11e9-a581-4ff78404524e; see also* ''US equities exchanges: If you can't beat them, join them,'' Euromoney, February 13, 2019, available at *https://www.euromoney.com/article/b1d3tfby4p3y4v/us-equities-exchanges-if-you-cant-beat-them-join-them.*

[42] *United States* v. *SunGard Data Sys.,* 172 F. Supp. 2d 172, 186 (D.D.C. 2001) (recognizing that ''[a]s a matter of law, courts have generally recognized that when a customer can replace the services of an external product with an internally-created system, this captive output (*i.e.* the self-production of all or part of the relevant product) should be included in the same market.''). In *SunGard,* the court rejected the Antitrust Division's attempt to block SunGuard's acquisition of the disaster recovery assets of Comdisco on the basis that the acquisition would ''substantially lessen competition in the market for shared hotsite disaster recovery services,'' when the evidence showed that ''internal hotsites'' created by customers competed with the ''external shared hotsite business'' engaged in by the merging parties. *Id.* at 173–74, 187.

[43] *United States* v. *Baker Hughes,* 908 F.2d 981, 987 (1990) (''In the absence of significant barriers [to entry], a company probably cannot maintain supracompetitive pricing for any length of time.''); *see also* David S. Evans and Richard Schmalensee, Markets with Two-Sided Platforms, in 1 Issues In Competition Law And Policy 667, 685 (ABA Section of Antitrust Law 2008) (noting that exchange mergers in 2005 and 2006 were approved by competition authorities in part in reliance on planned and likely entry of other firms).

[44] For example, in the National IF Approval Order, the Commission recognized that for some customers, the best bid and offer information from consolidated data feeds may function as a substitute for the NYSE National Integrated Feed product, which contains order by order information. *See* National IF Approval Order, *supra* note 26, at 67397 [release p. 21] (''[I]nformation provided by NYSE National demonstrates that a number of executing broker-dealers do not subscribe to the NYSE National Integrated Feed and executing broker-dealers can otherwise obtain NYSE National best bid and offer information from the consolidated data feeds.'' (internal quotations omitted)).

[45] *See* Cboe Global Markets U.S. Equities Market Volume Summary, available at *https://www.cboe.com/us/equities/market_share/.*

[46] *See* Securities Exchange Act Release Nos.86667 (August 14, 2019) (SR–CboeBZX–2019–069); 86670 (August 14, 2019) (SR–CboeBYX–2019–012); 86676 (August 14, 2019) (SR–CboeEDGA–2019–013); and 86678 (August 14, 2019) (SR–CboeEDGX–2019–048) (Notices of filing and Immediate effectiveness of proposed rule change to reduce fees for the Cboe One Feed) (collectively ''Cboe One Fee Filings''). The Cboe One Fee Filings were in effect from August 1, 2019 until September 30, 2019, when the Commission suspended them and instituted proceedings to determine whether to approve or disapprove those proposals. *See, e.g.,* Securities Exchange Act Release No. 87164 (September 30, 2019), 84 FR 53208 (October 4, 2019) (SR–CboeBZX–2019–069). On October 1, 2019, the Cboe equities exchanges refiled the Cboe One Fee Filings on the basis that they had new customers subscribe as a result of the Cboe One Fee Filings, and therefore its fee proposal had increased competition for top-of-book market data. *See* Securities Exchange Act Release Nos. 87312 (October 15, 2019), 84 FR 56235 (October 21, 2019) (SR–CboeBZX–2019–086); 87305 (October 14, 2019), 84 FR 56210 (October 21, 2019) (SR–CboeBYX–2019–015); 87295 (October 11, 2019), 84 FR 55624 (October 17, 2019) (SR–CboeEDGX–2019–059); and 87294 (October 11, 2019), 84 FR 55638 (October 17, 2019) (SR–CboeEDGA–2019–015) (Notices of filing and immediate effectiveness of proposed rule changes to re-file the Small Retail Broker Distribution Program) (''Cboe One Fee Re-Filings''). On November 26, 2019, the Commission suspended the Cboe One Fee Re-Filings and instituted proceedings to determine whether to approve or disapprove those proposals. *See, e.g.,* Securities Exchange Act Release No. 87629 (November 26, 2019), 84 FR 66245 (December 3, 2019) (SR–CboeBZX–2019–086). On November 27, 2019, the Cboe equities exchanges refiled the Cboe One Fee Filings with one revision to the requirements for participating in the Small Retail Broker Distribution Program and additional information about the basis for the proposed fee changes. *See* Securities Exchange Act Release Nos. 87712 (December 10, 2019), 84 FR 68508 (December 16, 2019) (SR–CboeBZX–2019–101); 88713 (December 10, 2019), 84 FR 68530 (December 16, 2019) (SR–CboeBYX–2019–023); 87709 (December 10, 2019), 84 FR 68523 (December 16, 2019) (SR–CboeEDGA–2019–021); and 87711 (December 10, 2019), 84 FR 68501 (December 16, 2019) (SR–Cboe-EDGX–2019–071) (Notices of filing and immediate effectiveness of proposed rule changes to introduce a Small Retail Broker Distribution Program) (''Cboe One Third Fee Re-Filings''). On February 4, 2020, the Cboe equities exchanges withdrew the Cboe One Third Fee Re-Filings and, on the same date, refiled the Cboe One Fee Filings. *See* Securities Exchange Act Release Nos. 88221 (February 14, 2020), 85 FR 9904 (February 20, 2020) (SR–CboeBYX–2020–007); 88218 (February 14, 2020), 85 FR 9827 (February

recently, Nasdaq filed a proposed rule change to lower the enterprise license fee for broker-dealers distributing Nasdaq Basic to internal Professional subscribers and the enterprise license fee for broker-dealers distributing Nasdaq Last Sale to Professional subscribers.[47]

The Exchange notes that NYSE Arca proprietary market data products are entirely optional. The Exchange is not required to make the proprietary data products that are the subject of this proposed rule change available or to offer any specific pricing alternatives to any customers, nor is any firm or investor required to purchase the Exchange's data products. Unlike some other data products (*e.g.,* the consolidated quotation and last-sale information feeds) that firms are required to purchase in order to fulfil regulatory obligations,[48] a customer's decision whether to purchase any of the Exchange's proprietary market data feeds is entirely discretionary. Most firms that choose to subscribe to proprietary market data feeds from the Exchange and its affiliates do so for the primary goals of using them to increase their revenues, reduce their expenses, and in some instances compete directly with the Exchange's trading services. Such firms are able to determine for themselves whether or not the products in question or any other similar products are attractively priced. If market data feeds from the Exchange and its affiliates do not provide sufficient value to firms based on the uses those firms may have for it, such firms may simply choose to conduct their business operations in ways that do not use the products.

In addition, in the case of products that are also redistributed through market data vendors, such as Bloomberg and Refinitiv, the vendors themselves provide additional price discipline for proprietary data products because they control the primary means of access to certain end users. These vendors impose price discipline based upon their business models. For example, vendors that assess a surcharge on data they sell are able to refuse to offer proprietary products that their end users do not or will not purchase in sufficient numbers. This competitive constraint is precisely what is driving the proposed fee changes here, which are designed to attract new market data vendors, and through them new subscribers, to the NYSE BQT product. Currently, only seven data feed vendors subscribe to NYSE BQT, and each vendor has limited redistribution of NYSE BQT. No other vendors currently subscribe to NYSE BQT and likely will not unless their customers request it, and customers will not elect to pay the proposed fees unless such product can provide value by sufficiently increasing revenues or reducing costs in the customer's business in a manner that will offset the fees. All of these factors operate as constraints on pricing proprietary data products.

Because of the availability of substitutes, an exchange that overprices its market data products stands a high risk that users may substitute another source of market data information for its own. Those competitive pressures imposed by available alternatives are evident in the Exchange's proposed pricing.

In setting the proposed fees, the Exchange considered the competitiveness of the market for proprietary data and all of the implications of that competition. The Exchange believes that it has considered all relevant factors and has not considered irrelevant factors in order to establish reasonable fees. The existence of numerous alternatives to the Exchange's platform and, more specifically, alternatives to the market data products, including proprietary data from other sources, ensures that the Exchange cannot set unreasonable fees when vendors and subscribers can elect these alternatives or choose not to purchase a specific proprietary data product if the attendant fees are not justified by the returns that any particular vendor or data recipient would achieve through the purchase.

2. The Proposed Fees Are Reasonable

The proposed expansion of the Per User Access Fee is reasonable, for the following additional reasons.

Overall. This proposed fee change is a result of the competitive environment, as the Exchange seeks to decrease certain of its fees to attract Redistributors that do not currently subscribe to the NYSE BQT market data product. The Exchange is proposing the fee reduction at issue to make the Exchange's fees more competitive for a specific segment of market participants, thereby increasing the availability of the Exchange's data products, and expanding the options available to firms making data purchasing decisions based on their business needs. The Exchange believes that this is consistent with the principles contained in Regulation NMS to ''promote the wide availability of market data and to allocate revenues to SROs that produce the most useful data for investors.'' [49]

Access Fee. By making the reduced Per User Access Fee available to Redistributors of NYSE ArcaBook for external distribution who do not subscribe to any other products listed on the Fee Schedule other than NYSE Arca BBO and NYSE Arca Trades, the Exchange believes that more Redistributors may choose to subscribe to these products, thereby expanding the distribution of this market data for the benefit of investors that participate in the national market system and increasing competition generally. The Exchange also believes that offering the Per User Access Fee to these Redistributors would expand the availability of NYSE BQT to potential data recipients that are interested in subscribing to NYSE BQT but do not have access to a Redistributor who subscribes to the data feeds.

The Exchange determined to make the reduced Per User Access Fee available to these Redistributors because it constitutes a substantial reduction of the current fee, with the intended purpose of increasing use of NYSE BQT by Redistributors. NYSE BQT has been in place since 2014 but has a very small number of subscribers. The Exchange believes that in order to compete with other indicative pricing products such as Nasdaq Basic and Cboe One Feed, it needs to provide a meaningful financial incentive for more Redistributors to choose to subscribe to NYSE BQT so that they can make it available to their

20, 2020) (SR–CboeBZX–2020–014); 88220 (February 14, 2020), 85 FR 9912 (February 20, 2020) (SR–CboeEDGA–2020–004); and 88219 (February 14, 2020), 85 FR 9872 (February 20, 2020) (SR–CboeEDGX–2020–008) (Notices of filing and immediate effectiveness of proposed rule changes to introduce a Small Retail Broker Distribution Program) (''Cboe One Fourth Fee Re-Filings''). On April 15, 2020, the Cboe equities exchanges withdrew the Cboe One Fee Filings and the Cboe One Fee Re-Filings. Pursuant to the Cboe One Fourth Fee Re-Filings, the Small Retail Broker Distribution Program is currently in effect at the Cboe equities exchanges.

[47] *See* Securities Exchange Act Release No. 90177 (October 14, 2020), 85 FR 66620 (October 20, 2020) (SR–NASDAQ–2020–065) (Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Lower the Enterprise License Fee for Broker-Dealers Distributing Nasdaq Basic to Internal Professional Subscribers as Set Forth in the Equity 7 Pricing Schedule, Section 147, and the Enterprise License Fee for Broker-Dealers Distributing Nasdaq Last Sale to Professional Subscribers at Equity 7, Section 139).

[48] The Exchange notes that broker-dealers are not required to purchase proprietary market data to comply with their best execution obligations. *See In the Matter of the Application of Securities Industry and Financial Markets Association for Review of Actions Taken by Self-Regulatory Organizations,* Release Nos. 34–72182; AP–3–15350; AP–3–15351 (May 16, 2014). Similarly, there is no requirement in Regulation NMS or any other rule that proprietary data be utilized for order routing decisions, and some broker-dealers and ATSs have chosen not to do so.

[49] *See* Regulation NMS Adopting Release, 70 FR 37495, at 37503.

customers. Accordingly, the proposed expansion of the Per User Access Fee, together with the proposed expansion of the Per User Access Fee filed by the Exchange's affiliates, is reasonable because the reductions will make NYSE BQT a more attractive offering for Redistributors that do not currently subscribe to any NYSE Arca market data products other than NYSE ArcaBook and make it more competitive with Nasdaq Basic and Cboe One Feed.

Evidence of the competition among exchange groups for these products has previously been demonstrated via fee changes. For example, following the introduction of the Cboe One Feed, Nasdaq responded by reducing its fees for the Nasdaq Basic product.[50] With the proposed changes by the Exchange, NYSE, and NYSE American, the Exchange is similarly seeking to compete by decreasing the total access fees for NYSE BQT from $6,250 to $850 for Redistributors that do not currently subscribe to any NYSE Arca market data products other than NYSE ArcaBook and have customers that are interested in subscribing to NYSE BQT but cannot do so until their Redistributor also subscribes. This proposed rule change therefore demonstrates the existence of an effective, competitive market because this proposal resulted from a need to generate innovative approaches in response to competition from other exchanges that offer market data for a specific segment of market participants.

For all of the foregoing reasons, the Exchange believes that the proposed fees are reasonable.

The Proposed Fees Are Equitably Allocated

The Exchange believes the proposed expansion of the Per User Access Fee is allocated fairly and equitably among the various categories of users of the Exchange's market data feed, and any differences among categories of users are justified.

Overall. As noted above, this proposed fee change is a result of the competitive environment for market data products that provide indicative pricing information across a family of exchanges. To respond to this competitive environment, the Exchange seeks to expand the application of the Per User Access Fee for Redistributors that would be subscribing to the NYSE Arca BBO, NYSE Arca Trades and NYSE ArcaBook data feeds and would use these market data products for external distribution only, which the Exchange hopes will attract new Redistributor subscribers for the NYSE BQT market data product so that the product can be made available to prospective market data recipients. The Exchange is proposing to expand the application of the reduced Per User Access Fee to make the Exchange's fees more competitive for a specific segment of market participants, thereby increasing the availability of the Exchange's data products, expanding the options available to firms making data purchasing decisions based on their business needs, and generally increasing competition.

Access Fee. The Exchange believes that making the Per User Access Fee available to Redistributors that would be subscribing to the NYSE Arca BBO, NYSE Arca Trades and NYSE ArcaBook data feeds and would use these market data products for external distribution only is equitable as the reduced fee would apply equally to all data recipients that choose to subscribe to NYSE Arca BBO, NYSE Arca Trades and NYSE ArcaBook for external distribution only. Because NYSE Arca BBO, NYSE Arca Trades and NYSE ArcaBook are optional products, any data recipient could choose to subscribe to such data feeds to distribute externally and be eligible for the Per User Access Fee. The Exchange does not believe that it is inequitable that the Per User Access Fee would be available only to data recipients that subscribe to NYSE Arca BBO, NYSE Arca Trades and NYSE ArcaBook and only for external distribution. Internal use of data represents a different set of use cases than a Redistributor that is engaged only in external distribution of data. For example, non-display data can be used by data recipients for a wide variety of profit-generating purposes, including proprietary and agency trading and smart order routing, as well as by data recipients that operate order matching and execution platforms that compete directly with the Exchange for order flow. The data also can be used for a variety of non-trading purposes that indirectly support trading, such as risk management and compliance. Although some of these non-trading uses do not directly generate revenues, they can nonetheless substantially reduce the recipient's costs by automating such functions so that they can be carried out in a more efficient and accurate manner and reduce errors and labor costs, thereby benefiting end users. The Exchange believes that charging a different access fee for a Redistributor that is engaged solely in external distribution of only the NYSE Arca BBO, NYSE Arca Trades and NYSE ArcaBook products is equitable because it would make NYSE BQT available to more data recipients that are customers of such Redistributors and who would not otherwise be able to access NYSE BQT if their Redistributor did not subscribe to and redistribute NYSE BQT.

For all of the foregoing reasons, the Exchange believes that the proposed fees for the NYSE Arca market data products are equitably allocated.

The Proposed Fees Are Not Unfairly Discriminatory

The Exchange believes the proposed fees are not unfairly discriminatory because any differences in the application of the fees are based on meaningful distinctions between customers, and those meaningful distinctions are not unfairly discriminatory between customers.

Overall. As noted above, this proposed fee change is a result of the competitive environment for market data products that provide indicative pricing information across a family of exchanges. To respond to this competitive environment, the Exchange seeks to amend its fees to provide a financial incentive for Redistributors of NYSE ArcaBook that do not currently subscribe to any NYSE Arca market data products that decide to subscribe to NYSE BQT, which the Exchange hopes will attract more subscribers for the NYSE BQT market data product. The Exchange is proposing to expand the application of the Per User Access Fee to make the Exchange's fees more competitive for a specific segment of market participants, thereby increasing the availability of the Exchange's data products, expanding the options available to firms making data purchasing decisions based on their business needs, and generally increasing competition.

Access Fee. The Exchange believes that making the Per User Access Fee available to Redistributors that would be subscribing to the NYSE Arca BBO, NYSE Arca Trades and NYSE ArcaBook data feeds and would use these market data products for external distribution only is not unfairly discriminatory as the reduced fee would apply equally to all Redistributors that choose to subscribe to NYSE Arca BBO, NYSE

[50] *See e.g.,* Securities Exchange Act Release No. 83751 (July 31, 2018), 83 FR 38428 (August 6, 2018) (SR–NASDAQ–2018–058) (Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Lower Fees and Administrative Costs for Distributors of Nasdaq Basic, Nasdaq Last Sale, NLS Plus and the Nasdaq Depth-of-Book Products Through a Consolidated Enterprise License). Nasdaq filed the proposed fee change to lower the Enterprise Fee for Nasdaq Basic and other market data products in response to the Enterprise Fee for the Cboe One Feed adopted by Cboe family of exchanges.

Arca Trades and NYSE ArcaBook for external distribution only. Because NYSE Arca BBO, NYSE Arca Trades and NYSE ArcaBook are optional products, any data recipient could choose to subscribe to such data feeds to distribute externally and be eligible for the Per User Access Fee. The Exchange does not believe that it is unfairly discriminatory that the Per User Access Fee would be available only to data recipients that subscribe to NYSE Arca BBO, NYSE Arca Trades and NYSE ArcaBook and only for external distribution. Internal use of data represents a different set of use cases than a Redistributor that is engaged only in external distribution of data. For example, non-display data can be used by data recipients for a wide variety of profit-generating purposes, including proprietary and agency trading and smart order routing, as well as by data recipients that operate order matching and execution platforms that compete directly with the Exchange for order flow. The data also can be used for a variety of non-trading purposes that indirectly support trading, such as risk management and compliance. While some of these non-trading uses do not directly generate revenues, they can nonetheless substantially reduce the recipient's costs by automating such functions so that they can be carried out in a more efficient and accurate manner and reduce errors and labor costs, thereby benefiting end users. The Exchange therefore believes that there is a meaningful distinction between internal use and redistribution of market data and that charging a different access fee to a Redistributor that is engaged solely in external distribution of only the NYSE Arca BBO, NYSE Arca Trades and NYSE ArcaBook products is not unfairly discriminatory because it would make NYSE BQT available to more data recipients that are customers of such Redistributors and who would not otherwise be able to access NYSE BQT if their Redistributor did not subscribe to and redistribute NYSE BQT.

Moreover, the Exchange does not believe that it is unfairly discriminatory to offer the Per User Access Fee only to those Redistributors that would subscribe to the NYSE Arca BBO, NYSE Arca Trades and NYSE ArcaBook data feeds, and only for external distribution. This proposed rule change is designed to provide an incentive for Redistributors that currently subscribe to NYSE ArcaBook, but do not subscribe to NYSE BQT, and may have customers that are interested in subscribing to NYSE BQT, to subscribe to the NYSE Arca BBO and NYSE Arca Trades data feeds so that they can make NYSE BQT available to their customers. This fee incentive is not necessary for Redistributors that currently subscribe to the NYSE Arca BBO and NYSE Arca Trades data feeds because such Redistributors could already subscribe to NYSE BQT, but have chosen not to, and a reduction in their existing access fees would likely not result in such Redistributors choosing to subscribe to NYSE BQT.

For all of the foregoing reasons, the Exchange believes that the proposed fees are not unfairly discriminatory.

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. Indeed, as demonstrated above, the Exchange believes the proposed rule changes are pro-competitive.

Intramarket Competition. The Exchange believes that the proposed fees do not put any market participants at a relative disadvantage compared to other market participants. As noted above, the proposed fee schedule would apply to all subscribers of NYSE Arca market data products, and customers may not only choose whether to subscribe to the products at all, but also may tailor their subscriptions to include only the products and uses that they deem suitable for their business needs. The Exchange also believes that the proposed fees neither favor nor penalize one or more categories of market participants in a manner that would impose an undue market on competition. As shown above, to the extent that particular proposed fees apply to only a subset of subscribers, those distinctions are not unfairly discriminatory and do unfairly burden one set of customers over another.

Intermarket Competition. The Exchange believes that the proposed fees do not impose a burden on competition on other exchanges that is not necessary or appropriate; indeed, the Exchange believes the proposed fee changes would have the effect of increasing competition. As described above, exchanges are platforms for market data and trading. In setting the proposed fees, the Exchange is constrained by the availability of substitute platforms also offering market data products and trading, and low barriers to entry mean new exchange platforms are frequently introduced. The fact that exchanges are platforms ensures that no exchange can make pricing decisions for one side of its platform without considering, and being constrained by, the effects that price will have on the other side of the platform. In setting fees at issue here, the Exchange is constrained by the fact that, if its pricing across the platform is unattractive to customers, customers will have its pick of an increasing number of alternative platforms to use instead of the Exchange. Given this intense competition between platforms, no one exchange's market data fees can impose an unnecessary burden on competition, and the Exchange's proposed fees do not do so here.

In addition, the Exchange believes that the proposed fees do not impose a burden on competition or on other exchanges that is not necessary or appropriate because of the availability of numerous substitute market data products. Specifically, as described above, NYSE BQT competes head-to-head with the Nasdaq Basic product and the Cboe One Feed. These products each serve as reasonable substitutes for one another as they are each designed to provide investors with a unified view of real-time quotes and last-sale prices in all Tape A, B, and C securities. Each product provides subscribers with consolidated top-of-book quotes and trades from multiple U.S. equities markets. NYSE BQT provides top-of-book quotes and trades data from five NYSE-affiliated U.S. equities exchanges, while Cboe One Feed similarly provides top-of-book quotes and trades data from Cboe's four U.S. equities exchanges. NYSE BQT, Nasdaq Basic, and Cboe One Feed are all intended to provide indicative pricing and therefore, are reasonable substitutes for one another. Additionally, market data vendors are also able to offer close substitutes to NYSE BQT. Because market data users can find suitable substitute feeds, an exchange that overprices its market data products stands a high risk that users may substitute another source of market data information for its own. These competitive pressures ensure that no one exchange's market data fees can impose an unnecessary burden on competition, and the Exchange's proposed fees do not do so here.

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 has become effective upon filing pursuant to Section 19(b)(3)(A)[51] of the Act and paragraph (f) thereunder. At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act.

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 (*https://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include file number SR–NYSEARCA–2023–78 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to file number SR–NYSEARCA–2023–78. 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 (*https://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 a.m. and 3 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. Do not include personal identifiable information in submissions; you should submit only information that you wish to make available publicly. We may redact in part or withhold entirely from publication submitted material that is obscene or subject to copyright protection. All submissions should refer to file number SR–NYSEARCA–2023–78 and should be submitted on or before December 13, 2023.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[52]

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2023–25780 Filed 11–21–23; 8:45 am]

BILLING CODE 8011–01–P

[51] 15 U.S.C. 78s(b)(3)(A).

[52] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–98966; File No. SR–NYSENAT–2023–26]

Self-Regulatory Organizations; NYSE National, Inc.; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend the Connectivity Fee Schedule

November 16, 2023.

Pursuant to Section 19(b)(1)[1] of the Securities Exchange Act of 1934 (''Act'')[2] and Rule 19b–4 thereunder,[3] notice is hereby given that on November 9, 2023, NYSE National, Inc. (''NYSE National'' or the ''Exchange'') filed with the Securities and Exchange Commission (the ''Commission'') the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend the Connectivity Fee Schedule (''Fee Schedule'') regarding colocation services and fees to provide Users with wireless connectivity to CME Group market data. The proposed rule change is available on the Exchange's website at *www.nyse.com,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

[1] 15 U.S.C. 78s(b)(1).

[2] 15 U.S.C. 78a.

[3] 17 CFR 240.19b–4.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of those statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant parts of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend the Connectivity Fee Schedule (''Fee Schedule'') regarding colocation services and fees to provide Users[4] with wireless connectivity to CME Group market data.[5]

The Exchange currently provides Users with wireless connections to eight market data feeds or combinations of feeds from third-party markets (the ''Existing Third Party Data''),[6] and wired connections to more than 45 market data feeds or combinations of feeds.[7] The Exchange proposes to add to the Fee Schedule wireless connections to CME Group, Inc. (''CME Group'') market data (''CME Group Data'' and, together with the Existing Third Party Data, the ''Third Party Data''). Users would be offered the proposed wireless connection to the CME Group Data

[4] For purposes of the Exchange's colocation services, a ''User'' means any market participant that requests to receive colocation services directly from the Exchange. *See* Securities Exchange Act Release No. 83351 (May 31, 2018), 83 FR 26314 at n.9 (June 6, 2018) (SR–NYSENAT–2018–07) (''NYSE National Colocation Notice''). As specified in the Fee Schedule, a User that incurs colocation fees for a particular colocation service pursuant thereto would not be subject to colocation fees for the same colocation service charged by the Exchange's affiliates the New York Stock Exchange LLC, NYSE American LLC, NYSE Arca, Inc., and NYSE Chicago, Inc. (together, the ''Affiliate SROs''). Each Affiliate SRO has submitted substantially the same proposed rule change to propose the changes described herein. *See* SR–NYSE–2023–44, SR–NYSEAMER–2023–59, SR–NYSEARCA–2023–79, and SR–NYSECHX–2023–22.

[5] The Exchange filed a similar proposal in 2021, which it subsequently withdrew. *See* Securities Exchange Act Release No. 93810 (December 17, 2021), 86 FR 73026 (December 23, 2021) (SR–NYSE–2021–67, SR–NYSEAMER–2021–43, SR–NYSEARCA–2021–97, SR–NYSECHX–2021–17, SR–NYSENAT–2021–23).

[6] *See* NYSE National Colocation Notice, *supra* note 4, at 26319–20.

[7] *See id.* at 26322–23.

through connections into the colocation center in the Mahwah, New Jersey data center (''MDC'').[8]

The Exchange expects that the proposed rule change would become operative in the fourth quarter of 2023, and in any event, no later than December 31, 2023. The Exchange will announce the date that the wireless connection to the CME Group Data will be available through a customer notice.

To receive CME Group Data, the User would enter into an agreement with a third party for permission to receive the data, if required. The User would pay this third party any fees for the data content.

The Exchange proposes to revise the Fee Schedule to reflect fees related to the wireless connection to CME Group Data. For each wireless connection to CME Group Data, a User would be charged a $5,000 non-recurring initial charge and a monthly recurring charge of $6,000. If a User were to purchase more than one wireless connection to CME Group Data, it would pay more than one non-recurring initial charge. Each proposed wireless connection would include the use of one port for connectivity to CME Group Data, and a User would not pay a separate fee for the use of such port.[9]

The Exchange's proposed wireless connectivity to CME Group market data would not include the entire CME Group market data feed, which includes market data for approximately 1,200 futures symbols. Wireless bandwidth capacity is a small fraction of the capacity required to transport the full CME Group feed. Accordingly, FIDS has consulted with customers about which of the CME Group symbols they would like to be available wirelessly and plans to offer connectivity to a subgroup of symbols based on this customer feedback. The Exchange understands that Quincy Data LLC (''Quincy''),[10] a third party that already provides wireless connectivity to CME Group market data in the MDC, similarly provides wireless connectivity to a subset of CME Group market data based on customer demand for particular symbols.[11]

Application and Impact of the Proposed Changes

The proposed changes would not apply differently to distinct types or sizes of market participants. Rather, they would apply to all Users equally.

As is currently the case, the purchase of any colocation service, including connectivity to Third Party Data, is completely voluntary and the Fee Schedule is applied uniformly to all Users.

Competitive Environment

The Exchange operates in a highly competitive market in which other vendors offer colocation services as a means to facilitate the trading and other market activities of those market participants who believe that colocation enhances the efficiency of their operations. The Commission has repeatedly expressed its preference for competition over regulatory intervention in determining prices, products, and services in the securities markets. Specifically, in Regulation NMS, the Commission highlighted the importance of market forces in determining prices and SRO revenues and, also, recognized that current regulation of the market system ''has been remarkably successful in promoting market competition in its broader forms that are most important to investors and listed companies.'' [12]

As explained below in this filing, the Exchange's proposed wireless connection to CME Group Data would compete with the wireless connection to CME Group market data provided by Quincy. Third-party vendors such as Quincy are not at any competitive disadvantage created by the Exchange.

The proposed change is not otherwise intended to address any other issues relating to colocation services or related fees, and the Exchange is not aware of any problems that Users would have in complying with the proposed change.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with Section 6(b) of the Act,[13] in general, and furthers the objectives of Section 6(b)(5) of the Act,[14] 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. The Exchange further believes that the proposed rule change is consistent with Section 6(b)(4) of the Act,[15] because it provides for the equitable allocation of reasonable dues, fees, and other charges among its members and issuers and other persons using its facilities and does not unfairly discriminate between customers, issuers, brokers, or dealers.

The Proposed Change Is Reasonable

The Exchange believes that the proposed rule change is reasonable. In considering the reasonableness of proposed services and fees, the Commission's market-based test considers ''whether the exchange was subject to significant competitive forces in setting the terms of its proposal . . . , including the level of any fees.'' [16] If the Exchange meets that burden, ''the Commission will find that its proposal is consistent with the Act unless 'there is a substantial countervailing basis to find that the terms' of the proposal violate the Act or the rules thereunder.'' [17] Here, the Exchange is subject to significant competitive forces in setting the terms on which it offers its proposal, in particular because substantially similar substitutes are available, and the Exchange has not placed the third party

[8] Through its Fixed Income and Data Services (''FIDS'') (previously ICE Data Services) business, Intercontinental Exchange, Inc. (''ICE'') operates the MDC. The Exchange and the Affiliate SROs are indirect subsidiaries of ICE. The proposed service would be provided by FIDS pursuant to an agreement with a non-ICE entity. FIDS does not own the wireless network that would be used to provide the service.

[9] If a User also connects to Existing Third Party Data, it would not be able to connect to such Existing Third Party Data using the same port that it uses for connectivity to CME Group Data.

[10] The Exchange understands that Quincy is an affiliate of McKay Brothers LLC.

[11] The Exchange understands that the third parties that provide wireless connectivity to CME Group market data to the MDC and other data centers in New Jersey (as discussed later in this filing) follow a substantially similar model, offering wireless connectivity to a selection of market data rather than to entire feeds.

[12] *See* Securities Exchange Act Release No. 51808 (June 9, 2005), 70 FR 37496, 37499 (June 29, 2005).

[13] 15 U.S.C. 78f(b).

[14] 15 U.S.C. 78f(b)(5).

[15] 15 U.S.C. 78f(b)(4).

[16] *See* Securities Exchange Act Release No. 90209 (October 15, 2020), 85 FR 67044, 67049 (October 21, 2020) (Order Granting Accelerated Approval to Establish a Wireless Fee Schedule Setting Forth Available Wireless Bandwidth Connections and Wireless Market Data Connections) (SR–NYSE–2020–05, SR–NYSEAMER–2020–05, SR–NYSEArca-2020–08, SR–NYSECHX–2020–02, SR–NYSENAT–2020–03, SR–NYSE–2020–11, SR–NYSEAMER–2020–10, SR–NYSEArca-2020–15, SR–NYSECHX–2020–05, SR–NYSENAT–2020–08) (''Wireless Approval Order''), citing Securities Exchange Act Release No. 59039 (December 2, 2008), 73 FR 74770, 74781 (December 9, 2008) (''2008 ArcaBook Approval Order''). *See NetCoalition* v. *SEC,* 615 F.3d 525 (D.C. Cir. 2010).

[17] *See* Wireless Approval Order, *supra* note 16, at 67049, citing 2008 ArcaBook Approval Order, *supra* note 16, at 74781.

vendors at a competitive disadvantage created by the Exchange.

Substantially Similar Substitutes Are Available

The Exchange's proposed wireless connection to CME Group Data would compete with other methods by which both the Exchange and various third parties already provide connectivity to CME Group market data to Users.

Quincy already provides wireless connectivity to CME Group market data in the MDC. Like the Exchange's proposed wireless connectivity, Quincy's wireless connectivity to CME Group market data includes a similarly-sized subset of symbols that almost completely overlaps with the symbols for which the Exchange proposes to provide wireless connectivity—presumably because customers have requested the same symbols of each provider. Specifically, like the Quincy wireless connection, the Exchange's proposed wireless connection would include the main futures for equity indices, government bonds, foreign exchanges, oil, and precious metals.[18] In addition, the Exchange's proposed wireless connection would also include several additional symbols that proposed Users have specifically requested be included. The Exchange plans to continuously monitor Users' preferences and their views of the usefulness of the included symbols, and may adjust them accordingly. The Exchange believes that the Quincy wireless connection to CME Group market data is at a same or similar speed as the Exchange's proposed connection, and at a similar price.[19]

Accordingly, the Quincy wireless connection to CME Group market data would compete with the Exchange's proposed wireless connection, and would exert significant competitive forces on the Exchange in setting the terms of its proposal, including the level of the Exchange's proposed fees.[20] If the Exchange were to set its proposed fees too high, Users could respond by instead selecting Quincy's substantially similar wireless connectivity to CME Group data.[21]

Third Party Competitors Are Not at a Competitive Disadvantage Created by the Exchange

The Exchange does not believe that FIDS would have any competitive advantage over either the existing third-party provider or any future providers of wireless connectivity to CME Group market data. The Exchange's proposed service for connectivity to CME Group Data does not have any special access to or advantage within the MDC. The Exchange's proposed wireless connection would lead to a pole, from which a fiber connection would lead into the MDC. The pole is owned by a third party and is not on the grounds of the MDC, and the path into the MDC through a meet-me-room is available to any telecommunications provider. Within the MDC, the proposed connection would follow the same route as that of any User, connecting to equipment in colocation and then to any Users that are customers.

Further, all distances in the MDC are normalized and Exchange rules require that the distance from the Patch Panel Point to each User cabinet in colocation be the same.[22] Every provider of wireless connectivity to Users, including FIDS, is connected to the Patch Panel Point, and the length of the fiber path from the Patch Panel Point to each User cabinet in colocation is the same.

Nor does the Exchange have a competitive advantage over the third-party competitors offering wireless connectivity to CME Group market data by virtue of the fact that it owns and operates the MDC's meet-me-rooms. Users purchasing wireless connectivity to CME Group market data—like Users of any other colocation service—would require a circuit connecting out of the MDC, and in most cases, such circuits are provided by third-party telecommunications service providers that have installed their equipment in the MDC's two meet-me-rooms (''Telecoms'').[23] Currently, 16 Telecoms operate in the meet-me-rooms and provide a variety of circuit choices. It is in the Exchange's best interest to set the fees that Telecoms pay to operate in the meet-me-rooms at a reasonable level[24] so that market participants, including Telecoms, will maximize their use of the MDC. By setting the meet-me-room fees at a reasonable level, the Exchange encourages Telecoms to participate in the meet-me-rooms and to sell circuits to Users for connecting into and out of the MDC. These Telecoms then compete with each other by pricing such circuits at competitive rates. These competitive rates for circuits help draw in more Users and Hosted Customers to the MDC, which directly benefits the Exchange by increasing the customer base to whom the Exchange can sell its colocation services, which include cabinets, power, ports, and connectivity to many third-party data feeds, and because having more Users and Hosted Customers leads, in many cases, to greater participation on the Exchange. In this way, by setting the meet-me-room fees at a level attractive to telecommunications firms, the Exchange spurs demand for all of the services it sells at the MDC, while setting the meet-me-room fees too high would negatively affect the Exchange's ability to sell its services at the MDC.[25] Accordingly, there are real constraints on the meet-me-room fees the Exchange charges, such that the Exchange does not have an advantage in terms of costs when compared to third parties that enter the MDC through the meet-me-rooms to provide services to compete with the Exchange's services.

If anything, the Exchange is subject to a competitive disadvantage vis-à-vis third-party competitors offering wireless connectivity to CME Group market data. Third-party competitors are not subject to the Commission's filing requirements, and therefore can freely change their services and pricing in response to competitive forces. In contrast, the Exchange's service and pricing would be standardized as set out in this filing, and the Exchange would be unable to respond to pricing pressure from its

[18] Quincy's symbol list for wireless connectivity to CME Group data is available at *https://www.quincy-data.com/product-page/* under the heading ''2023 Quincy Extreme Data Symbol Set/North America QED Symbol Set.'' The Exchange understands that the Quincy wireless connection to CME Group data currently includes 26 symbols. The Exchange's proposed wireless connection to CME Group data would contain a similar number of symbols, nearly all of which are included in the Quincy wireless connection.

[19] Because Quincy is not a regulated entity, it is not obligated to make its latency figures or fees publicly available or the same for all entities.

[20] *See* 2008 ArcaBook Approval Order, *supra* note 16, at 74789 and n.295 (recognizing that products need not be identical to be substitutable).

[21] In addition, the Exchange believes that at least two third-party market participants, in addition to FIDS, offer fiber connections to CME Group market data in colocation. *See* NYSE National Colocation Notice, *supra* note 4, at 26318. Unlike the proposed wireless connectivity, FIDS' fiber connection to CME Group market data includes the entire CME Group data feed, instead of a subset of symbols.

[22] *See* NYSE Rule 3.13(c), NYSE American Rule 3.13E(c), NYSE Arca Rule 3.13(c), NYSE Chicago Rule 3.13(c), and NYSE National Rule 3.13(c) (Data Center Pole Restrictions—Connectivity to Co-Location Space). ''Patch Panel Point'' is defined as ''the patch panel where fiber connections for wireless services connect to the network row in the space used for co-location in the Data Center.'' *Id.* The proposed service would not use the MDC pole, so Rule 3.13(b) would not apply.

[23] Note that in the case of wireless connectivity, a User in colocation still requires a fiber circuit to transport data. If a Telecom is used, the data is transmitted wirelessly to the relevant pole, and then from the pole to the meet-me-room using a fiber circuit.

[24] *See* Securities Exchange Act Release No. 98002 (July 26, 2023), 88 FR 50232 (August 1, 2023) (SR–NYSENAT–2023–12) (''MMR Notice'').

[25] *See id.* at 50235. Importantly, the Exchange is prevented from making any alteration to its meet-me-room services or fees without filing a proposal for such changes with the Commission.

competitors without seeking a formal fee change in a filing before the Commission.

In sum, because the Exchange is subject to significant competitive forces in setting the terms on which it offers its proposal, in particular because a substantially similar substitute is available, and the Exchange has not placed the third-party vendors at a competitive disadvantage created by the Exchange, the proposed fees for the Exchange's wireless connectivity to CME Group Data are reasonable.[26] If the Exchange were to set its prices for wireless connectivity to CME Group Data at a level that Users found to be too high, Users could easily choose to connect to CME Group market data in colocation at the MDC through the competing Quincy wireless connection, as detailed above.

Additional Considerations

The Exchange believes that it is reasonable for the proposed wireless connection to CME Group Data not to transport information for all of the symbols included in CME Group data feeds to the MDC, but rather to transport a subset of that data. Wireless bandwidth capacity is a small fraction of the capacity required to transport the full CME Group feed. The Exchange believes it is reasonable for FIDS to select the symbols it will make available for wireless connectivity based on customer input and demand. The Exchange understands that Quincy similarly provides wireless connectivity to a subset of CME Group market data based on customer demand for particular symbols.

The Exchange believes that it is reasonable that a User that connects to both CME Group Data and Existing Third Party Data may not use the same port for connectivity to both, and so would have at least two ports, because the proposed wireless connection would include the use of one port for connectivity to CME Group Data, and the connectivity to the Existing Third Party Data includes the use of one port for connectivity to Existing Third Party Data. A User would not pay a separate fee for using such ports.

The Proposed Change Is an Equitable Allocation of Fees and Credits

The Exchange believes that its proposal equitably allocates its fees among Users. Without this proposed rule change, Users would have fewer options for connectivity to CME Group market data. The proposed change would provide Users with an additional choice with respect to the form and optimal latency of the connectivity they use to receive CME Group market data, allowing a User to select the connectivity that better suits its needs, helping it tailor its colocation operations to the requirements of its business operations. Users that do not opt to utilize the Exchange's proposed wireless connection would still be able to obtain CME Group market data wirelessly using Quincy's wireless connection.

The Exchange believes that the proposed change is equitable because it will result in fees being charged only to Users that voluntarily select to receive the corresponding services and because those services will be available to all Users. Furthermore, the Exchange believes that the services and fees proposed herein are equitably allocated because, in addition to the services being completely voluntary, they are available to all Users on an equal basis (*i.e.,* the same products and services are available to all Users). All Users that voluntarily select the Exchange's proposed wireless connections to CME Group Data would be charged the same amount for the same services.

The Proposed Change Is Not Unfairly Discriminatory

The Exchange believes that the proposed rule change is not unfairly discriminatory, for the following reasons. Without this proposed rule change, Users would have fewer options for connectivity to CME Group Data. The proposed change would provide Users with an additional choice with respect to the form and optimal latency of the connectivity they use to receive CME Group market data, allowing a User to select the connectivity that better suits its needs, helping it tailor its colocation operations to the requirements of its business operations. Users that do not opt to utilize the Exchange's proposed wireless connection would still be able to obtain CME Group market data wirelessly using Quincy's wireless connection.

The Exchange believes that it is not unfairly discriminatory to not transport information for all of the symbols included in CME Group data feeds to the MDC, but rather to transport a subset of that data. There is limited bandwidth available on the wireless network to colocation, and there are a number of CME Group data feeds. Limiting the feeds to the selection of CME Group market data regarding securities for which FIDS determines there is demand would allow Users to receive the relevant CME Group Data over a wireless network.

The Exchange believes that the proposed change is not unfairly discriminatory because it will result in fees being charged only to Users that voluntarily select to receive the corresponding services and because those services will be available to all Users. Furthermore, the Exchange believes that the services and fees proposed herein are not unfairly discriminatory because, in addition to the services being completely voluntary, they are available to all Users on an equal basis (*i.e.,* the same products and services are available to all Users). All Users that voluntarily select wireless connections to CME Group Data would be charged the same amount for the same services. Users that opt to use wireless connections to CME Group Data would receive the CME Group Data that is available to all Users, as all market participants that contract with CME Group or its affiliate for CME Group Data, as required, may receive it.

For the reasons above, the proposed changes do not unfairly discriminate between or among market participants that are otherwise capable of satisfying any applicable colocation fees, requirements, terms, and conditions established from time to time by the Exchange.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange believes that the proposal will not impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of Section 6(b)(8) of the Act.[27]

The proposed change would not affect competition among national securities exchanges or among members of the Exchange, but rather between FIDS and its commercial competitors. The proposed wireless connection would provide Users with an alternative means of connectivity to CME Group Data. The proposed change would provide Users with an additional choice with respect to the form and optimal latency of the connectivity they use to receive CME Group market data, allowing a User to select the connectivity that better suits its needs, helping it tailor its colocation operations to the requirements of its business operations.

Users that do not opt to utilize the Exchange's proposed wireless connection would still be able to obtain CME Group market data wirelessly using Quincy's wireless connection. The Exchange's proposed wireless connection and the existing Quincy wireless connection to CME Group market data are sufficiently similar

[26] *See* Wireless Approval Order, *supra* note 16.

[27] 15 U.S.C. 78f(b)(8).

substitutes and thus provide market participants with choices to meet their wireless connectivity needs.

In addition, the Exchange does not believe that FIDS would have any competitive advantage over either the existing third-party provider or any future providers of wireless connectivity to CME Group market data. The Exchange's proposed service for connectivity to CME Group Data does not have any special access to or advantage within the MDC. The Exchange's proposed wireless connection would lead to a pole, from which a fiber connection would lead into the MDC. The pole is owned by a third party and is not on the grounds of the MDC, and the path into the MDC through a meet-me-room is the same path followed by any Telecom. Within the MDC, the proposed connection would follow the same route as that of any User, connecting to equipment in colocation and then to any Users that are customers.

Further, all distances in the MDC are normalized and Exchange rules require that the distance from the Patch Panel Point to each User cabinet in colocation be the same.[28] Every provider of wireless connectivity to Users, including FIDS, is connected to the Patch Panel Point, and the length of the fiber path from the Patch Panel Point to each User cabinet in colocation is the same.

Nor does the Exchange have a competitive advantage over the third-party competitors offering wireless connectivity to CME Group market data by virtue of the fact that it owns and operates the MDC's meet-me-rooms. Users purchasing wireless connectivity to CME Group market data—like Users of any other colocation service—would require a circuit connecting out of the MDC, and in most cases, such circuits are provided by third-party Telecoms that have installed their equipment in the MDC's two meet-me-rooms.[29] Currently, 16 Telecoms operate in the meet-me-rooms and provide a variety of circuit choices. It is in the Exchange's best interest to set the fees that Telecoms pay to operate in the meet-me-rooms at a reasonable level[30] so that market participants, including Telecoms, will maximize their use of the MDC. By setting the meet-me-room fees at a reasonable level, the Exchange encourages Telecoms to participate in the meet-me-rooms and to sell circuits to Users for connecting into and out of the MDC. These Telecoms then compete with each other by pricing such circuits at competitive rates. These competitive rates for circuits help draw in more Users and Hosted Customers to the MDC, which directly benefits the Exchange by increasing the customer base to whom the Exchange can sell its colocation services, which include cabinets, power, ports, and connectivity to many third-party data feeds, and because having more Users and Hosted Customers leads, in many cases, to greater participation on the Exchange. In this way, by setting the meet-me-room fees at a level attractive to telecommunications firms, the Exchange spurs demand for all of the services it sells at the MDC, while setting the meet-me-room fees too high would negatively affect the Exchange's ability to sell its services at the MDC.[31] Accordingly, there are real constraints on the meet-me-room fees the Exchange charges, such that the Exchange does not have an advantage in terms of costs when compared to third parties that enter the MDC through the meet-me-rooms to provide services to compete with the Exchange's services.

If anything, the Exchange is subject to a competitive disadvantage vis-à-vis third party competitors offering wireless connectivity to CME Group market data. Third-party competitors are not subject to the Commission's filing requirements, and therefore can freely change their services and pricing in response to competitive forces. In contrast, the Exchange's service and pricing would be standardized as set out in this filing, and the Exchange would be unable to respond to pricing pressure from its competitors without seeking a formal fee change in a filing before the Commission.

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 Exchange has filed the proposed rule change pursuant to Section 19(b)(3)(A)(iii) of the Act[32] and Rule 19b–4(f)(6) thereunder.[33] Because the 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 prior to 30 days from the date on which it was filed, or such shorter time as the Commission may designate, if consistent with the protection of investors and the public interest, the proposed rule change has become effective pursuant to Section 19(b)(3)(A) of the Act and Rule 19b–4(f)(6)(iii) thereunder.

A proposed rule change filed under Rule 19b–4(f)(6)[34] normally does not become operative prior to 30 days after the date of the filing. However, pursuant to Rule 19b–4(f)(6)(iii),[35] the Commission may designate a shorter time if such action is consistent with the protection of investors and the public interest.

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)[36] of the Act to determine whether the proposed rule change should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*https://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include file number SR–NYSENAT–2023–26 on the subject line.

Paper Comments

- Send paper comments in triplicate to: Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to file number SR–NYSENAT–2023–26. 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

[28] *See supra* note 22.

[29] *See supra* note 23.

[30] *See* MMR Notice, *supra* note 24.

[31] *See supra* note 25.

[32] 15 U.S.C. 78s(b)(3)(A)(iii).

[33] 17 CFR 240.19b–4(f)(6).

[34] 17 CFR 240.19b–4(f)(6).

[35] 17 CFR 240.19b–4(f)(6)(iii).

[36] 15 U.S.C. 78s(b)(2)(B).

internet website (*https://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 a.m. and 3 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. Do not include personal identifiable information in submissions; you should submit only information that you wish to make available publicly. We may redact in part or withhold entirely from publication submitted material that is obscene or subject to copyright protection. All submissions should refer to file number SR–NYSENAT–2023–26 and should be submitted on or before December 13, 2023.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[37]

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2023–25773 Filed 11–21–23; 8:45 am]

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SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–98972; File No. SR–CboeEDGX–2023–069]

Self-Regulatory Organizations; Cboe EDGX Exchange, Inc.; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Amend its Rules To Adopt Monthly Options Series

November 16, 2023.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on November 15, 2023, Cboe EDGX Exchange, Inc. (''EDGX Options'' or ''Exchange'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I and II below, which Items have been prepared by the Exchange. The 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 EDGX Exchange, Inc. (the ''Exchange'' or ''EDGX Options'') proposes to amend its Rules to adopt Monthly Options Series. The text of the proposed rule change is provided in Exhibit 5.

The text of the proposed rule change is also available on the Exchange's website (*http://markets.cboe.com/us/options/regulation/rule_filings/edgx/*), at the Exchange's Office of the Secretary, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend its Rules to accommodate the listing of option series that would expire at the close of business on the last business day of a calendar month (''Monthly Options Series''). Pursuant to proposed Rules 19.6, Interpretation and Policy .08(a) and 29.11(k)(1),[5] the Exchange may list Monthly Options Series for up to five currently listed option classes that are either index options or options on exchange-traded funds (''ETFs'').[6] In addition, the Exchange may also list Monthly Options Series on any options classes that are selected by other securities exchanges that employ a similar program under their respective rules.[7] The Exchange may list 12 expirations for Monthly Options Series. Monthly Options Series need not be for consecutive months; however, the expiration date of a nonconsecutive expiration may not be beyond what would be considered the last expiration date if the maximum number of expirations were listed consecutively.[8] Other expirations in the same class are not counted as part of the maximum

[37] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] 15 U.S.C. 78s(b)(3)(A)(iii).

[4] 17 CFR 240.19b–4(f)(6).

[5] The proposed rule change defines the term ''Monthly Options series'' in Rule 29.2(l) (and reletters current paragraphs (l) through (p) to be (m) through (q)) as a series in an options class that is approved for listing and trading on the Exchange in which the series is opened for trading on any business day and that expires at the close of business on the last business day of a calendar month.

[6] The Exchange proposes to amend Rule 19.6(a) and (b) to provide that proposed Rule 19.6, Interpretation and Policy .08 will describe how the Exchange will fix a specific expiration date and exercise price for Monthly Options Series and will govern the procedures for opening Monthly Options Series, respectively. The proposed change to Rule 19.6(a) is consistent with language in current Rule 19.6(a) for other Short Term Option Series and Quarterly Options Series. The proposed rule change also makes a nonsubstantive correction to pluralize the term ''policy'' (to become ''policies'') to be consistent with the terminology in the Rules. Additionally, the proposed rule change adds to Rule 19.6(b) that Interpretation and Policies .04 and .05 will govern the procedures for opening Quarterly Options Series and Short Term Option Series, respectively (as well as adding exception language to the beginning of that paragraph). This is merely a clarification, as Rule 19.6, Interpretations and Policies .04 and .05 clearly govern the opening procedures for those options listing programs. This proposed change is also consistent with Cboe Exchange, Inc. (''Cboe Options'') Rule 4.5(b), which has similar options listing programs.

[7] The Securities and Exchange Commission (the ''Commission'') recently approved a Cboe Options proposed rule change to adopt a substantively identical Monthly Options Series program. *See* Securities Exchange Act Release No. 98915 (November 13, 2023) (SR–CBOE–2023–049) (''Cboe Options Approval Order'').

[8] The Exchange notes this provision considers consecutive monthly listings. In other words, as other expirations (such as Quarterly Options Series) are not counted as part of the maximum, those expirations would not be considered when considering when the last expiration date would be if the maximum number were listed consecutively. For example, if it is January 2024 and the Exchange lists Quarterly Options Series in class ABC with expirations in March, June, September, December, and the following March, the Exchange could also list Monthly Options Series in class ABC with expirations in January, February, April, May, July, August, October, and November 2024 and January and February of 2025. This is because, if Quarterly Options Series, for example, were counted, the Exchange would otherwise never be able to list the maximum number of Monthly Options Series. This is consistent with the listing provisions for Quarterly Options Series, which permit calendar quarter expirations. The need to list series with the same expiration in the current calendar year and the following calendar year (whether Monthly or Quarterly expiration) is to allow market participants to execute one-year strategies pursuant to which they may roll their exposures in the longer-dated options (*e.g.* January 2025) prior to the expiration of the nearer-dated option (*e.g.* January 2024).

numbers of Monthly Options Series expirations for a class.[9] Monthly Options Series will be P.M.-settled.[10]

The strike price of each Monthly Options Series will be fixed at a price per share, with at least two, but no more than five, strike prices above and at least two, but no more than five, strike prices below the value of the underlying index or price of the underlying security at about the time that a Monthly Options Series is opened for trading on the Exchange. The Exchange will list strike prices for Monthly Options Series that are reasonably related to the current price of the underlying security or current index value of the underlying index to which such series relates at about the time such series of options is first opened for trading on the Exchange. The term ''reasonably related to the current price of the underlying security or index value of the underlying index'' means that the exercise price is within 30% of the current underlying security price or index value.[11] Additional Monthly Options Series of the same class may be open for trading on the Exchange when the Exchange deems it necessary to maintain an orderly market, to meet customer demand, or when the market price of the underlying security moves substantially from the initial exercise price or prices. To the extent that any additional strike prices are listed by the Exchange, such additional strike prices will be within 30% above or below the closing price of the underlying index or security on the preceding day. The Exchange may also open additional strike prices of Monthly Options Series that are more than 30% above or below the current price of the underlying security, provided that demonstrated customer interest exists for such series, as expressed by institutional, corporate, or individual customers or their brokers. Market-Makers trading for their own account will not be considered when determining customer interest under this provision. The opening of the new Monthly Options Series will not affect the series of options of the same class previously opened.[12] The interval between strike prices on Monthly Options Series will be the same as the interval for strike prices for series in that same options class that expire in accordance with the normal monthly expiration cycle.[13]

By definition, Monthly Options Series can never expire in the same week as a standard expiration series (which expire on the third Friday of a month) in the same class expires. The same, however, is not the case with regards to Short Term Option Series [14] or Quarterly Options Series. Therefore, to avoid any confusion in the marketplace, the Exchange proposes to amend Rules 19.6, Interpretation and Policy .05 (introductory paragraph), (b), and (h) and 22.11(h) (introductory paragraph) and (2) to provide the Exchange will not list a Short Term Option Series in a class on a date on which a Monthly Options Series or Quarterly Options Series expires.[15] Similarly, proposed Rules 19.6, Interpretation and Policy .08(b) and 22.11(k)(2) provide that no Monthly Options Series may expire on a date that coincides with an expiration date of a Quarterly Options Series in the same index or ETF class. In other words, the Exchange will not list a Short Term Option Series on an index or ETF if a Monthly Options Series on that index or ETF were to expire on the same date, nor will the Exchange list a Monthly Options Series on an ETF or index if a Quarterly Options Series on that index or ETF were to expire on the same date to prevent the listing of series with concurrent expirations.[16]

With respect to Monthly Options Series added pursuant to proposed Rules 19.6, Interpretation and Policy .08(a) through (f) and 22.11(k)(1) through (6), the Exchange will, on a monthly basis, review series that are outside a range of five strikes above and five strikes below the current price of the underlying index or security, and delist series with no open interest in both the put and the call series having a: (i) strike higher than the highest strike price with open interest in the put and/or call series for a given expiration month; and (ii) strike lower than the lowest strike price with open interest in the put and/or call series for a given expiration month. Notwithstanding this delisting policy, customer requests to add strikes and/or maintain strikes in Monthly Options Series in series eligible for delisting will be granted. In connection with this delisting policy, if the Exchange identifies series for delisting, the Exchange will notify other options exchanges with similar delisting policies regarding eligible series for delisting and will work with such other exchanges to develop a uniform list of series to be delisted, so as to ensure uniform series delisting of multiply listed Monthly Options Series.[17]

The Exchange believes that Monthly Options Series will provide investors with another flexible and valuable tool to manage risk exposure, minimize capital outlays, and be more responsive to the timing of events affecting the securities that underlie option contracts. The Exchange believes limiting Monthly Options Series to five classes will ensure the addition of these new series will have a negligible impact on the Exchange's and the Options Price Reporting Authority's (''OPRA's'') quoting capacity. The Exchange represents it has the necessary systems capacity to support new options series

[9] *See* proposed Rules 19.6, Interpretation and Policy .08(b) and 29.11(k)(2).

[10] *See* proposed Rules 19.6, Interpretation and Policy .08(c) and 29.11(k)(3).

[11] *See* proposed Rules 19.6, Interpretation and Policy .08(d) and 29.11(k)(4). The Exchange notes these proposed provisions are consistent with the initial series provision for the Quarterly Options Series program in Rule 29.11(g)(3). While different than the initial strike listing provision for the Quarterly Options Series program in current Rule 19.6, Interpretation and Policy .04(b), the Exchange believes the proposed provision is appropriate, as it contemplates classes that may have strike intervals of $5 or greater. For consistency, the Exchange also proposes to amend Rule 19.6, Interpretation and Policy .04(b) to incorporate the same provision for initial series.

[12] *See* proposed Rules 19.6, Interpretation and Policy .08(e) and 29.11(k)(5).

[13] *See* proposed Rules 19.6, Interpretation and Policy .08(f) and 29.11(k)(6); *see also* Rule 19.6(d), (f), (g) and Interpretations and Policies .01–.03 and .06 (permissible strike prices for ETF classes) and Rule 29.11(c) (permissible strike prices for index options).

[14] The proposed rule change clarifies in Rule 29.11(a)(3) that index options have expiration months and weeks, which expirations may occur in consecutive weeks as specified in Rule 29.11(h). This is merely a clarification, as Rule 29.11(h) currently permits weekly expirations. This language is consistent with Cboe Options Rule 4.13(a)(2). Additionally, the proposed rule change adds to rule 29.11(a)(3) that index options may expire more than 12 months out as specified elsewhere in the Rule. This is consistent with current Rule 29.11(b), which permits long term index options to expire between 12 and 180 months after issuance, as well as proposed Rule 29.11(k)(2), as discussed above.

[15] The Exchange also proposes to make a nonsubstantive change to Rules 19.6, Interpretation and Policy .05 and 22.11(h) to change current references to ''monthly options series'' to ''standard expiration options series'' (*i.e.,* series that expire on the third Friday of a month), to eliminate potential confusion. The current references to ''monthly options series'' are intended to refer to those series that expire on the third Friday of a month, which are generally referred to in the industry as standard expirations. The proposed rule change also adds a heading to Rule 19.6, Interpretation and Policy .05 for consistency with other Interpretations and Policies in that Rule.

[16] The Exchange notes this would not prevent the Exchange from listing a P.M.-settled Monthly Options Series on an index with the same expiration date as an A.M.-settled Short Term Option Series on the same index, both of which may expire on a Friday. In other words, the Exchange may list a P.M-settled Monthly Options Series on an index concurrent with an A.M.-settled Short Term Option Series on that index and both of which expire on a Friday. The Exchange believes this concurrent listing would provide investors with yet another hedging mechanism and is reasonable given these series would not be identical (unlike if they were both P.M-settled). This could not occur with respect to ETFs, as all Short Term Option Series on ETFs are P.M.-settled.

[17] *See* proposed Rules 19.6, Interpretation and Policy .08(g) and 22.11(k)(7).

that will result from the introduction of Monthly Options Series.

The Exchange notes that Rules 18.7 and 29.5 through 29.7 regarding position limits will apply to Monthly Options Series. These Rules provide that the position limits fixed by Cboe Options apply to options contracts traded on EDGX Options, which would include Monthly Options Series. As noted above, Cboe Options recently received Commission approval to adopt a substantively identical Monthly Options Series Program as the one proposed in this rule filing.[18] Pursuant to those recently approved Cboe Options rules, Monthly Options Series will be aggregated with positions in options contracts on the same underlying security or index.[19] This is consistent with how position (and exercise) limits are currently imposed on series with other expirations (Short Term Option Series and Quarterly Options Series). Therefore, positions in options within class of index or ETF options, regardless of their expirations, would continue to be subject to existing position (and exercise) limits. The Exchange believes this will address potential manipulative schemes and adverse market impacts surrounding the use of options.

The Exchange also represents its current surveillance programs will apply to Monthly Options Series and will properly monitor trading in the proposed Monthly Options Series. The Exchange currently lists Quarterly Options Series in certain ETF classes, which expire at the close of business at the end of four calendar months (*i.e.,* the end of each calendar quarter), and has not experienced any market disruptions nor issues with capacity. The Exchange's surveillance programs currently in place to support and properly monitor trading in these Quarterly Options Series, as well as Short Term Option Series and standard expiration series, will apply to the proposed Monthly Options Series. The Exchange believes its surveillances continue to be designed to deter and detect violations of its Rules, including position and exercise limits and possible manipulative behavior, and these surveillances will apply to Monthly Options Series that the Exchange determines to list for trading. Ultimately, the Exchange does not believe the proposed rule change raises any unique regulatory concerns because existing safeguards—such as position and exercise limits (and the aggregation of options overlying the same index or ETF) and reporting requirements—would continue to apply.

2. Statutory Basis

The Exchange believes the proposed rule change is consistent with the Securities Exchange Act of 1934 (the ''Act'') and the rules and regulations thereunder applicable to the Exchange and, in particular, the requirements of Section 6(b) of the Act.[20] Specifically, the Exchange believes the proposed rule change is consistent with the Section 6(b)(5) [21] requirements that the rules of an exchange be 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. Additionally, the Exchange believes the proposed rule change is consistent with the Section 6(b)(5) [22] requirement that the rules of an exchange not be designed to permit unfair discrimination between customers, issuers, brokers, or dealers.

In particular, the Exchange believes the introduction of Monthly Options Series will remove impediments to and perfect the mechanism of a free and open market and a national market system by expanding hedging tools available to market participants. The Exchange believes the proposed monthly expirations will allow market participants to transact in the index and ETF options listed pursuant to the proposed rule change based on their timing as needed and allow them to tailor their investment and hedging needs more effectively. Further, the Exchange believes the availability of Monthly Options Series would protect investors and the public interest by providing investors with more flexibility to closely tailor their investment and hedging decisions in these options, thus allowing them to better manage their risk exposure.

The Exchange believes the Quarterly Options Series Program has been successful to date and the proposed Monthly Options Series program simply expands the ability of investors to hedge risk against market movements stemming from economic releases or market events that occur at months' ends in the same way the Quarterly Options Series Program has expanded the landscape of hedging for quarter-end news. Monthly Options Series will also complement Short Term Option Series, which allow investors to hedge risk against events that occur throughout a month. The Exchange believes the availability of additional expirations should create greater trading and hedging opportunities for investors, as well as provide investors with the ability to tailor their investment objectives more effectively.

The Exchange notes the proposed terms of Monthly Options Series, including the limitation to five index and ETF option classes, are substantively the same as the current terms of Quarterly Options Series.[23] Quarterly Options Series expire on the last business day of a calendar quarter, which is the last business day of every third month. The proposed Monthly Options Series would fill the gaps between Quarterly Options Series expirations by permitting series to expire on the last business day of every month, rather than every third month. The proposed Monthly Options Series may be listed in accordance with the same terms as Quarterly Options Series, including permissible strikes.[24] As is the case with Quarterly Options Series, no Short Term Option Series may expire on the same day as a Monthly Options Series. Similarly, as proposed, no Monthly Options Series may expire on the same day as a Quarterly Options Series. The Exchange believes preventing listing series with concurrent expirations in a class will eliminate potential investors confusion and thus protect investors and the public interest. Given that Quarterly Options Series the Exchange currently lists are essentially Monthly Options Series that can expire at the end of only certain calendar

[18] *See* Cboe Options Approval Order.

[19] *See id.; see also* Cboe Options Rules 8.30, Interpretation and Policy .09 (regarding position limits for options on stocks and ETFs), 8.31(e) (regarding position limits for broad-based index options), 8.32(f) (regarding position limits for industry index options), 8.33(c) (regarding position limits for micro narrow-based indexes), and 8.34(c) (regarding position limits for individual stock or ETF based volatility index options). Pursuant to Cboe Options Rule 8.42 (and Exchange Rules 18.9 and 29.9), exercise limits for impacted index and ETF classes would be equal to the applicable position limits.

[20] 15 U.S.C. 78f(b).

[21] 15 U.S.C. 78f(b)(5).

[22] *Id.*

[23] *Compare* proposed Rules 19.6, Interpretation and Policy .08 and 29.11(k) *to* Rules 19.6, Interpretation and Policy .04 and 29.11(g), respectively.

[24] The Exchange notes the proposed maximum number of expirations is consistent with the maximum number of expirations permitted for end-of-month series in index classes. *See* Rule 29.11(j)(2) (which references Rule 29.11(a)(3), which permits up to 12 standard monthly expirations on the majority of index options currently listed on the Exchange).

months, the Exchange believes it is reasonable to list Monthly Options Series in accordance with the same terms, as it will promote just and equitable principles of trade. The Exchange believes limiting Monthly Options Series to five classes will ensure the addition of these new series will have a negligible impact on the Exchange's and OPRA's quoting capacity. The Exchange represents it has the necessary systems capacity to support new options series that will result from the introduction of Monthly Options Series.

The Exchange further believes the proposed rule change regarding the treatment of Monthly Options Series with respect to determining compliance with position and exercise limits is designed to prevent fraudulent and manipulative acts and practices and promote just and equitable principles of trade. Monthly Options Series will be aggregated with options overlying the same ETF or index for purposes of compliance with position (and exercise) limits, which is consistent with how position (and exercise) limits are currently imposed on series with other expirations (Short Term Option Series, Quarterly Options Series, and Delayed Start Options Series).[25] Therefore, options positions within ETF or index option classes for which Monthly Options Series are listed, regardless of their expirations, would continue to be subject to existing position (and exercise) limits. The Exchange believes this will address potential manipulative schemes and adverse market impacts surrounding the use of options. The Exchange also represents its current surveillance programs will apply to Monthly Options Series and will properly monitor trading in the proposed Monthly Options Series. The Exchange currently trades Quarterly Options Series in certain index and ETF classes, which expire at the close of business at the end of four calendar months (*i.e.,* the end of each calendar quarter), and has not experienced any market disruptions nor issues with capacity. The Exchange's surveillance programs currently in place to support and properly monitor trading in these Quarterly Options Series, as well as Short Term Option Series and standard expiration series, will apply to the proposed Monthly Options Series. The Exchange believes its surveillances continue to be designed to deter and detect violations of its Rules, including position and exercise limits and possible manipulative behavior, and these surveillances will apply to Monthly Options Series that the Exchange determines to list for trading. Ultimately, the Exchange does not believe the proposed rule change raises any unique regulatory concerns because existing safeguards—such as position and exercise limits (and the aggregation of options overlying the same ETF or index) and reporting requirements—would continue to apply.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. The Exchange does not believe the proposed rule change to list Monthly Options Series will impose any burden on intramarket competition that is not necessary or appropriate in furtherance of the purposes of the Act, as any Monthly Options Series the Exchange lists for trading will be available in the same manner for all market participants who wish to trade such options. The Exchange notes the proposed terms of Monthly Options Series, including the limitation to five index and ETF option classes, are substantively the same as the current terms of Quarterly Options Series.[26] Quarterly Options Series expire on the last business day of a calendar quarter, which is the last business day of every third month, making the concept of Monthly Options Series in a limited number of index and ETF options not novel. The proposed Monthly Options Series will fill the gaps between Quarterly Options Series expirations by permitting series to expire on the last business day of every month, rather than every third month. The proposed Monthly Options Series may be listed in accordance with the same terms as Quarterly Options Series, including permissible strikes.[27] Monthly Options Series will trade on the Exchange in the same manner as other options in the same class.

The Exchange does not believe the proposed rule change to list Monthly Options Series will impose any burden on intermarket competition that is not necessary or appropriate in furtherance of the purposes of the Act, as nothing prevents other options exchanges from proposing similar rules.[28] As discussed above, the proposed rule change would permit listing of Monthly Options Series in five index or ETF options, as well as any other classes that other exchanges may list under similar programs. To the extent that the availability of Monthly Options Series makes the Exchange a more attractive marketplace to market participants at other exchanges, market participants are free to elect to become market participants on the Exchange.

The Exchange believes that the proposed rule change may relieve any burden on, or otherwise promote, competition. Similar to Short Term Option Series and Quarterly Options Series, the Exchange believes the introduction of Monthly Options Series will not impose an undue burden on competition. The Exchange believes that it will, among other things, expand hedging tools available to market participants. The Exchange believes Monthly Options Series will allow market participants to purchase options based on their timing as needed and allow them to tailor their investment and hedging needs more effectively.

The Exchange does not believe the proposed rule change regarding aggregation of positions for purposes of determining compliance with position (and exercise) limits will impose any burden on intramarket competition that is not necessary or appropriate in furtherance of the purposes of the Act, because it will apply in the same manner to all market participants. The Exchange proposes to apply position (and exercise) limits to Monthly Options Series in the same manner it applies position limits to series with other expirations (Short Term Option Series and Quarterly Options Series). Therefore, positions in options in a class of ETF or index options, regardless of their expirations, would continue to be subject to existing position (and exercise) limits. Additionally, the Exchange does not believe this proposed rule change will impose any burden on intermarket competition that is not necessary or appropriate in furtherance

[25] *See* Cboe Options Approval Order; *see also* Cboe Options Rules 8.30, Interpretation and Policy .09 (regarding position limits for options on stocks and ETFs), 8.31(e) (regarding position limits for broad-based index options), 8.32(f) (regarding position limits for industry index options), 8.33(c) (regarding position limits for micro narrow-based indexes), and 8.34(c) (regarding position limits for individual stock or ETF based volatility index options). Pursuant to Cboe Options Rule 8.42 (and Exchange Rules 18.9 and 29.9), exercise limits for impacted index and ETF classes would be equal to the applicable position limits.

[26] *See* Rules 19.6, Interpretation and Policy .04 and 29.11(g).

[27] The Exchange notes the proposed maximum number of expirations is consistent with the maximum number of expirations permitted for end-of-month series in index classes. *See* Rule 29.11(j)(2) (which references Rule 29.11(a)(3), which permits up to 12 standard monthly expirations on the majority of index options currently listed on the Exchange).

[28] As noted above, at least one other options exchange recently adopted a substantively identical Monthly Options Series program. *See* Cboe Options Approval Order.

of the purposes of the Act, because it will address potential manipulative schemes and adverse market impacts surrounding the use of options.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

The Exchange neither solicited nor received comments on the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The Exchange has filed the proposed rule change pursuant to Section 19(b)(3)(A)(iii) of the Act [29] and Rule 19b–4(f)(6) thereunder.[30] Because the foregoing proposed rule change does not: (i) significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative for 30 days from the date on which it was filed, or such shorter time as the Commission may designate, it has become effective pursuant to Section 19(b)(3)(A)(iii) of the Act [31] and subparagraph (f)(6) of Rule 19b–4 thereunder.[32]

A proposed rule change filed pursuant to Rule 19b–4(f)(6) under the Act [33] normally does not become operative for 30 days after the date of its filing. However, Rule 19b–4(f)(6)(iii) [34] permits the Commission to designate a shorter time if such action is consistent with the protection of investors and the public interest. The Exchange has requested that the Commission waive the 30-day operative delay so that the Exchange may list Monthly Options Series at the same time as Cboe Options, which the Exchange believes will benefit investors by promoting competition in Monthly Options Series. The Commission believes that the proposed rule change presents no novel issues and that waiver of the 30-day operative delay is consistent with the protection of investors and the public interest. Accordingly, the Commission hereby waives the operative delay and designates the proposed rule change operative upon filing.[35]

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 (*https://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include file number SR–CboeEDGX–2023–069 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to file number SR-CboeEDGX–2023–069. 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 (*https://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 a.m. and 3 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. Do not include personal identifiable information in submissions; you should submit only information that you wish to make available publicly. We may redact in part or withhold entirely from publication submitted material that is obscene or subject to copyright protection. All submissions should refer to file number SR–CboeEDGX–2023–069 and should be submitted on or before December 13, 2023.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[36]

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2023–25778 Filed 11–21–23; 8:45 am]

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[29] 15 U.S.C. 78s(b)(3)(A)(iii).

[30] 17 CFR 240.19b–4(f)(6).

[31] 15 U.S.C. 78s(b)(3)(A)(iii).

[32] 17 CFR 240.19b–4(f)(6). In addition, Rule 19b–4(f)(6)(iii) requires a self-regulatory organization to give the Commission written notice of its intent to file the proposed rule change, along with a brief description and text of the proposed rule change, at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.

[33] 17 CFR 240.19b–4(f)(6).

[34] 17 CFR 240.19b–4(f)(6)(iii).

[35] For purposes only of waiving the 30-day operative delay, the Commission has also considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

[36] 17 CFR 200.30–3(a)(12), (59).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–98962; File No. SR–NYSE–2023–44]

Self-Regulatory Organizations; New York Stock Exchange LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend the Connectivity Fee Schedule

November 16, 2023.

Pursuant to Section 19(b)(1) [1] of the Securities Exchange Act of 1934 (''Act'') [2] and Rule 19b–4 thereunder,[3] notice is hereby given that on November 9, 2023, 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 the Connectivity Fee Schedule (''Fee Schedule'') regarding colocation services and fees to provide Users with wireless connectivity to CME Group market data. The proposed rule change is available on the Exchange's website at

[1] 15 U.S.C. 78s(b)(1).

[2] 15 U.S.C. 78a.

[3] 17 CFR 240.19b–4.

www.nyse.com, at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of those statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant parts of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend the Connectivity Fee Schedule (''Fee Schedule'') regarding colocation services and fees to provide Users [4] with wireless connectivity to CME Group market data.[5]

The Exchange currently provides Users with wireless connections to eight market data feeds or combinations of feeds from third-party markets (the ''Existing Third Party Data''),[6] and wired connections to more than 45 market data feeds or combinations of feeds.[7] The Exchange proposes to add to the Fee Schedule wireless connections to CME Group, Inc. (''CME Group'') market data (''CME Group Data'' and, together with the Existing Third Party Data, the ''Third Party Data''). Users would be offered the proposed wireless connection to the CME Group Data through connections into the colocation center in the Mahwah, New Jersey data center (''MDC'').[8]

The Exchange expects that the proposed rule change would become operative in the fourth quarter of 2023, and in any event, no later than December 31, 2023. The Exchange will announce the date that the wireless connection to the CME Group Data will be available through a customer notice.

To receive CME Group Data, the User would enter into an agreement with a third party for permission to receive the data, if required. The User would pay this third party any fees for the data content.

The Exchange proposes to revise the Fee Schedule to reflect fees related to the wireless connection to CME Group Data. For each wireless connection to CME Group Data, a User would be charged a $5,000 non-recurring initial charge and a monthly recurring charge of $6,000. If a User were to purchase more than one wireless connection to CME Group Data, it would pay more than one non-recurring initial charge. Each proposed wireless connection would include the use of one port for connectivity to CME Group Data, and a User would not pay a separate fee for the use of such port.[9]

The Exchange's proposed wireless connectivity to CME Group market data would not include the entire CME Group market data feed, which includes market data for approximately 1,200 futures symbols. Wireless bandwidth capacity is a small fraction of the capacity required to transport the full CME Group feed. Accordingly, FIDS has consulted with customers about which of the CME Group symbols they would like to be available wirelessly and plans to offer connectivity to a subgroup of symbols based on this customer feedback. The Exchange understands that Quincy Data LLC (''Quincy''),[10] a third party that already provides wireless connectivity to CME Group market data in the MDC, similarly provides wireless connectivity to a subset of CME Group market data based on customer demand for particular symbols.[11]

Application and Impact of the Proposed Changes

The proposed changes would not apply differently to distinct types or sizes of market participants. Rather, they would apply to all Users equally.

As is currently the case, the purchase of any colocation service, including connectivity to Third Party Data, is completely voluntary and the Fee Schedule is applied uniformly to all Users.

Competitive Environment

The Exchange operates in a highly competitive market in which other vendors offer colocation services as a means to facilitate the trading and other market activities of those market participants who believe that colocation enhances the efficiency of their operations. The Commission has repeatedly expressed its preference for competition over regulatory intervention in determining prices, products, and services in the securities markets. Specifically, in Regulation NMS, the Commission highlighted the importance of market forces in determining prices and SRO revenues and, also, recognized that current regulation of the market system ''has been remarkably successful in promoting market competition in its broader forms that are most important to investors and listed companies.'' [12]

As explained below in this filing, the Exchange's proposed wireless connection to CME Group Data would compete with the wireless connection to CME Group market data provided by Quincy. Third-party vendors such as Quincy are not at any competitive disadvantage created by the Exchange.

The proposed change is not otherwise intended to address any other issues relating to colocation services or related fees, and the Exchange is not aware of any problems that Users would have in complying with the proposed change.

[4] For purposes of the Exchange's colocation services, a ''User'' means any market participant that requests to receive colocation services directly from the Exchange. *See* Securities Exchange Act Release No. 76008 (September 29, 2015), 80 FR 60190 (October 5, 2015) (SR–NYSE–2015–40). As specified in the Fee Schedule, a User that incurs colocation fees for a particular colocation service pursuant thereto would not be subject to colocation fees for the same colocation service charged by the Exchange's affiliates NYSE American LLC, NYSE Arca, Inc., NYSE Chicago, Inc., and NYSE National, Inc. (together, the ''Affiliate SROs''). Each Affiliate SRO has submitted substantially the same proposed rule change to propose the changes described herein. *See* SR–NYSEAMER–2023–59, SR–NYSEARCA–2023–79, SR–NYSECHX–2023–22, and SR–NYSENAT–2023–26.

[5] The Exchange filed a similar proposal in 2021, which it subsequently withdrew. *See* Securities Exchange Act Release No. 93810 (December 17, 2021), 86 FR 73026 (December 23, 2021) (SR–NYSE–2021–67, SR–NYSEAMER–2021–43, SR–NYSEARCA–2021–97, SR–NYSECHX–2021–17, SR–NYSENAT–2021–23).

[6] *See* Securities Exchange Act Release Nos. 76748 (December 23, 2015), 80 FR 81609 (December 30, 2015) (SR–NYSE–2015–52); 78378 (July 21, 2016), 81 FR 49315 (July 27, 2016) (SR–NYSE–2016–49); and 80215 (February 28, 2017), 82 FR 12658 (March 6, 2017) (SR–NYSE–2017–05).

[7] *See* Securities Exchange Act Release No. 80311 (March 24, 2017), 82 FR 15741 (March 30, 2017) (SR–NYSE–2016–45).

[8] Through its Fixed Income and Data Services (''FIDS'') (previously ICE Data Services) business, Intercontinental Exchange, Inc. (''ICE'') operates the MDC. The Exchange and the Affiliate SROs are indirect subsidiaries of ICE. The proposed service would be provided by FIDS pursuant to an agreement with a non-ICE entity. FIDS does not own the wireless network that would be used to provide the service.

[9] If a User also connects to Existing Third Party Data, it would not be able to connect to such Existing Third Party Data using the same port that it uses for connectivity to CME Group Data.

[10] The Exchange understands that Quincy is an affiliate of McKay Brothers LLC.

[11] The Exchange understands that the third parties that provide wireless connectivity to CME Group market data to the MDC and other data centers in New Jersey (as discussed later in this filing) follow a substantially similar model, offering wireless connectivity to a selection of market data rather than to entire feeds.

[12] *See* Securities Exchange Act Release No. 51808 (June 9, 2005), 70 FR 37496, 37499 (June 29, 2005).

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with Section 6(b) of the Act,[13] in general, and furthers the objectives of Section 6(b)(5) of the Act,[14] 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. The Exchange further believes that the proposed rule change is consistent with Section 6(b)(4) of the Act,[15] because it provides for the equitable allocation of reasonable dues, fees, and other charges among its members and issuers and other persons using its facilities and does not unfairly discriminate between customers, issuers, brokers, or dealers.

The Proposed Change Is Reasonable

The Exchange believes that the proposed rule change is reasonable. In considering the reasonableness of proposed services and fees, the Commission's market-based test considers ''whether the exchange was subject to significant competitive forces in setting the terms of its proposal . . . , including the level of any fees.'' [16] If the Exchange meets that burden, ''the Commission will find that its proposal is consistent with the Act unless 'there is a substantial countervailing basis to find that the terms' of the proposal violate the Act or the rules thereunder.'' [17] Here, the Exchange is subject to significant competitive forces in setting the terms on which it offers its proposal, in particular because substantially similar substitutes are available, and the Exchange has not placed the third party vendors at a competitive disadvantage created by the Exchange.

Substantially Similar Substitutes Are Available

The Exchange's proposed wireless connection to CME Group Data would compete with other methods by which both the Exchange and various third parties already provide connectivity to CME Group market data to Users.

Quincy already provides wireless connectivity to CME Group market data in the MDC. Like the Exchange's proposed wireless connectivity, Quincy's wireless connectivity to CME Group market data includes a similarly-sized subset of symbols that almost completely overlaps with the symbols for which the Exchange proposes to provide wireless connectivity—presumably because customers have requested the same symbols of each provider. Specifically, like the Quincy wireless connection, the Exchange's proposed wireless connection would include the main futures for equity indices, government bonds, foreign exchanges, oil, and precious metals.[18] In addition, the Exchange's proposed wireless connection would also include several additional symbols that proposed Users have specifically requested be included. The Exchange plans to continuously monitor Users' preferences and their views of the usefulness of the included symbols, and may adjust them accordingly. The Exchange believes that the Quincy wireless connection to CME Group market data is at a same or similar speed as the Exchange's proposed connection, and at a similar price.[19]

Accordingly, the Quincy wireless connection to CME Group market data would compete with the Exchange's proposed wireless connection, and would exert significant competitive forces on the Exchange in setting the terms of its proposal, including the level of the Exchange's proposed fees.[20] If the Exchange were to set its proposed fees too high, Users could respond by instead selecting Quincy's substantially similar wireless connectivity to CME Group data.[21]

Third Party Competitors Are Not at a Competitive Disadvantage Created by the Exchange

The Exchange does not believe that FIDS would have any competitive advantage over either the existing third-party provider or any future providers of wireless connectivity to CME Group market data. The Exchange's proposed service for connectivity to CME Group Data does not have any special access to or advantage within the MDC. The Exchange's proposed wireless connection would lead to a pole, from which a fiber connection would lead into the MDC. The pole is owned by a third party and is not on the grounds of the MDC, and the path into the MDC through a meet-me-room is available to any telecommunications provider. Within the MDC, the proposed connection would follow the same route as that of any User, connecting to equipment in colocation and then to any Users that are customers.

Further, all distances in the MDC are normalized and Exchange rules require that the distance from the Patch Panel Point to each User cabinet in colocation be the same.[22] Every provider of wireless connectivity to Users, including FIDS, is connected to the Patch Panel Point, and the length of the fiber path from the Patch Panel Point to each User cabinet in colocation is the same.

Nor does the Exchange have a competitive advantage over the third-party competitors offering wireless connectivity to CME Group market data by virtue of the fact that it owns and operates the MDC's meet-me-rooms.

[13] 15 U.S.C. 78f(b).

[14] 15 U.S.C. 78f(b)(5).

[15] 15 U.S.C. 78f(b)(4).

[16] *See* Securities Exchange Act Release No. 90209 (October 15, 2020), 85 FR 67044, 67049 (October 21, 2020) (Order Granting Accelerated Approval to Establish a Wireless Fee Schedule Setting Forth Available Wireless Bandwidth Connections and Wireless Market Data Connections) (SR–NYSE–2020–05, SR–NYSEAMER–2020–05, SR–NYSEARCA–2020–08, SR–NYSECHX–2020–02, SR–NYSENAT–2020–03, SR–NYSE–2020–11, SR–NYSEAMER–2020–10, SR–NYSEArca–2020–15, SR–NYSECHX–2020–05, SR–NYSENAT–2020–08) (''Wireless Approval Order''), citing Securities Exchange Act Release No. 59039 (December 2, 2008), 73 FR 74770, 74781 (December 9, 2008) (''2008 ArcaBook Approval Order''). *See NetCoalition* v. *SEC,* 615 F.3d 525 (D.C. Cir. 2010).

[17] *See* Wireless Approval Order, *supra* note 16, at 67049, citing 2008 ArcaBook Approval Order, *supra* note 16, at 74781.

[18] Quincy's symbol list for wireless connectivity to CME Group data is available at *https://www.quincy-data.com/product-page/* under the heading ''2023 Quincy Extreme Data Symbol Set/North America QED Symbol Set.'' The Exchange understands that the Quincy wireless connection to CME Group data currently includes 26 symbols. The Exchange's proposed wireless connection to CME Group data would contain a similar number of symbols, nearly all of which are included in the Quincy wireless connection.

[19] Because Quincy is not a regulated entity, it is not obligated to make its latency figures or fees publicly available or the same for all entities.

[20] *See* 2008 ArcaBook Approval Order, *supra* note 16, at 74789 and n.295 (recognizing that products need not be identical to be substitutable).

[21] In addition, the Exchange believes that at least two third-party market participants, in addition to FIDS, offer fiber connections to CME Group market data in colocation. *See* Securities Exchange Act Release No. 81014 (June 23, 2017), 82 FR 29615 (June 29, 2017) (SR–NYSE–2017–25). Unlike the proposed wireless connectivity, FIDS' fiber connection to CME Group market data includes the entire CME Group data feed, instead of a subset of symbols.

[22] *See* NYSE Rule 3.13(c), NYSE American Rule 3.13E(c), NYSE Arca Rule 3.13(c), NYSE Chicago Rule 3.13(c), and NYSE National Rule 3.13(c) (Data Center Pole Restrictions—Connectivity to Co-Location Space). ''Patch Panel Point'' is defined as ''the patch panel where fiber connections for wireless services connect to the network row in the space used for co-location in the Data Center.'' *Id.* The proposed service would not use the MDC pole, so Rule 3.13(b) would not apply.

Users purchasing wireless connectivity to CME Group market data—like Users of any other colocation service—would require a circuit connecting out of the MDC, and in most cases, such circuits are provided by third-party telecommunications service providers that have installed their equipment in the MDC's two meet-me-rooms (''Telecoms'').[23] Currently, 16 Telecoms operate in the meet-me-rooms and provide a variety of circuit choices. It is in the Exchange's best interest to set the fees that Telecoms pay to operate in the meet-me-rooms at a reasonable level [24] so that market participants, including Telecoms, will maximize their use of the MDC. By setting the meet-me-room fees at a reasonable level, the Exchange encourages Telecoms to participate in the meet-me-rooms and to sell circuits to Users for connecting into and out of the MDC. These Telecoms then compete with each other by pricing such circuits at competitive rates. These competitive rates for circuits help draw in more Users and Hosted Customers to the MDC, which directly benefits the Exchange by increasing the customer base to whom the Exchange can sell its colocation services, which include cabinets, power, ports, and connectivity to many third-party data feeds, and because having more Users and Hosted Customers leads, in many cases, to greater participation on the Exchange. In this way, by setting the meet-me-room fees at a level attractive to telecommunications firms, the Exchange spurs demand for all of the services it sells at the MDC, while setting the meet-me-room fees too high would negatively affect the Exchange's ability to sell its services at the MDC.[25] Accordingly, there are real constraints on the meet-me-room fees the Exchange charges, such that the Exchange does not have an advantage in terms of costs when compared to third parties that enter the MDC through the meet-me-rooms to provide services to compete with the Exchange's services.

If anything, the Exchange is subject to a competitive disadvantage vis-à-vis third-party competitors offering wireless connectivity to CME Group market data. Third-party competitors are not subject to the Commission's filing requirements, and therefore can freely change their services and pricing in response to competitive forces. In contrast, the Exchange's service and pricing would be standardized as set out in this filing, and the Exchange would be unable to respond to pricing pressure from its competitors without seeking a formal fee change in a filing before the Commission.

In sum, because the Exchange is subject to significant competitive forces in setting the terms on which it offers its proposal, in particular because a substantially similar substitute is available, and the Exchange has not placed the third-party vendors at a competitive disadvantage created by the Exchange, the proposed fees for the Exchange's wireless connectivity to CME Group Data are reasonable.[26] If the Exchange were to set its prices for wireless connectivity to CME Group Data at a level that Users found to be too high, Users could easily choose to connect to CME Group market data in colocation at the MDC through the competing Quincy wireless connection, as detailed above.

Additional Considerations

The Exchange believes that it is reasonable for the proposed wireless connection to CME Group Data not to transport information for all of the symbols included in CME Group data feeds to the MDC, but rather to transport a subset of that data. Wireless bandwidth capacity is a small fraction of the capacity required to transport the full CME Group feed. The Exchange believes it is reasonable for FIDS to select the symbols it will make available for wireless connectivity based on customer input and demand. The Exchange understands that Quincy similarly provides wireless connectivity to a subset of CME Group market data based on customer demand for particular symbols.

The Exchange believes that it is reasonable that a User that connects to both CME Group Data and Existing Third Party Data may not use the same port for connectivity to both, and so would have at least two ports, because the proposed wireless connection would include the use of one port for connectivity to CME Group Data, and the connectivity to the Existing Third Party Data includes the use of one port for connectivity to Existing Third Party Data. A User would not pay a separate fee for using such ports.

The Proposed Change Is an Equitable Allocation of Fees and Credits

The Exchange believes that its proposal equitably allocates its fees among Users. Without this proposed rule change, Users would have fewer options for connectivity to CME Group market data. The proposed change would provide Users with an additional choice with respect to the form and optimal latency of the connectivity they use to receive CME Group market data, allowing a User to select the connectivity that better suits its needs, helping it tailor its colocation operations to the requirements of its business operations. Users that do not opt to utilize the Exchange's proposed wireless connection would still be able to obtain CME Group market data wirelessly using Quincy's wireless connection.

The Exchange believes that the proposed change is equitable because it will result in fees being charged only to Users that voluntarily select to receive the corresponding services and because those services will be available to all Users. Furthermore, the Exchange believes that the services and fees proposed herein are equitably allocated because, in addition to the services being completely voluntary, they are available to all Users on an equal basis (*i.e.,* the same products and services are available to all Users). All Users that voluntarily select the Exchange's proposed wireless connections to CME Group Data would be charged the same amount for the same services.

The Proposed Change Is Not Unfairly Discriminatory

The Exchange believes that the proposed rule change is not unfairly discriminatory, for the following reasons. Without this proposed rule change, Users would have fewer options for connectivity to CME Group Data. The proposed change would provide Users with an additional choice with respect to the form and optimal latency of the connectivity they use to receive CME Group market data, allowing a User to select the connectivity that better suits its needs, helping it tailor its colocation operations to the requirements of its business operations. Users that do not opt to utilize the Exchange's proposed wireless connection would still be able to obtain CME Group market data wirelessly using Quincy's wireless connection.

The Exchange believes that it is not unfairly discriminatory to not transport information for all of the symbols included in CME Group data feeds to the MDC, but rather to transport a subset

[23] Note that in the case of wireless connectivity, a User in colocation still requires a fiber circuit to transport data. If a Telecom is used, the data is transmitted wirelessly to the relevant pole, and then from the pole to the meet-me-room using a fiber circuit.

[24] *See* Securities Exchange Act Release No. 97998 (July 26, 2023), 88 FR 50238 (August 1, 2023) (SR–NYSE–2023–27) (''MMR Notice'').

[25] *See id.* at 50241. Importantly, the Exchange is prevented from making any alteration to its meet-me-room services or fees without filing a proposal for such changes with the Commission.

[26] *See* Wireless Approval Order, *supra* note 16.

of that data. There is limited bandwidth available on the wireless network to colocation, and there are a number of CME Group data feeds. Limiting the feeds to the selection of CME Group market data regarding securities for which FIDS determines there is demand would allow Users to receive the relevant CME Group Data over a wireless network.

The Exchange believes that the proposed change is not unfairly discriminatory because it will result in fees being charged only to Users that voluntarily select to receive the corresponding services and because those services will be available to all Users. Furthermore, the Exchange believes that the services and fees proposed herein are not unfairly discriminatory because, in addition to the services being completely voluntary, they are available to all Users on an equal basis (*i.e.,* the same products and services are available to all Users). All Users that voluntarily select wireless connections to CME Group Data would be charged the same amount for the same services. Users that opt to use wireless connections to CME Group Data would receive the CME Group Data that is available to all Users, as all market participants that contract with CME Group or its affiliate for CME Group Data, as required, may receive it.

For the reasons above, the proposed changes do not unfairly discriminate between or among market participants that are otherwise capable of satisfying any applicable colocation fees, requirements, terms, and conditions established from time to time by the Exchange.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange believes that the proposal will not impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of Section 6(b)(8) of the Act.[27]

The proposed change would not affect competition among national securities exchanges or among members of the Exchange, but rather between FIDS and its commercial competitors. The proposed wireless connection would provide Users with an alternative means of connectivity to CME Group Data. The proposed change would provide Users with an additional choice with respect to the form and optimal latency of the connectivity they use to receive CME Group market data, allowing a User to select the connectivity that better suits its needs, helping it tailor its colocation operations to the requirements of its business operations.

Users that do not opt to utilize the Exchange's proposed wireless connection would still be able to obtain CME Group market data wirelessly using Quincy's wireless connection. The Exchange's proposed wireless connection and the existing Quincy wireless connection to CME Group market data are sufficiently similar substitutes and thus provide market participants with choices to meet their wireless connectivity needs.

In addition, the Exchange does not believe that FIDS would have any competitive advantage over either the existing third-party provider or any future providers of wireless connectivity to CME Group market data. The Exchange's proposed service for connectivity to CME Group Data does not have any special access to or advantage within the MDC. The Exchange's proposed wireless connection would lead to a pole, from which a fiber connection would lead into the MDC. The pole is owned by a third party and is not on the grounds of the MDC, and the path into the MDC through a meet-me-room is the same path followed by any Telecom. Within the MDC, the proposed connection would follow the same route as that of any User, connecting to equipment in colocation and then to any Users that are customers.

Further, all distances in the MDC are normalized and Exchange rules require that the distance from the Patch Panel Point to each User cabinet in colocation be the same.[28] Every provider of wireless connectivity to Users, including FIDS, is connected to the Patch Panel Point, and the length of the fiber path from the Patch Panel Point to each User cabinet in colocation is the same.

Nor does the Exchange have a competitive advantage over the third-party competitors offering wireless connectivity to CME Group market data by virtue of the fact that it owns and operates the MDC's meet-me-rooms. Users purchasing wireless connectivity to CME Group market data—like Users of any other colocation service—would require a circuit connecting out of the MDC, and in most cases, such circuits are provided by third-party Telecoms that have installed their equipment in the MDC's two meet-me-rooms.[29] Currently, 16 Telecoms operate in the meet-me-rooms and provide a variety of circuit choices. It is in the Exchange's best interest to set the fees that Telecoms pay to operate in the meet-me-rooms at a reasonable level[30] so that market participants, including Telecoms, will maximize their use of the MDC. By setting the meet-me-room fees at a reasonable level, the Exchange encourages Telecoms to participate in the meet-me-rooms and to sell circuits to Users for connecting into and out of the MDC. These Telecoms then compete with each other by pricing such circuits at competitive rates. These competitive rates for circuits help draw in more Users and Hosted Customers to the MDC, which directly benefits the Exchange by increasing the customer base to whom the Exchange can sell its colocation services, which include cabinets, power, ports, and connectivity to many third-party data feeds, and because having more Users and Hosted Customers leads, in many cases, to greater participation on the Exchange. In this way, by setting the meet-me-room fees at a level attractive to telecommunications firms, the Exchange spurs demand for all of the services it sells at the MDC, while setting the meet-me-room fees too high would negatively affect the Exchange's ability to sell its services at the MDC.[31] Accordingly, there are real constraints on the meet-me-room fees the Exchange charges, such that the Exchange does not have an advantage in terms of costs when compared to third parties that enter the MDC through the meet-me-rooms to provide services to compete with the Exchange's services.

If anything, the Exchange is subject to a competitive disadvantage vis-à-vis third party competitors offering wireless connectivity to CME Group market data. Third-party competitors are not subject to the Commission's filing requirements, and therefore can freely change their services and pricing in response to competitive forces. In contrast, the Exchange's service and pricing would be standardized as set out in this filing, and the Exchange would be unable to respond to pricing pressure from its competitors without seeking a formal fee change in a filing before the Commission.

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.

[27] 15 U.S.C. 78f(b)(8).

[28] *See supra* note 22.

[29] *See supra* note 23.

[30] *See* MMR Notice, *supra* note 24.

[31] *See supra* note 25.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The Exchange has filed the proposed rule change pursuant to Section 19(b)(3)(A)(iii) of the Act [32] and Rule 19b–4(f)(6) thereunder.[33] Because the 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 prior to 30 days from the date on which it was filed, or such shorter time as the Commission may designate, if consistent with the protection of investors and the public interest, the proposed rule change has become effective pursuant to Section 19(b)(3)(A) of the Act and Rule 19b–4(f)(6)(iii) thereunder.

A proposed rule change filed under Rule 19b–4(f)(6) [34] normally does not become operative prior to 30 days after the date of the filing. However, pursuant to Rule 19b4(f)(6)(iii),[35] the Commission may designate a shorter time if such action is consistent with the protection of investors and the public interest.

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 Section 19(b)(2)(B) [36] of the Act to determine whether the proposed rule change should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*https://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include file number SR–NYSE–2023–44 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–2023–44. 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 (*https://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 a.m. and 3 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. Do not include personal identifiable information in submissions; you should submit only information that you wish to make available publicly. We may redact in part or withhold entirely from publication submitted material that is obscene or subject to copyright protection. All submissions should refer to file number SR–NYSE–2023–44 and should be submitted on or before December 13, 2023.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[37]

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2023–25769 Filed 11–21–23; 8:45 am]

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[32] 15 U.S.C. 78s(b)(3)(A)(iii).

[33] 17 CFR 240.19b–4(f)(6).

[34] 17 CFR 240.19b–4(f)(6).

[35] 17 CFR 240.19b–4(f)(6)(iii).

[36] 15 U.S.C. 78s(b)(2)(B).

[37] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–98965; File No. SR–NYSECHX–2023–22]

Self-Regulatory Organizations; NYSE Chicago, Inc.; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend the Connectivity Fee Schedule

November 16, 2023.

Pursuant to Section 19(b)(1) [1] of the Securities Exchange Act of 1934 (''Act'') [2] and Rule 19b–4 thereunder,[3] notice is hereby given that on November 9, 2023, the NYSE Chicago, Inc. (''NYSE Chicago'' 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 Connectivity Fee Schedule (''Fee Schedule'') regarding colocation services and fees to provide Users with wireless connectivity to CME Group market data. 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.

[1] 15 U.S.C. 78s(b)(1).

[2] 15 U.S.C. 78a.

[3] 17 CFR 240.19b–4.

A. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend the Connectivity Fee Schedule (''Fee Schedule'') regarding colocation services and fees to provide Users [4] with wireless connectivity to CME Group market data.[5]

The Exchange currently provides Users with wireless connections to eight market data feeds or combinations of feeds from third-party markets (the ''Existing Third Party Data''),[6] and wired connections to more than 45 market data feeds or combinations of feeds.[7] The Exchange proposes to add to the Fee Schedule wireless connections to CME Group, Inc. (''CME Group'') market data (''CME Group Data'' and, together with the Existing Third Party Data, the ''Third Party Data''). Users would be offered the proposed wireless connection to the CME Group Data through connections into the colocation center in the Mahwah, New Jersey data center (''MDC'').[8]

The Exchange expects that the proposed rule change would become operative in the fourth quarter of 2023, and in any event, no later than December 31, 2023. The Exchange will announce the date that the wireless connection to the CME Group Data will be available through a customer notice.

To receive CME Group Data, the User would enter into an agreement with a third party for permission to receive the data, if required. The User would pay this third party any fees for the data content.

The Exchange proposes to revise the Fee Schedule to reflect fees related to the wireless connection to CME Group Data. For each wireless connection to CME Group Data, a User would be charged a $5,000 non-recurring initial charge and a monthly recurring charge of $6,000. If a User were to purchase more than one wireless connection to CME Group Data, it would pay more than one non-recurring initial charge. Each proposed wireless connection would include the use of one port for connectivity to CME Group Data, and a User would not pay a separate fee for the use of such port.[9]

The Exchange's proposed wireless connectivity to CME Group market data would not include the entire CME Group market data feed, which includes market data for approximately 1,200 futures symbols. Wireless bandwidth capacity is a small fraction of the capacity required to transport the full CME Group feed. Accordingly, FIDS has consulted with customers about which of the CME Group symbols they would like to be available wirelessly and plans to offer connectivity to a subgroup of symbols based on this customer feedback. The Exchange understands that Quincy Data LLC (''Quincy''),[10] a third party that already provides wireless connectivity to CME Group market data in the MDC, similarly provides wireless connectivity to a subset of CME Group market data based on customer demand for particular symbols.[11]

Application and Impact of the Proposed Changes

The proposed changes would not apply differently to distinct types or sizes of market participants. Rather, they would apply to all Users equally.

As is currently the case, the purchase of any colocation service, including connectivity to Third Party Data, is completely voluntary and the Fee Schedule is applied uniformly to all Users.

Competitive Environment

The Exchange operates in a highly competitive market in which other vendors offer colocation services as a means to facilitate the trading and other market activities of those market participants who believe that colocation enhances the efficiency of their operations. The Commission has repeatedly expressed its preference for competition over regulatory intervention in determining prices, products, and services in the securities markets. Specifically, in Regulation NMS, the Commission highlighted the importance of market forces in determining prices and SRO revenues and, also, recognized that current regulation of the market system ''has been remarkably successful in promoting market competition in its broader forms that are most important to investors and listed companies.'' [12]

As explained below in this filing, the Exchange's proposed wireless connection to CME Group Data would compete with the wireless connection to CME Group market data provided by Quincy. Third-party vendors such as Quincy are not at any competitive disadvantage created by the Exchange.

The proposed change is not otherwise intended to address any other issues relating to colocation services or related fees, and the Exchange is not aware of any problems that Users would have in complying with the proposed change.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with Section 6(b) of the Act,[13] in general, and furthers the objectives of Section 6(b)(5) of the Act,[14] 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. The

[4] For purposes of the Exchange's colocation services, a ''User'' means any market participant that requests to receive colocation services directly from the Exchange. *See* Securities Exchange Act Release No. 87408 (October 28, 2019), 84 FR 58778 at n.6 (November 1, 2019) (SR–NYSECHX–2019–12) (''NYSE Chicago Colocation Notice''). As specified in the Fee Schedule, a User that incurs colocation fees for a particular colocation service pursuant thereto would not be subject to colocation fees for the same colocation service charged by the Exchange's affiliates the New York Stock Exchange LLC, NYSE American LLC, NYSE Arca, Inc., and NYSE National, Inc. (together, the ''Affiliate SROs''). Each Affiliate SRO has submitted substantially the same proposed rule change to propose the changes described herein. *See* SR–NYSE–2023–44, SR–NYSEAMER–2023–59, SR–NYSEARCA–2023–79, and SR–NYSENAT–2023–26.

[5] The Exchange filed a similar proposal in 2021, which it subsequently withdrew. *See* Securities Exchange Act Release No. 93810 (December 17, 2021), 86 FR 73026 (December 23, 2021) (SR–NYSE–2021–67, SR–NYSEAMER–2021–43, SR–NYSEARCA–2021–97, SR–NYSECHX–2021–17, SR–NYSENAT–2021–23).

[6] *See* NYSE Chicago Colocation Notice, *supra* note 4, at 58784–85.

[7] *See id.* at 58787–88.

[8] Through its Fixed Income and Data Services (''FIDS'') (previously ICE Data Services) business, Intercontinental Exchange, Inc. (''ICE'') operates the MDC. The Exchange and the Affiliate SROs are indirect subsidiaries of ICE. The proposed service would be provided by FIDS pursuant to an agreement with a non-ICE entity. FIDS does not own the wireless network that would be used to provide the service.

[9] If a User also connects to Existing Third Party Data, it would not be able to connect to such Existing Third Party Data using the same port that it uses for connectivity to CME Group Data.

[10] The Exchange understands that Quincy is an affiliate of McKay Brothers LLC.

[11] The Exchange understands that the third parties that provide wireless connectivity to CME Group market data to the MDC and other data centers in New Jersey (as discussed later in this filing) follow a substantially similar model, offering wireless connectivity to a selection of market data rather than to entire feeds.

[12] *See* Securities Exchange Act Release No. 51808 (June 9, 2005), 70 FR 37496, 37499 (June 29, 2005).

[13] 15 U.S.C. 78f(b).

[14] 15 U.S.C. 78f(b)(5).

Exchange further believes that the proposed rule change is consistent with Section 6(b)(4) of the Act,[15] because it provides for the equitable allocation of reasonable dues, fees, and other charges among its members and issuers and other persons using its facilities and does not unfairly discriminate between customers, issuers, brokers, or dealers.

The Proposed Change Is Reasonable

The Exchange believes that the proposed rule change is reasonable. In considering the reasonableness of proposed services and fees, the Commission's market-based test considers ''whether the exchange was subject to significant competitive forces in setting the terms of its proposal . . . , including the level of any fees.'' [16] If the Exchange meets that burden, ''the Commission will find that its proposal is consistent with the Act unless 'there is a substantial countervailing basis to find that the terms' of the proposal violate the Act or the rules thereunder.'' [17] Here, the Exchange is subject to significant competitive forces in setting the terms on which it offers its proposal, in particular because substantially similar substitutes are available, and the Exchange has not placed the third party vendors at a competitive disadvantage created by the Exchange.

Substantially Similar Substitutes Are Available

The Exchange's proposed wireless connection to CME Group Data would compete with other methods by which both the Exchange and various third parties already provide connectivity to CME Group market data to Users.

Quincy already provides wireless connectivity to CME Group market data in the MDC. Like the Exchange's proposed wireless connectivity, Quincy's wireless connectivity to CME Group market data includes a similarly-sized subset of symbols that almost completely overlaps with the symbols for which the Exchange proposes to provide wireless connectivity—presumably because customers have requested the same symbols of each provider. Specifically, like the Quincy wireless connection, the Exchange's proposed wireless connection would include the main futures for equity indices, government bonds, foreign exchanges, oil, and precious metals.[18] In addition, the Exchange's proposed wireless connection would also include several additional symbols that proposed Users have specifically requested be included. The Exchange plans to continuously monitor Users' preferences and their views of the usefulness of the included symbols, and may adjust them accordingly. The Exchange believes that the Quincy wireless connection to CME Group market data is at a same or similar speed as the Exchange's proposed connection, and at a similar price.[19]

Accordingly, the Quincy wireless connection to CME Group market data would compete with the Exchange's proposed wireless connection, and would exert significant competitive forces on the Exchange in setting the terms of its proposal, including the level of the Exchange's proposed fees.[20] If the Exchange were to set its proposed fees too high, Users could respond by instead selecting Quincy's substantially similar wireless connectivity to CME Group data.[21]

Third Party Competitors Are Not at a Competitive Disadvantage Created by the Exchange

The Exchange does not believe that FIDS would have any competitive advantage over either the existing third-party provider or any future providers of wireless connectivity to CME Group market data. The Exchange's proposed service for connectivity to CME Group Data does not have any special access to or advantage within the MDC. The Exchange's proposed wireless connection would lead to a pole, from which a fiber connection would lead into the MDC. The pole is owned by a third party and is not on the grounds of the MDC, and the path into the MDC through a meet-me-room is available to any telecommunications provider. Within the MDC, the proposed connection would follow the same route as that of any User, connecting to equipment in colocation and then to any Users that are customers.

Further, all distances in the MDC are normalized and Exchange rules require that the distance from the Patch Panel Point to each User cabinet in colocation be the same.[22] Every provider of wireless connectivity to Users, including FIDS, is connected to the Patch Panel Point, and the length of the fiber path from the Patch Panel Point to each User cabinet in colocation is the same.

Nor does the Exchange have a competitive advantage over the third-party competitors offering wireless connectivity to CME Group market data by virtue of the fact that it owns and operates the MDC's meet-me-rooms. Users purchasing wireless connectivity to CME Group market data—like Users of any other colocation service—would require a circuit connecting out of the MDC, and in most cases, such circuits are provided by third-party telecommunications service providers that have installed their equipment in the MDC's two meet-me-rooms (''Telecoms'').[23] Currently, 16 Telecoms operate in the meet-me-rooms and provide a variety of circuit choices. It is in the Exchange's best interest to set the fees that Telecoms pay to operate in the meet-me-rooms at a reasonable level [24] so that market participants, including Telecoms, will maximize their use of the MDC. By setting the meet-me-room fees at a reasonable level, the Exchange

[15] 15 U.S.C. 78f(b)(4).

[16] *See* Securities Exchange Act Release No. 90209 (October 15, 2020), 85 FR 67044, 67049 (October 21, 2020) (Order Granting Accelerated Approval to Establish a Wireless Fee Schedule Setting Forth Available Wireless Bandwidth Connections and Wireless Market Data Connections) (SR–NYSE–2020–05, SR–NYSEAMER–2020–05, SR–NYSEArca–2020–08, SR–NYSECHX–2020–02, SR–NYSENAT–2020–03, SR–NYSE–2020–11, SR–NYSEAMER–2020–10, SR–NYSEArca–2020–15, SR–NYSECHX–2020–05, SR–NYSENAT–2020–08) (''Wireless Approval Order''), citing Securities Exchange Act Release No. 59039 (December 2, 2008), 73 FR 74770, 74781 (December 9, 2008) (''2008 ArcaBook Approval Order''). *See NetCoalition* v. *SEC,* 615 F.3d 525 (D.C. Cir. 2010).

[17] *See* Wireless Approval Order, *supra* note 16, at 67049, citing 2008 ArcaBook Approval Order, *supra* note 16, at 74781.

[18] Quincy's symbol list for wireless connectivity to CME Group data is available at *https://www.quincy-data.com/product-page/* under the heading ''2023 Quincy Extreme Data Symbol Set/North America QED Symbol Set.'' The Exchange understands that the Quincy wireless connection to CME Group data currently includes 26 symbols. The Exchange's proposed wireless connection to CME Group data would contain a similar number of symbols, nearly all of which are included in the Quincy wireless connection.

[19] Because Quincy is not a regulated entity, it is not obligated to make its latency figures or fees publicly available or the same for all entities.

[20] *See* 2008 ArcaBook Approval Order, *supra* note 16, at 74789 and n.295 (recognizing that products need not be identical to be substitutable).

[21] In addition, the Exchange believes that at least two third-party market participants, in addition to FIDS, offer fiber connections to CME Group market data in colocation. *See* NYSE Chicago Colocation Notice, *supra* note 4, at 58788. Unlike the proposed wireless connectivity, FIDS' fiber connection to CME Group market data includes the entire CME Group data feed, instead of a subset of symbols.

[22] *See* NYSE Rule 3.13(c), NYSE American Rule 3.13E(c), NYSE Arca Rule 3.13(c), NYSE Chicago Rule 3.13(c), and NYSE National Rule 3.13(c) (Data Center Pole Restrictions—Connectivity to Co-Location Space). ''Patch Panel Point'' is defined as ''the patch panel where fiber connections for wireless services connect to the network row in the space used for co-location in the Data Center.'' *Id.* The proposed service would not use the MDC pole, so Rule 3.13(b) would not apply.

[23] Note that in the case of wireless connectivity, a User in colocation still requires a fiber circuit to transport data. If a Telecom is used, the data is transmitted wirelessly to the relevant pole, and then from the pole to the meet-me-room using a fiber circuit.

[24] *See* Securities Exchange Act Release No. 98001 (July 26, 2023), 88 FR 50196 (August 1, 2023) (SR–NYSECHX–2023–14) (''MMR Notice'').

encourages Telecoms to participate in the meet-me-rooms and to sell circuits to Users for connecting into and out of the MDC. These Telecoms then compete with each other by pricing such circuits at competitive rates. These competitive rates for circuits help draw in more Users and Hosted Customers to the MDC, which directly benefits the Exchange by increasing the customer base to whom the Exchange can sell its colocation services, which include cabinets, power, ports, and connectivity to many third-party data feeds, and because having more Users and Hosted Customers leads, in many cases, to greater participation on the Exchange. In this way, by setting the meet-me-room fees at a level attractive to telecommunications firms, the Exchange spurs demand for all of the services it sells at the MDC, while setting the meet-me-room fees too high would negatively affect the Exchange's ability to sell its services at the MDC.[25] Accordingly, there are real constraints on the meet-me-room fees the Exchange charges, such that the Exchange does not have an advantage in terms of costs when compared to third parties that enter the MDC through the meet-me-rooms to provide services to compete with the Exchange's services.

If anything, the Exchange is subject to a competitive disadvantage vis-à-vis third-party competitors offering wireless connectivity to CME Group market data. Third-party competitors are not subject to the Commission's filing requirements, and therefore can freely change their services and pricing in response to competitive forces. In contrast, the Exchange's service and pricing would be standardized as set out in this filing, and the Exchange would be unable to respond to pricing pressure from its competitors without seeking a formal fee change in a filing before the Commission.

In sum, because the Exchange is subject to significant competitive forces in setting the terms on which it offers its proposal, in particular because a substantially similar substitute is available, and the Exchange has not placed the third-party vendors at a competitive disadvantage created by the Exchange, the proposed fees for the Exchange's wireless connectivity to CME Group Data are reasonable.[26] If the Exchange were to set its prices for wireless connectivity to CME Group Data at a level that Users found to be too high, Users could easily choose to connect to CME Group market data in colocation at the MDC through the competing Quincy wireless connection, as detailed above.

Additional Considerations

The Exchange believes that it is reasonable for the proposed wireless connection to CME Group Data not to transport information for all of the symbols included in CME Group data feeds to the MDC, but rather to transport a subset of that data. Wireless bandwidth capacity is a small fraction of the capacity required to transport the full CME Group feed. The Exchange believes it is reasonable for FIDS to select the symbols it will make available for wireless connectivity based on customer input and demand. The Exchange understands that Quincy similarly provides wireless connectivity to a subset of CME Group market data based on customer demand for particular symbols.

The Exchange believes that it is reasonable that a User that connects to both CME Group Data and Existing Third Party Data may not use the same port for connectivity to both, and so would have at least two ports, because the proposed wireless connection would include the use of one port for connectivity to CME Group Data, and the connectivity to the Existing Third Party Data includes the use of one port for connectivity to Existing Third Party Data. A User would not pay a separate fee for using such ports.

The Proposed Change Is an Equitable Allocation of Fees and Credits

The Exchange believes that its proposal equitably allocates its fees among Users. Without this proposed rule change, Users would have fewer options for connectivity to CME Group market data. The proposed change would provide Users with an additional choice with respect to the form and optimal latency of the connectivity they use to receive CME Group market data, allowing a User to select the connectivity that better suits its needs, helping it tailor its colocation operations to the requirements of its business operations. Users that do not opt to utilize the Exchange's proposed wireless connection would still be able to obtain CME Group market data wirelessly using Quincy's wireless connection.

The Exchange believes that the proposed change is equitable because it will result in fees being charged only to Users that voluntarily select to receive the corresponding services and because those services will be available to all Users. Furthermore, the Exchange believes that the services and fees proposed herein are equitably allocated because, in addition to the services being completely voluntary, they are available to all Users on an equal basis (*i.e.,* the same products and services are available to all Users). All Users that voluntarily select the Exchange's proposed wireless connections to CME Group Data would be charged the same amount for the same services.

The Proposed Change Is Not Unfairly Discriminatory

The Exchange believes that the proposed rule change is not unfairly discriminatory, for the following reasons. Without this proposed rule change, Users would have fewer options for connectivity to CME Group Data. The proposed change would provide Users with an additional choice with respect to the form and optimal latency of the connectivity they use to receive CME Group market data, allowing a User to select the connectivity that better suits its needs, helping it tailor its colocation operations to the requirements of its business operations. Users that do not opt to utilize the Exchange's proposed wireless connection would still be able to obtain CME Group market data wirelessly using Quincy's wireless connection.

The Exchange believes that it is not unfairly discriminatory to not transport information for all of the symbols included in CME Group data feeds to the MDC, but rather to transport a subset of that data. There is limited bandwidth available on the wireless network to colocation, and there are a number of CME Group data feeds. Limiting the feeds to the selection of CME Group market data regarding securities for which FIDS determines there is demand would allow Users to receive the relevant CME Group Data over a wireless network.

The Exchange believes that the proposed change is not unfairly discriminatory because it will result in fees being charged only to Users that voluntarily select to receive the corresponding services and because those services will be available to all Users. Furthermore, the Exchange believes that the services and fees proposed herein are not unfairly discriminatory because, in addition to the services being completely voluntary, they are available to all Users on an equal basis (*i.e.,* the same products and services are available to all Users). All Users that voluntarily select wireless connections to CME Group Data would be charged the same amount for the same services. Users that opt to use

[25] *See id.* at 50199. Importantly, the Exchange is prevented from making any alteration to its meet-me-room services or fees without filing a proposal for such changes with the Commission.

[26] *See* Wireless Approval Order, *supra* note 16.

wireless connections to CME Group Data would receive the CME Group Data that is available to all Users, as all market participants that contract with CME Group or its affiliate for CME Group Data, as required, may receive it.

For the reasons above, the proposed changes do not unfairly discriminate between or among market participants that are otherwise capable of satisfying any applicable colocation fees, requirements, terms, and conditions established from time to time by the Exchange.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange believes that the proposal will not impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of Section 6(b)(8) of the Act.[27]

The proposed change would not affect competition among national securities exchanges or among members of the Exchange, but rather between FIDS and its commercial competitors. The proposed wireless connection would provide Users with an alternative means of connectivity to CME Group Data. The proposed change would provide Users with an additional choice with respect to the form and optimal latency of the connectivity they use to receive CME Group market data, allowing a User to select the connectivity that better suits its needs, helping it tailor its colocation operations to the requirements of its business operations.

Users that do not opt to utilize the Exchange's proposed wireless connection would still be able to obtain CME Group market data wirelessly using Quincy's wireless connection. The Exchange's proposed wireless connection and the existing Quincy wireless connection to CME Group market data are sufficiently similar substitutes and thus provide market participants with choices to meet their wireless connectivity needs.

In addition, the Exchange does not believe that FIDS would have any competitive advantage over either the existing third-party provider or any future providers of wireless connectivity to CME Group market data. The Exchange's proposed service for connectivity to CME Group Data does not have any special access to or advantage within the MDC. The Exchange's proposed wireless connection would lead to a pole, from which a fiber connection would lead into the MDC. The pole is owned by a third party and is not on the grounds of the MDC, and the path into the MDC through a meet-me-room is the same path followed by any Telecom. Within the MDC, the proposed connection would follow the same route as that of any User, connecting to equipment in colocation and then to any Users that are customers.

Further, all distances in the MDC are normalized and Exchange rules require that the distance from the Patch Panel Point to each User cabinet in colocation be the same.[28] Every provider of wireless connectivity to Users, including FIDS, is connected to the Patch Panel Point, and the length of the fiber path from the Patch Panel Point to each User cabinet in colocation is the same.

Nor does the Exchange have a competitive advantage over the third-party competitors offering wireless connectivity to CME Group market data by virtue of the fact that it owns and operates the MDC's meet-me-rooms. Users purchasing wireless connectivity to CME Group market data—like Users of any other colocation service—would require a circuit connecting out of the MDC, and in most cases, such circuits are provided by third-party Telecoms that have installed their equipment in the MDC's two meet-me-rooms.[29] Currently, 16 Telecoms operate in the meet-me-rooms and provide a variety of circuit choices. It is in the Exchange's best interest to set the fees that Telecoms pay to operate in the meet-me-rooms at a reasonable level [30] so that market participants, including Telecoms, will maximize their use of the MDC. By setting the meet-me-room fees at a reasonable level, the Exchange encourages Telecoms to participate in the meet-me-rooms and to sell circuits to Users for connecting into and out of the MDC. These Telecoms then compete with each other by pricing such circuits at competitive rates. These competitive rates for circuits help draw in more Users and Hosted Customers to the MDC, which directly benefits the Exchange by increasing the customer base to whom the Exchange can sell its colocation services, which include cabinets, power, ports, and connectivity to many third-party data feeds, and because having more Users and Hosted Customers leads, in many cases, to greater participation on the Exchange. In this way, by setting the meet-me-room fees at a level attractive to telecommunications firms, the Exchange spurs demand for all of the services it sells at the MDC, while setting the meet-me-room fees too high would negatively affect the Exchange's ability to sell its services at the MDC.[31] Accordingly, there are real constraints on the meet-me-room fees the Exchange charges, such that the Exchange does not have an advantage in terms of costs when compared to third parties that enter the MDC through the meet-me-rooms to provide services to compete with the Exchange's services.

If anything, the Exchange is subject to a competitive disadvantage vis-à-vis third party competitors offering wireless connectivity to CME Group market data. Third-party competitors are not subject to the Commission's filing requirements, and therefore can freely change their services and pricing in response to competitive forces. In contrast, the Exchange's service and pricing would be standardized as set out in this filing, and the Exchange would be unable to respond to pricing pressure from its competitors without seeking a formal fee change in a filing before the Commission.

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 Exchange has filed the proposed rule change pursuant to Section 19(b)(3)(A)(iii) of the Act [32] and Rule 19b–4(f)(6) thereunder.[33] Because the 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 prior to 30 days from the date on which it was filed, or such shorter time as the Commission may designate, if consistent with the protection of investors and the public interest, the proposed rule change has become effective pursuant to Section 19(b)(3)(A) of the Act and Rule 19b–4(f)(6)(iii) thereunder.

A proposed rule change filed under Rule 19b–4(f)(6) [34] normally does not become operative prior to 30 days after the date of the filing. However, pursuant to Rule 19b4(f)(6)(iii),[35] the Commission may designate a shorter time if such

[27] 15 U.S.C. 78f(b)(8).

[28] *See supra* note 22.

[29] *See supra* note 23.

[30] *See* MMR Notice, *supra* note 24.

[31] *See supra* note 25.

[32] 15 U.S.C. 78s(b)(3)(A)(iii).

[33] 17 CFR 240.19b–4(f)(6).

[34] 17 CFR 240.19b–4(f)(6).

[35] 17 CFR 240.19b–4(f)(6)(iii).

action is consistent with the protection of investors and the public interest.

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) [36] of the Act to determine whether the proposed rule change should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic comments

- Use the Commission's internet comment form (*https://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include file number SR–NYSECHX–2023–22 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–NYSECHX–2023–22. 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 (*https://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 a.m. and 3 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. Do not include personal identifiable information in submissions; you should submit only information that you wish to make available publicly. We may redact in part or withhold entirely from publication submitted material that is obscene or subject to copyright protection. All submissions should refer to file number SR–NYSECHX–2023–22 and should be submitted on or before December 13, 2023.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[37]

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2023–25772 Filed 11–21–23; 8:45 am]

BILLING CODE 8011–01–P

[36] 15 U.S.C. 78s(b)(2)(B).

[37] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–98973; File No. SR–MIAX–2023–44]

Self-Regulatory Organizations; Miami International Securities Exchange LLC; Notice of Filing of a Proposed Rule Change To Accommodate the Listings of Monthly Options Series

November 16, 2023.

Pursuant to the provisions of Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'') [1] and Rule 19b–4 thereunder,[2] notice is hereby given that on November 14, 2023, Miami International Securities Exchange LLC (''MIAX'' or ''Exchange'') filed with the Securities and Exchange Commission (''Commission'') a proposed rule change as described in Items I and II below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange is filing a proposal to amend its Rules to adopt Monthly Options Series.

The text of the proposed rule change is available on the Exchange's website at *http://www.miaxoptions.com/rule-filings,* at MIAX's principal office, and at the Commission's Public Reference Room.

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend its Rules to accommodate the listing of options series that would expire at the close of business on the last business day of a calendar month (''Monthly Options Series'').

Pursuant to proposed Interpretation and Policy .13 to Exchange Rule 404 and Interpretation and Policy .03 to Exchange Rule 1809, the Exchange may list Monthly Options Series for up to five currently listed option classes that are either index options or options on exchange-traded funds (''ETFs'').[3] In addition, the Exchange may also list Monthly Options Series on any options classes that are selected by other securities exchanges that employ a similar program under their respective rules.[4] The Exchange may list 12 expirations for Monthly Options Series. Monthly Options Series need not be for consecutive months; however, the expiration date of a nonconsecutive expiration may not be beyond what would be considered the last expiration date if the maximum number of expirations were listed consecutively.[5]

[3] The Exchange proposes to amend Exchange Rule 404(a) to provide that proposed Interpretation and Policy .13 to Exchange Rule 404 will describe how the Exchange will fix a specific expiration date and exercise price for Monthly Options Series and that proposed Interpretation and Policy .13 to Exchange Rule 404 will govern the procedures for opening Monthly Options Series, respectively. This is consistent with language in current Exchange Rules 404(a) for other Short Term Options Series and Quarterly Options Series.

[4] Currently, Cboe Exchange, Inc. has a similar program. *See* Securities Exchange Act Release No. 98915 (Nov. 13, 2023) (SR–CBOE–2023–049) (Order Approving a Proposed Rule Change To Adopt Monthly Options Series).

[5] The Exchange notes this provision considers consecutive monthly listings. In other words, as other expirations (such as Quarterly Options Series) are not counted as part of the maximum, those

Continued

Other expirations in the same class are not counted as part of the maximum numbers of Monthly Options Series expirations for a class.[6] Monthly Options Series will be P.M.-settled.[7]

The strike price of each Monthly Options Series will be fixed at a price per share, with at least two, but no more than five, strike prices above and at least two, but no more than five, strike prices below the value of the underlying index or price of the underlying security at about the time that a Monthly Options Series is opened for trading on the Exchange. The Exchange will list strike prices for Monthly Options Series that are reasonably related to the current price of the underlying security or current index value of the underlying index to which such series relates at about the time such series of options is first opened for trading on the Exchange. The term ''reasonably related to the current price of the underlying security or index value of the underlying index'' means that the exercise price is within 30% of the current underlying security price or index value.[8] Additional Monthly Options Series of the same class may be open for trading on the Exchange when the Exchange deems it necessary to maintain an orderly market, to meet Member[9] demand, or when the market price of the underlying security moves substantially from the initial exercise price or prices. To the extent that any additional strike prices are listed by the Exchange, such additional strike prices will be within 30% above or below the closing price of the underlying index or security on the preceding day. The Exchange may also open additional strike prices of Monthly Options Series that are more than 30% above or below the current price of the underlying security, provided that demonstrated Member interest exists for such series, as expressed by institutional, corporate, Members or their brokers. Market Makers trading for their own account will not be considered when determining Member interest under this provision. The opening of the new Monthly Options Series will not affect the series of options of the same class previously opened.[10] The interval between strike prices on Monthly Options Series will be the same as the interval for strike prices for series in that same options class that expire in accordance with the normal monthly expiration cycle.[11]

By definition, Monthly Options Series can never expire in the same week that a standard options series that expires on the third Friday of a month in the same class expires. The same, however, is not the case with respect to Short Term Options Series or Quarterly Options Series. Therefore, to avoid any confusion in the marketplace, the Exchange proposes to amend Interpretation and Policy .02 to Exchange Rule 404 to provide that the Exchange will not list a Short Term Options Series in a class on a date on which a Monthly Options Series or Quarterly Options Series expires.[12] Similarly, proposed Interpretation and Policy .13(b) to Exchange Rule 404 provide that no Monthly Options Series may expire on a date that coincides with an expiration date of a Quarterly Options Series in the same index or ETF class. In other words, the Exchange will not list a Short Terms Options Series on an index or ETF if a Monthly Options Series on that index or ETF were to expire on the same date, nor will the Exchange list a Monthly Options Series on an index or ETF if a Quarterly Options Series on that ETF were to expire on the same date to prevent the listing of series with concurrent expirations.[13]

With respect to Monthly Options Series added pursuant to proposed Interpretation and Policy .13(a)–(f) to Exchange Rule 404, the Exchange will, on a monthly basis, review series that are outside a range of five strikes above and five strikes below the current price of the underlying index or security, and delist series with no open interest in both the put and the call series having a strike: (i) higher than the highest strike price with open interest in the put and/or call series for a given expiration month; and (ii) lower than the lowest strike price with open interest in the put and/or call series for a given expiration month. Notwithstanding this delisting policy, Member requests to add strikes and/or maintain strikes in Monthly Options Series in series eligible for delisting will be granted. In connection with this delisting policy, if the Exchange identifies series for delisting, the Exchange will notify other options exchanges with similar delisting policies regarding eligible series for delisting and will work with such other exchanges to develop a uniform list of series to be delisted, so as to ensure uniform series delisting of multiply listed Monthly Options Series.[14]

The Exchange believes that Monthly Options Series will provide investors with another flexible and valuable tool to manage risk exposure, minimize capital outlays, and be more responsive to the timing of events affecting the securities that underlie options contracts. The Exchange believes limiting Monthly Options Series to five classes will ensure the addition of these new series will have a negligible impact

expirations would not be considered when considering when the last expiration date would be if the maximum number were listed consecutively. For example, if it is January 2024 and the Exchange lists Quarterly Options Series in class ABC with expirations in March, June, September, December, and the following March, the Exchange could also list Monthly Options Series in class ABC with expirations in January, February, April, May, July, August, October, and November 2024 and January and February of 2025. This is because, if Quarterly Options Series, for example, were counted, the Exchange would otherwise never be able to list the maximum number of Monthly Options Series. This is consistent with the listing provisions for Quarterly Options Series, which permit calendar quarter expirations. The need to list series with the same expiration in the current calendar year and the following calendar year (whether Monthly or Quarterly expiration) is to allow market participants to execute one-year strategies pursuant to which they may not roll their exposures in the longer-dated options (*e.g.,* January 2025) prior to the expiration of the nearer-dated option (*e.g.,* January 2024).

[6] *See* proposed Interpretation and Policy .13(b) to Exchange Rule 404.

[7] *See* proposed Interpretation and Policy .13(c) to Exchange Rule 404.

[8] *See* proposed Interpretation and Policy .13(d). The Exchange notes these proposed provisions are consistent with the initial series provision for the Quarterly Options Series program in Interpretation and Policy .03 to Exchange Rule 404. While different than the initial strike listing provision for the Quarterly Options Series program in current Interpretation and Policy .03 to Exchange Rule 404, the Exchange believes the proposed provision is appropriate, as it contemplates classes that may have strike intervals of $5 or greater.

[9] The term ''Member'' means an individual or organization approved to exercise the trading rights associated with a Trading Permit. Members are deemed ''members'' under the Exchange Act. *See* Exchange Rule 100.

[10] *See* proposed Interpretation and Policy .13(e) to Exchange Rule 404.

[11] *See* proposed Interpretation and Policy .13(f) to Exchange Rule 404; *see also* Interpretations and Policies .01 and .04, .06, .08, .09, .10 to Exchange Rule 404 (permissible strike prices for ETF classes) and Interpretations and Policies .05, .07, .11 to Exchange Rule 404 (permissible strike prices for index options).

[12] The Exchange also proposes to make a non-substantive change to Interpretation and Policy .02 to Exchange Rule 404 to change current references to ''monthly options series'' to ''standard expiration options series'' (*i.e.,* series that expire on the third Friday of a month), to eliminate potential confusion. The current references to ''monthly options series'' are intended to refer to those series that expire on the third Friday of a month, which are generally referred to in the industry as standard expirations.

[13] The Exchange notes this would not prevent the Exchange from listing a P.M.-settled Monthly Options Series on an index with the same expiration date as an A.M.-settled Short Term Options Series on the same index, both of which may expire on a Friday. The Exchange believes this concurrent listing would provide investors with yet another hedging mechanism and is reasonable given these series would not be identical (unlike if they were both P.M.-settled). This could not occur with respect to ETFs, as all Short Term Options Series on ETFs are P.M.-settled.

[14] *See* proposed Interpretation and Policy .13(g) to Exchange Rule. Pursuant to Exchange Rule 1807, exercise limits for impacted index and ETF classes would be equal to the applicable position limits.

on the Options Price Reporting Authority (''OPRA'') and the Exchange's quoting capacity. The Exchange represents it has the necessary systems capacity to support new options series that will result from the introduction of Monthly Options Series.

The Exchange also proposes to amend Exchange Rules 1804(d) and 1805(d) to provide that positions in Monthly Options Series will be aggregated with positions in options contracts on the same underlying security or index.[15] This is consistent with how position (and exercise) limits are currently imposed on series with other expirations (Short Term Options Series and Quarterly Options Series). Therefore, positions in options within class of index or ETF options, regardless of their expirations, would continue to be subject to existing position (and exercise) limits. The Exchange believes this will address potential manipulative schemes and adverse market impacts surrounding the use of options.

The Exchange also represents its current surveillance programs will apply to Monthly Options Series and will properly monitor trading in the proposed Monthly Options Series. The Exchange currently lists Quarterly Options Series in certain ETF classes [16], which expire at the close of business at the end of four calendar months (*i.e.,* the end of each calendar quarter), and has not experienced any market disruptions nor issues with capacity. The Exchange's surveillance programs currently in place to support and properly monitor trading in these Quarterly Options Series, as well as Short Term Options Series and standard expiration series, will apply to the proposed Monthly Options Series. The Exchange believes its surveillances continue to be designed to deter and detect violations of its Rules, including position and exercise limits and possible manipulative behavior, and these surveillances will apply to Monthly Options Series that the Exchange determines to list for trading. Ultimately, the Exchange does not believe the proposed rule change raises any unique regulatory concerns because existing safeguards—such as position and exercise limits (and the aggregation of options overlying the same index or ETF) and reporting requirements—would continue to apply.

[15] *See* proposed Exchange Rules 1804(d) (regarding position limits for broad-based index options) and 1805(d) (regarding position limits for industry index options).

[16] The Exchange notes it currently lists quarterly expirations on certain ETF options pursuant to Interpretation and Policy .03 to Exchange Rule 404.

The Exchange notes that the proposed rule change is substantively identical to the proposed rule changes recently filed by the Cboe Exchange, Inc. (''Cboe'').[17] The Exchange notes that MIAX Chapters IV and XVIII are incorporated by reference into the rulebook of the Exchange's affiliate, MIAX Emerald, LLC (''Emerald''). As such, the amendments to MIAX Chapters IV and XVIII proposed herein will also apply to MIAX Emerald Chapters IV and XVIII.

2. Statutory Basis

The Exchange believes the proposed rule change is consistent with the Act and the rules and regulations thereunder applicable to the Exchange and, in particular, the requirements of Section 6(b) of the Act.[18] Specifically, the Exchange believes the proposed rule change is consistent with the Section 6(b)(5) [19] requirements that the rules of an exchange be 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. Additionally, the Exchange believes the proposed rule change is consistent with the Section 6(b)(5) [20] requirement that the rules of an exchange not be designed to permit unfair discrimination between Members, issuers, brokers, or dealers.

In particular, the Exchange believes the introduction of Monthly Options Series will remove impediments to and perfect the mechanism of a free and open market and a national market system by expanding hedging tools available to market participants. The Exchange believes the proposed monthly expirations will allow market participants to transact in the index and ETF options listed pursuant to the proposed rule change based on their timings as needed and allow them to tailor their investment and hedging needs more effectively. Further, the Exchange believes the availability of Monthly Options Series would protect investors and the public interest by providing investors with more flexibility to closely tailor their investment and hedging decisions in these options, thus allowing them to better manage their risk exposure.

The Exchange believes the Quarterly Options Series Program has been successful to date and the proposed Monthly Options Series program simply expands the ability of investors to hedge risk against market movements stemming from economic releases or market events that occur at month's end in the same way the Quarterly Options Series Program has expanded the landscape of hedging for quarter-end news. Monthly Options Series will also complement Short Term Options Series, which will allow investors to hedge risk against events that occur throughout a month. The Exchange believes the availability of additional expirations should create greater trading and hedging opportunities for investors, as well as provide investors with the ability to tailor their investment objectives more effectively.

The Exchange notes the proposed terms of Monthly Options Series, including the limitation to five index and ETF option classes, are substantively the same as the current terms of Quarterly Options Series.[21] Quarterly Options Series expire on the last business day of a calendar quarter, which is the last business day of every third month. The proposed Monthly Options Series would fills the gaps between Quarterly Options Series expirations by permitting series to expire on the last business day of every month, rather than every third month. The proposed Monthly Options Series may be listed in accordance with the same terms as Quarterly Options Series, including permissible strikes. As is the case with Quarterly Options Series, no Short Term Options Series may expire on the same day as a Monthly Options Series. Similarly, as proposed, no Monthly Options Series may expire on the same day as a Quarterly Options Series. The Exchange believes preventing listing series with concurrent expirations in a class will eliminate potential investors confusion and thus protect investors and the public interest. Given that Quarterly Options Series the Exchange currently lists are essentially Monthly Options Series that can expire at the end of only certain calendar months, the Exchange believes it is reasonable to list Monthly Options Series in accordance with the same terms, as it will promote just and equitable principles of trade. The Exchange believes limiting Monthly Options Series to five classes will

[17] *See* supra note 4.

[18] 15 U.S.C. 78f(b).

[19] 15 U.S.C. 78f(b)(5).

[20] *Id.*

[21] *Compare* proposed Interpretation and Policy .13 Exchange Rule 404 *to* Interpretation and Policy .03 to Exchange Rule 404.

ensure the addition of these new series will have a negligible impact on the Exchange and OPRA's quoting capacity. The Exchange represents it has the necessary systems capacity to support new options series that will result from the introduction of Monthly Options Series.

The Exchange further believes the proposed rule change regarding the treatment of Monthly Options Series with respect to determining compliance with position and exercise limits is designed to prevent fraudulent and manipulative acts and practices and promote just and equitable principles of trade. Monthly Options Series will be aggregated with options overlying the same ETF or index for purposes of compliance with position (and exercise) limits, which is consistent with how position (and exercise) limits are currently imposed on series with other expirations (Short Term Options Series and Quarterly Options Series). Therefore, options positions within ETF or index option classes for which Monthly Options Series are listed, regardless of their expirations, would continue to be subject to existing position (and exercise) limits. The Exchange believes this will address potential manipulative schemes and adverse market impacts surrounding the use of options. The Exchange also represents its current surveillance programs will apply to Monthly Options Series and will properly monitor trading in the proposed Monthly Options Series. As mentioned above, the Exchange currently trades Quarterly Options Series in certain ETF classes, which expire at the close of business at the end of three calendar months (*i.e.,* the end of each calendar quarter), and has not experienced any market disruptions nor issues with capacity. The Exchange's surveillance programs currently in place to support and properly monitor trading in these Quarterly Options Series, as well as Short Term Options Series, and standard expiration series, will apply to the proposed Monthly Options Series. The Exchange believes its surveillances continue to be designed to deter and detect violations of its Rules, including position and exercise limits and possible manipulative behavior, and these surveillances will apply to Monthly Options Series that the Exchange determines to list for trading. Ultimately, the Exchange does not believe the proposed rule change raises any unique regulatory concerns because existing safeguards—such as position and exercise limits (and the aggregation of options overlying the same ETF or index) and reporting requirements—would continue to apply.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

Written comments were neither solicited nor received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The Exchange has filed the proposed rule change pursuant to Section 19(b)(3)(A)(iii) of the Act[22] and Rule 19b–4(f)(6) thereunder.[23] Because the foregoing proposed rule change does not: (i) significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative for 30 days from the date on which it was filed, or such shorter time as the Commission may designate, it has become effective pursuant to Section 19(b)(3)(A)(iii) of the Act[24] and subparagraph (f)(6) of Rule 19b–4 thereunder.[25]

A proposed rule change filed pursuant to Rule 19b–4(f)(6) under the Act[26] normally does not become operative for 30 days after the date of its filing. However, Rule 19b–4(f)(6)(iii)[27] permits the Commission to designate a shorter time if such action is consistent with the protection of investors and the public interest. The Exchange has requested that the Commission waive the 30-day operative delay so that the Exchange may immediately list Monthly Options Series, thereby providing an additional market to investors, which the Exchange believes will benefit investors by promoting competition in Monthly Options Series. The Commission notes that it recently approved Cboe's substantially similar proposal.[28] The Commission believes that the proposed rule change presents no novel issues and that waiver of the 30-day operative delay is consistent with the protection of investors and the public interest. Accordingly, the Commission hereby waives the operative delay and designates the proposed rule change operative upon filing.[29]

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 (*https://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include file number SR–MIAX–2023–44 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–MIAX–2023–44. 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 (*https://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,

[22] 15 U.S.C. 78s(b)(3)(A)(iii).

[23] 17 CFR 240.19b–4(f)(6).

[24] 15 U.S.C. 78s(b)(3)(A)(iii).

[25] 17 CFR 240.19b–4(f)(6). In addition, Rule 19b–4(f)(6)(iii) requires a self-regulatory organization to give the Commission written notice of its intent to file the proposed rule change, along with a brief description and text of the proposed rule change, at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.

[26] 17 CFR 240.19b–4(f)(6).

[27] 17 CFR 240.19b–4(f)(6)(iii).

[28] *See* supra note 4.

[29] For purposes only of waiving the 30-day operative delay, the Commission has also considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

Washington, DC 20549, on official business days between the hours of 10 a.m. and 3 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. Do not include personal identifiable information in submissions; you should submit only information that you wish to make available publicly. We may redact in part or withhold entirely from publication submitted material that is obscene or subject to copyright protection. All submissions should refer to file number SR–MIAX–2023–44 and should be submitted on or before December 13, 2023.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[30]

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2023–25779 Filed 11–21–23; 8:45 am]

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SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–98963; File No. SR–NYSEAMER–2023–59]

Self-Regulatory Organizations; NYSE American LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend the Connectivity Fee Schedule

November 16, 2023.

Pursuant to Section 19(b)(1)[1] of the Securities Exchange Act of 1934 (''Act'')[2] and Rule 19b–4 thereunder,[3] notice is hereby given that on November 9, 2023, 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 Connectivity Fee Schedule (''Fee Schedule'') regarding colocation services and fees to provide Users with wireless connectivity to CME Group market data. The proposed rule change is available on the Exchange's website at *www.nyse.com,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of those statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant parts of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend the Connectivity Fee Schedule (''Fee Schedule'') regarding colocation services and fees to provide Users[4] with wireless connectivity to CME Group market data.[5]

The Exchange currently provides Users with wireless connections to eight market data feeds or combinations of feeds from third-party markets (the ''Existing Third Party Data''),[6] and wired connections to more than 45 market data feeds or combinations of feeds.[7] The Exchange proposes to add to the Fee Schedule wireless connections to CME Group, Inc. (''CME Group'') market data (''CME Group Data'' and, together with the Existing Third Party Data, the ''Third Party Data''). Users would be offered the proposed wireless connection to the CME Group Data through connections into the colocation center in the Mahwah, New Jersey data center (''MDC'').[8]

The Exchange expects that the proposed rule change would become operative in the fourth quarter of 2023, and in any event, no later than December 31, 2023. The Exchange will announce the date that the wireless connection to the CME Group Data will be available through a customer notice.

To receive CME Group Data, the User would enter into an agreement with a third party for permission to receive the data, if required. The User would pay this third party any fees for the data content.

The Exchange proposes to revise the Fee Schedule to reflect fees related to the wireless connection to CME Group Data. For each wireless connection to CME Group Data, a User would be charged a $5,000 non-recurring initial charge and a monthly recurring charge of $6,000. If a User were to purchase more than one wireless connection to CME Group Data, it would pay more than one non-recurring initial charge. Each proposed wireless connection would include the use of one port for connectivity to CME Group Data, and a User would not pay a separate fee for the use of such port.[9]

The Exchange's proposed wireless connectivity to CME Group market data would not include the entire CME Group market data feed, which includes market data for approximately 1,200 futures symbols. Wireless bandwidth capacity is a small fraction of the capacity required to transport the full CME Group feed. Accordingly, FIDS has consulted with customers about which of the CME Group symbols they would like to be available wirelessly and plans to offer connectivity to a subgroup of symbols based on this customer feedback. The Exchange understands

[30] 17 CFR 200.30–3(a)(12), (59).

[1] 15 U.S.C. 78s(b)(1).

[2] 15 U.S.C. 78a.

[3] 17 CFR 240.19b–4.

[4] For purposes of the Exchange's colocation services, a ''User'' means any market participant that requests to receive colocation services directly from the Exchange. *See* Securities Exchange Act Release No. 76009 (September 29, 2015), 80 FR 60213 (October 5, 2015) (SR–NYSEMKT–2015–67). As specified in the Fee Schedule, a User that incurs colocation fees for a particular colocation service pursuant thereto would not be subject to colocation fees for the same colocation service charged by the Exchange's affiliates the New York Stock Exchange LLC, NYSE Arca, Inc., NYSE Chicago, Inc., and NYSE National, Inc. (together, the ''Affiliate SROs''). Each Affiliate SRO has submitted substantially the same proposed rule change to propose the changes described herein. *See* SR–NYSE–2023–44, SR–NYSEARCA–2023–79, SR–NYSECHX–2023–22, and SR–NYSENAT–2023–26.

[5] The Exchange filed a similar proposal in 2021, which it subsequently withdrew. *See* Securities Exchange Act Release No. 93810 (December 17, 2021), 86 FR 73026 (December 23, 2021) (SR–NYSE–2021–67, SR–NYSEAMER–2021–43, SR–NYSEARCA–2021–97, SR–NYSECHX–2021–17, SR–NYSENAT–2021–23).

[6] *See* Securities Exchange Act Release Nos. 76748 (December 23, 2015), 80 FR 81648 (December 30, 2015) (SR–NYSEMKT–2015–85); 78376 (July 21, 2016), 81 FR 49311 (July 27, 2016) (SR–NYSEMKT–2016–17); and 80117 (February 28, 2017), 82 FR 12646 (March 6, 2017) (SR–NYSEMKT–2017–09).

[7] *See* Securities Exchange Act Release No. 80309 (March 24, 2017), 82 FR 15725 (March 30, 2017) (SR–NYSEMKT–2016–63).

[8] Through its Fixed Income and Data Services (''FIDS'') (previously ICE Data Services) business, Intercontinental Exchange, Inc. (''ICE'') operates the MDC. The Exchange and the Affiliate SROs are indirect subsidiaries of ICE. The proposed service would be provided by FIDS pursuant to an agreement with a non-ICE entity. FIDS does not own the wireless network that would be used to provide the service.

[9] If a User also connects to Existing Third Party Data, it would not be able to connect to such Existing Third Party Data using the same port that it uses for connectivity to CME Group Data.

that Quincy Data LLC (''Quincy''),[10] a third party that already provides wireless connectivity to CME Group market data in the MDC, similarly provides wireless connectivity to a subset of CME Group market data based on customer demand for particular symbols.[11]

Application and Impact of the Proposed Changes

The proposed changes would not apply differently to distinct types or sizes of market participants. Rather, they would apply to all Users equally.

As is currently the case, the purchase of any colocation service, including connectivity to Third Party Data, is completely voluntary and the Fee Schedule is applied uniformly to all Users.

Competitive Environment

The Exchange operates in a highly competitive market in which other vendors offer colocation services as a means to facilitate the trading and other market activities of those market participants who believe that colocation enhances the efficiency of their operations. The Commission has repeatedly expressed its preference for competition over regulatory intervention in determining prices, products, and services in the securities markets. Specifically, in Regulation NMS, the Commission highlighted the importance of market forces in determining prices and SRO revenues and, also, recognized that current regulation of the market system ''has been remarkably successful in promoting market competition in its broader forms that are most important to investors and listed companies.'' [12]

As explained below in this filing, the Exchange's proposed wireless connection to CME Group Data would compete with the wireless connection to CME Group market data provided by Quincy. Third-party vendors such as Quincy are not at any competitive disadvantage created by the Exchange.

The proposed change is not otherwise intended to address any other issues relating to colocation services or related fees, and the Exchange is not aware of any problems that Users would have in complying with the proposed change.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with Section 6(b) of the Act,[13] in general, and furthers the objectives of Section 6(b)(5) of the Act,[14] 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. The Exchange further believes that the proposed rule change is consistent with Section 6(b)(4) of the Act,[15] because it provides for the equitable allocation of reasonable dues, fees, and other charges among its members and issuers and other persons using its facilities and does not unfairly discriminate between customers, issuers, brokers, or dealers.

The Proposed Change Is Reasonable

The Exchange believes that the proposed rule change is reasonable. In considering the reasonableness of proposed services and fees, the Commission's market-based test considers ''whether the exchange was subject to significant competitive forces in setting the terms of its proposal . . . , including the level of any fees.'' [16] If the Exchange meets that burden, ''the Commission will find that its proposal is consistent with the Act unless 'there is a substantial countervailing basis to find that the terms' of the proposal violate the Act or the rules thereunder.'' [17] Here, the Exchange is subject to significant competitive forces in setting the terms on which it offers its proposal, in particular because substantially similar substitutes are available, and the Exchange has not placed the third party vendors at a competitive disadvantage created by the Exchange.

Substantially Similar Substitutes Are Available

The Exchange's proposed wireless connection to CME Group Data would compete with other methods by which both the Exchange and various third parties already provide connectivity to CME Group market data to Users.

Quincy already provides wireless connectivity to CME Group market data in the MDC. Like the Exchange's proposed wireless connectivity, Quincy's wireless connectivity to CME Group market data includes a similarly-sized subset of symbols that almost completely overlaps with the symbols for which the Exchange proposes to provide wireless connectivity—presumably because customers have requested the same symbols of each provider. Specifically, like the Quincy wireless connection, the Exchange's proposed wireless connection would include the main futures for equity indices, government bonds, foreign exchanges, oil, and precious metals.[18] In addition, the Exchange's proposed wireless connection would also include several additional symbols that proposed Users have specifically requested be included. The Exchange plans to continuously monitor Users' preferences and their views of the usefulness of the included symbols, and may adjust them accordingly. The Exchange believes that the Quincy wireless connection to CME Group market data is at a same or similar speed as the Exchange's proposed connection, and at a similar price.[19]

Accordingly, the Quincy wireless connection to CME Group market data would compete with the Exchange's proposed wireless connection, and would exert significant competitive forces on the Exchange in setting the terms of its proposal, including the level

[10] The Exchange understands that Quincy is an affiliate of McKay Brothers LLC.

[11] The Exchange understands that the third parties that provide wireless connectivity to CME Group market data to the MDC and other data centers in New Jersey (as discussed later in this filing) follow a substantially similar model, offering wireless connectivity to a selection of market data rather than to entire feeds.

[12] *See* Securities Exchange Act Release No. 51808 (June 9, 2005), 70 FR 37496, 37499 (June 29, 2005).

[13] 15 U.S.C. 78f(b).

[14] 15 U.S.C. 78f(b)(5).

[15] 15 U.S.C. 78f(b)(4).

[16] *See* Securities Exchange Act Release No. 90209 (October 15, 2020), 85 FR 67044, 67049 (October 21, 2020) (Order Granting Accelerated Approval to Establish a Wireless Fee Schedule Setting Forth Available Wireless Bandwidth Connections and Wireless Market Data Connections) (SR–NYSE–2020–05, SR–NYSEAMER–2020–05, SR–NYSEArca–2020–08, SR–NYSECHX–2020–02, SR–NYSENAT–2020–03, SR–NYSE–2020–11, SR–NYSEAMER–2020–10, SR–NYSEArca–2020–15, SR–NYSECHX–2020–05, SR–NYSENAT–2020–08) (''Wireless Approval Order''), citing Securities Exchange Act Release No. 59039 (December 2, 2008), 73 FR 74770, 74781 (December 9, 2008) (''2008 ArcaBook Approval Order''). *See NetCoalition* v. *SEC,* 615 F.3d 525 (D.C. Cir. 2010).

[17] *See* Wireless Approval Order, *supra* note 16, at 67049, citing 2008 ArcaBook Approval Order, *supra* note 16, at 74781.

[18] Quincy's symbol list for wireless connectivity to CME Group data is available at *https://www.quincy-data.com/product-page/* under the heading ''2023 Quincy Extreme Data Symbol Set/North America QED Symbol Set.'' The Exchange understands that the Quincy wireless connection to CME Group data currently includes 26 symbols. The Exchange's proposed wireless connection to CME Group data would contain a similar number of symbols, nearly all of which are included in the Quincy wireless connection.

[19] Because Quincy is not a regulated entity, it is not obligated to make its latency figures or fees publicly available or the same for all entities.

of the Exchange's proposed fees.[20] If the Exchange were to set its proposed fees too high, Users could respond by instead selecting Quincy's substantially similar wireless connectivity to CME Group data.[21]

Third Party Competitors Are Not at a Competitive Disadvantage Created by the Exchange

The Exchange does not believe that FIDS would have any competitive advantage over either the existing third-party provider or any future providers of wireless connectivity to CME Group market data. The Exchange's proposed service for connectivity to CME Group Data does not have any special access to or advantage within the MDC. The Exchange's proposed wireless connection would lead to a pole, from which a fiber connection would lead into the MDC. The pole is owned by a third party and is not on the grounds of the MDC, and the path into the MDC through a meet-me-room is available to any telecommunications provider. Within the MDC, the proposed connection would follow the same route as that of any User, connecting to equipment in colocation and then to any Users that are customers.

Further, all distances in the MDC are normalized and Exchange rules require that the distance from the Patch Panel Point to each User cabinet in colocation be the same.[22] Every provider of wireless connectivity to Users, including FIDS, is connected to the Patch Panel Point, and the length of the fiber path from the Patch Panel Point to each User cabinet in colocation is the same.

Nor does the Exchange have a competitive advantage over the third-party competitors offering wireless connectivity to CME Group market data by virtue of the fact that it owns and operates the MDC's meet-me-rooms. Users purchasing wireless connectivity to CME Group market data—like Users of any other colocation service—would require a circuit connecting out of the MDC, and in most cases, such circuits are provided by third-party telecommunications service providers that have installed their equipment in the MDC's two meet-me-rooms (''Telecoms'').[23] Currently, 16 Telecoms operate in the meet-me-rooms and provide a variety of circuit choices. It is in the Exchange's best interest to set the fees that Telecoms pay to operate in the meet-me-rooms at a reasonable level [24] so that market participants, including Telecoms, will maximize their use of the MDC. By setting the meet-me-room fees at a reasonable level, the Exchange encourages Telecoms to participate in the meet-me-rooms and to sell circuits to Users for connecting into and out of the MDC. These Telecoms then compete with each other by pricing such circuits at competitive rates. These competitive rates for circuits help draw in more Users and Hosted Customers to the MDC, which directly benefits the Exchange by increasing the customer base to whom the Exchange can sell its colocation services, which include cabinets, power, ports, and connectivity to many third-party data feeds, and because having more Users and Hosted Customers leads, in many cases, to greater participation on the Exchange. In this way, by setting the meet-me-room fees at a level attractive to telecommunications firms, the Exchange spurs demand for all of the services it sells at the MDC, while setting the meet-me-room fees too high would negatively affect the Exchange's ability to sell its services at the MDC.[25] Accordingly, there are real constraints on the meet-me-room fees the Exchange charges, such that the Exchange does not have an advantage in terms of costs when compared to third parties that enter the MDC through the meet-me-rooms to provide services to compete with the Exchange's services.

If anything, the Exchange is subject to a competitive disadvantage vis-à-vis third-party competitors offering wireless connectivity to CME Group market data. Third-party competitors are not subject to the Commission's filing requirements, and therefore can freely change their services and pricing in response to competitive forces. In contrast, the Exchange's service and pricing would be standardized as set out in this filing, and the Exchange would be unable to respond to pricing pressure from its competitors without seeking a formal fee change in a filing before the Commission.

In sum, because the Exchange is subject to significant competitive forces in setting the terms on which it offers its proposal, in particular because a substantially similar substitute is available, and the Exchange has not placed the third-party vendors at a competitive disadvantage created by the Exchange, the proposed fees for the Exchange's wireless connectivity to CME Group Data are reasonable.[26] If the Exchange were to set its prices for wireless connectivity to CME Group Data at a level that Users found to be too high, Users could easily choose to connect to CME Group market data in colocation at the MDC through the competing Quincy wireless connection, as detailed above.

Additional Considerations

The Exchange believes that it is reasonable for the proposed wireless connection to CME Group Data not to transport information for all of the symbols included in CME Group data feeds to the MDC, but rather to transport a subset of that data. Wireless bandwidth capacity is a small fraction of the capacity required to transport the full CME Group feed. The Exchange believes it is reasonable for FIDS to select the symbols it will make available for wireless connectivity based on customer input and demand. The Exchange understands that Quincy similarly provides wireless connectivity to a subset of CME Group market data based on customer demand for particular symbols.

The Exchange believes that it is reasonable that a User that connects to both CME Group Data and Existing Third Party Data may not use the same port for connectivity to both, and so would have at least two ports, because the proposed wireless connection would include the use of one port for connectivity to CME Group Data, and the connectivity to the Existing Third Party Data includes the use of one port for connectivity to Existing Third Party Data. A User would not pay a separate fee for using such ports.

[20] *See* 2008 ArcaBook Approval Order, *supra* note 16, at 74789 and n.295 (recognizing that products need not be identical to be substitutable).

[21] In addition, the Exchange believes that at least two third-party market participants, in addition to FIDS, offer fiber connections to CME Group market data in colocation. *See* Securities Exchange Act Release No. 81015 (June 23, 2017), 82 FR 29610 (June 29, 2017) (SR–NYSEMKT–2017–32). Unlike the proposed wireless connectivity, FIDS' fiber connection to CME Group market data includes the entire CME Group data feed, instead of a subset of symbols.

[22] *See* NYSE Rule 3.13(c), NYSE American Rule 3.13E(c), NYSE Arca Rule 3.13(c), NYSE Chicago Rule 3.13(c), and NYSE National Rule 3.13(c) (Data Center Pole Restrictions—Connectivity to Co-Location Space). ''Patch Panel Point'' is defined as ''the patch panel where fiber connections for wireless services connect to the network row in the space used for co-location in the Data Center.'' *Id.* The proposed service would not use the MDC pole, so Rule 3.13(b) would not apply.

[23] Note that in the case of wireless connectivity, a User in colocation still requires a fiber circuit to transport data. If a Telecom is used, the data is transmitted wirelessly to the relevant pole, and then from the pole to the meet-me-room using a fiber circuit.

[24] *See* Securities Exchange Act Release No. 97999 (July 26, 2023), 88 FR 50190 (August 1, 2023) (SR–NYSEAMER–2023–36) (''MMR Notice'').

[25] *See id.* at 50193. Importantly, the Exchange is prevented from making any alteration to its meet-me-room services or fees without filing a proposal for such changes with the Commission.

[26] *See* Wireless Approval Order, *supra* note 16.

The Proposed Change Is an Equitable Allocation of Fees and Credits

The Exchange believes that its proposal equitably allocates its fees among Users. Without this proposed rule change, Users would have fewer options for connectivity to CME Group market data. The proposed change would provide Users with an additional choice with respect to the form and optimal latency of the connectivity they use to receive CME Group market data, allowing a User to select the connectivity that better suits its needs, helping it tailor its colocation operations to the requirements of its business operations. Users that do not opt to utilize the Exchange's proposed wireless connection would still be able to obtain CME Group market data wirelessly using Quincy's wireless connection.

The Exchange believes that the proposed change is equitable because it will result in fees being charged only to Users that voluntarily select to receive the corresponding services and because those services will be available to all Users. Furthermore, the Exchange believes that the services and fees proposed herein are equitably allocated because, in addition to the services being completely voluntary, they are available to all Users on an equal basis (*i.e.,* the same products and services are available to all Users). All Users that voluntarily select the Exchange's proposed wireless connections to CME Group Data would be charged the same amount for the same services.

The Proposed Change Is Not Unfairly Discriminatory

The Exchange believes that the proposed rule change is not unfairly discriminatory, for the following reasons. Without this proposed rule change, Users would have fewer options for connectivity to CME Group Data. The proposed change would provide Users with an additional choice with respect to the form and optimal latency of the connectivity they use to receive CME Group market data, allowing a User to select the connectivity that better suits its needs, helping it tailor its colocation operations to the requirements of its business operations. Users that do not opt to utilize the Exchange's proposed wireless connection would still be able to obtain CME Group market data wirelessly using Quincy's wireless connection.

The Exchange believes that it is not unfairly discriminatory to not transport information for all of the symbols included in CME Group data feeds to the MDC, but rather to transport a subset of that data. There is limited bandwidth available on the wireless network to colocation, and there are a number of CME Group data feeds. Limiting the feeds to the selection of CME Group market data regarding securities for which FIDS determines there is demand would allow Users to receive the relevant CME Group Data over a wireless network.

The Exchange believes that the proposed change is not unfairly discriminatory because it will result in fees being charged only to Users that voluntarily select to receive the corresponding services and because those services will be available to all Users. Furthermore, the Exchange believes that the services and fees proposed herein are not unfairly discriminatory because, in addition to the services being completely voluntary, they are available to all Users on an equal basis (*i.e.,* the same products and services are available to all Users). All Users that voluntarily select wireless connections to CME Group Data would be charged the same amount for the same services. Users that opt to use wireless connections to CME Group Data would receive the CME Group Data that is available to all Users, as all market participants that contract with CME Group or its affiliate for CME Group Data, as required, may receive it.

For the reasons above, the proposed changes do not unfairly discriminate between or among market participants that are otherwise capable of satisfying any applicable colocation fees, requirements, terms, and conditions established from time to time by the Exchange.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange believes that the proposal will not impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of Section 6(b)(8) of the Act.[27]

The proposed change would not affect competition among national securities exchanges or among members of the Exchange, but rather between FIDS and its commercial competitors. The proposed wireless connection would provide Users with an alternative means of connectivity to CME Group Data. The proposed change would provide Users with an additional choice with respect to the form and optimal latency of the connectivity they use to receive CME Group market data, allowing a User to select the connectivity that better suits its needs, helping it tailor its colocation operations to the requirements of its business operations.

Users that do not opt to utilize the Exchange's proposed wireless connection would still be able to obtain CME Group market data wirelessly using Quincy's wireless connection. The Exchange's proposed wireless connection and the existing Quincy wireless connection to CME Group market data are sufficiently similar substitutes and thus provide market participants with choices to meet their wireless connectivity needs.

In addition, the Exchange does not believe that FIDS would have any competitive advantage over either the existing third-party provider or any future providers of wireless connectivity to CME Group market data. The Exchange's proposed service for connectivity to CME Group Data does not have any special access to or advantage within the MDC. The Exchange's proposed wireless connection would lead to a pole, from which a fiber connection would lead into the MDC. The pole is owned by a third party and is not on the grounds of the MDC, and the path into the MDC through a meet-me-room is the same path followed by any Telecom. Within the MDC, the proposed connection would follow the same route as that of any User, connecting to equipment in colocation and then to any Users that are customers.

Further, all distances in the MDC are normalized and Exchange rules require that the distance from the Patch Panel Point to each User cabinet in colocation be the same.[28] Every provider of wireless connectivity to Users, including FIDS, is connected to the Patch Panel Point, and the length of the fiber path from the Patch Panel Point to each User cabinet in colocation is the same.

Nor does the Exchange have a competitive advantage over the third-party competitors offering wireless connectivity to CME Group market data by virtue of the fact that it owns and operates the MDC's meet-me-rooms. Users purchasing wireless connectivity to CME Group market data—like Users of any other colocation service—would require a circuit connecting out of the MDC, and in most cases, such circuits are provided by third-party Telecoms that have installed their equipment in the MDC's two meet-me-rooms.[29] Currently, 16 Telecoms operate in the meet-me-rooms and provide a variety of circuit choices. It is in the Exchange's best interest to set the fees that

[27] 15 U.S.C. 78f(b)(8).

[28] *See supra* note 22.

[29] *See supra* note 23.

Telecoms pay to operate in the meet-me-rooms at a reasonable level [30] so that market participants, including Telecoms, will maximize their use of the MDC. By setting the meet-me-room fees at a reasonable level, the Exchange encourages Telecoms to participate in the meet-me-rooms and to sell circuits to Users for connecting into and out of the MDC. These Telecoms then compete with each other by pricing such circuits at competitive rates. These competitive rates for circuits help draw in more Users and Hosted Customers to the MDC, which directly benefits the Exchange by increasing the customer base to whom the Exchange can sell its colocation services, which include cabinets, power, ports, and connectivity to many third-party data feeds, and because having more Users and Hosted Customers leads, in many cases, to greater participation on the Exchange. In this way, by setting the meet-me-room fees at a level attractive to telecommunications firms, the Exchange spurs demand for all of the services it sells at the MDC, while setting the meet-me-room fees too high would negatively affect the Exchange's ability to sell its services at the MDC.[31] Accordingly, there are real constraints on the meet-me-room fees the Exchange charges, such that the Exchange does not have an advantage in terms of costs when compared to third parties that enter the MDC through the meet-me-rooms to provide services to compete with the Exchange's services.

If anything, the Exchange is subject to a competitive disadvantage vis-à-vis third party competitors offering wireless connectivity to CME Group market data. Third-party competitors are not subject to the Commission's filing requirements, and therefore can freely change their services and pricing in response to competitive forces. In contrast, the Exchange's service and pricing would be standardized as set out in this filing, and the Exchange would be unable to respond to pricing pressure from its competitors without seeking a formal fee change in a filing before the Commission.

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.

[30] *See* MMR Notice, *supra* note 24.

[31] *See supra* note 25.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The Exchange has filed the proposed rule change pursuant to Section 19(b)(3)(A)(iii) of the Act [32] and Rule 19b–4(f)(6) thereunder.[33] Because the 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 prior to 30 days from the date on which it was filed, or such shorter time as the Commission may designate, if consistent with the protection of investors and the public interest, the proposed rule change has become effective pursuant to Section 19(b)(3)(A) of the Act and Rule 19b–4(f)(6)(iii) thereunder.

A proposed rule change filed under Rule 19b–4(f)(6) [34] normally does not become operative prior to 30 days after the date of the filing. However, pursuant to Rule 19b–4(f)(6)(iii),[35] the Commission may designate a shorter time if such action is consistent with the protection of investors and the public interest.

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) [36] of the Act to determine whether the proposed rule change should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic comments

- Use the Commission's internet comment form (*https://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include file number SR–NYSEAMER–2023–59 on the subject line.

[32] 15 U.S.C. 78s(b)(3)(A)(iii).

[33] 17 CFR 240.19b–4(f)(6).

[34] 17 CFR 240.19b–4(f)(6).

[35] 17 CFR 240.19b–4(f)(6)(iii).

[36] 15 U.S.C. 78s(b)(2)(B).

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–2023–59. 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 (*https://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 a.m. and 3 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. Do not include personal identifiable information in submissions; you should submit only information that you wish to make available publicly. We may redact in part or withhold entirely from publication submitted material that is obscene or subject to copyright protection. All submissions should refer to file number SR–NYSEAMER–2023–59 and should be submitted on or before December 13, 2023.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[37]

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2023–25770 Filed 11–21–23; 8:45 am]

BILLING CODE 8011–01–P

[37] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–98976; File No. SR–NYSE–2023–42]

Self-Regulatory Organizations; New York Stock Exchange LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Expand the Application of the per User Access Fee for Use of Certain Market Data Products by Redistributors

November 16, 2023.

Pursuant to Section 19(b)(1) [1] of the Securities Exchange Act of 1934 (''Act'') [2] and Rule 19b–4 thereunder,[3] notice is hereby given that on November 1, 2023, 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 and II 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 fees for NYSE BBO and NYSE Trades by expanding the application of the Per User Access Fee. The Exchange proposes to implement the proposed fee change on November 1, 2023. 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.

[1] 15 U.S.C. 78s(b)(1).

[2] 15 U.S.C. 78a.

[3] 17 CFR 240.19b–4.

A. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to expand the application of the Per User Access Fee [4] for certain NYSE market data products, as set forth on the NYSE Proprietary Market Data Fee Schedule (''Fee Schedule''). Specifically, the Exchange proposes to expand the application of the Per User Access Fee, which is currently available for Redistributors [5] of NYSE BBO and NYSE Trades that subscribe to only such data feeds and do not subscribe to any other market data product listed on the Fee Schedule other than NYSE BQT and use such market data product for external distribution only. The Exchange proposes to make the Per User Access Fee available to Redistributors of NYSE OpenBook as well.

The proposed fee change, taken together with similar fee changes filed by the Exchange's affiliated exchanges, NYSE American LLC (''NYSE American'') and NYSE Arca, Inc. (''NYSE Arca''),[6] will reduce the fees associated with the NYSE BQT proprietary data product for Redistributors of NYSE OpenBook. As described below, NYSE BQT competes directly with similar products offered by both the Nasdaq and Cboe families of U.S. equity exchanges. Collectively, the proposed fee changes are intended to respond to the competition posed by similar products offered by the other exchange groups.

The Exchange proposes to implement the proposed fee change on November 1, 2023.

[4] The Per User Access Fee is a lower access fee that currently applies for subscribers of NYSE BBO and NYSE Trades that receive a data feed and use those market data products in a display-only format. *See* Fee Schedule. *See also* Securities Exchange Act Release Nos. 87803 (December 19, 2019), 84 FR 71505 (December 27, 2019) (SR–NYSE–2019–70) (Notice of Filing and Immediate Effectiveness of Proposed Rule Change, as Modified by Partial Amendment No. 1, To Amend the Fees for NYSE BBO and NYSE Trades) (''BQT Fee Reduction Filing''); and 90407 (November 12, 2020), 85 FR 73570 (November 18, 2020) (SR–NYSE–2020–91) (Notice of Filing and Immediate Effectiveness of Proposed Rule Change Amending the Fees for NYSE BBO and NYSE Trades by Modifying the Application of the Access Fee and Amending the Fees for NYSE Trades by Adopting a Waiver Applicable to the Redistribution Fee) (''Second BQT Fee Reduction Filing'').

[5] A Redistributor is a vendor or any other person that provides a NYSE data product to a data recipient or to any system that a data recipient uses, irrespective of the means of transmission or access.

[6] *See* SR–NYSEAMER–2023–57 and SR–NYSEArca–2023–78.

Background

The Securities and Exchange Commission (''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.'' [7]

While Regulation NMS has enhanced competition, it has also fostered a ''fragmented'' market structure where trading in a single stock can occur across multiple trading centers. When multiple trading centers compete for order flow in the same stock, the Commission has recognized that ''such competition can lead to the fragmentation of order flow in that stock.'' [8] Indeed, equity trading is currently dispersed across 16 exchanges,[9] numerous alternative trading systems,[10] and broker-dealer internalizers and wholesalers, all competing for order flow. Based on publicly-available information, no single exchange currently has more than 17% market share (whether including or excluding auction volume).[11]

With the NYSE BQT market data product, NYSE and its affiliates compete head to head with the Nasdaq Basic [12] and Cboe One Feed [13] market data

[7] *See* Securities Exchange Act Release No. 51808 (June 9, 2005), 70 FR 37495, 37499 (June 29, 2005) (S7–10–04) (Final Rule) (''Regulation NMS Adopting Release'').

[8] *See* Securities Exchange Act Release No. 61358, 75 3594, 3597 (January 21, 2010) (File No. S7–02–10) (Concept Release on Equity Market Structure).

[9] *See* Cboe U.S. Equities Market Volume Summary, available at *http://markets.cboe.com/us/equities/market_share/.*

[10] *See* FINRA ATS Transparency Data, *available at https://otctransparency.finra.org/otctransparency/AtsIssueData.* A list of alternative trading systems registered with the Commission is *available at https://www.sec.gov/foia/docs/atslist.htm.*

[11] *See* Cboe U.S. Equities Market Volume Summary, available at *http://markets.cboe.com/us/equities/market_share/.*

[12] As described on the Nasdaq website, available here: *http://www.nasdaqtrader.com/Trader.aspx?id=nasdaqbasic,* Nasdaq Basic is a ''low cost alternative'' that provides ''Best Bid and Offer and Last Sale information for all U.S. exchange-listed securities based on liquidity within the Nasdaq market center, as well as trades reported to the FINRA Trade Reporting Facility (''TRF'').''

[13] As described on the Cboe website, available here: *https://markets.cboe.com/us/equities/market_data_services/cboe_one/,* the Cboe One Feed is a ''market data product that provides cost-effective, high-quality reference quotes and trade data for market participants looking for comprehensive,

products. Similar to those market data products, NYSE BQT, which was established in 2014,[14] consists of certain elements from the NYSE BBO and NYSE Trades market data products as well as from market data products from the Exchange's affiliates, NYSE American, NYSE Arca, NYSE Chicago, Inc. (''NYSE Chicago''),[15] and NYSE National, Inc. (''NYSE National'').[16] Similar to both Nasdaq Basic and the Cboe One Feed, NYSE BQT provides investors with a unified view of comprehensive last sale and BBO data in all Tape A, B, and C securities that trade on the Exchange, NYSE American, NYSE Arca, NYSE Chicago, and NYSE National. Also similar to Nasdaq Basic and the Cboe One Feed, NYSE BQT is not intended to be used for purposes of making order-routing or trading decisions, but rather provides indicative prices for Tape A, B, and C securities.[17]

Together with NYSE American and NYSE Arca, the Exchange proposes to compete for subscribers to NYSE BQT by designing the proposed fee change to be attractive to Redistributors of NYSE OpenBook that intend to subscribe to and externally redistribute NYSE BQT. Currently, Redistributors of NYSE OpenBook that want to subscribe to and redistribute NYSE BQT must pay the General Access Fee. Redistributors of NYSE OpenBook who have data recipient customers interested in NYSE BQT may not be inclined to subscribe to NYSE BQT. When Redistributors do not subscribe to NYSE BQT, the prospective data recipients that are the customers of such Redistributors ae unable to subscribe to NYSE BQT. The proposed fee change is designed to provide a financial incentive for such Redistributors to subscribe to NYSE BQT so that their customers, which have expressed an interest in subscribing to NYSE BQT, would be able to access the product via such Redistributors.

Currently, subscribers of each of the NYSE BBO and NYSE Trades products that receive a data feed pay a General Access Fee of $1,500 per month. In February 2020, the Exchange added the Per User Access Fee, which is a reduced fee of $100 per month available at that time only for subscribers of NYSE BBO and NYSE Trades that use those products in a display-only format, including for internal use for Professional Users and external distribution to both Professional and Non-Professional Users.[18]

In November 2020, the Exchange expanded the application of the reduced Per User Access Fee to Redistributors of NYSE BBO and NYSE Trades data feeds that do not subscribe to any other market data product listed on the Fee Schedule other than NYSE BQT and use such market data products for external distribution only.[19]

As noted above, the Exchange now proposes to further expand the applicability of the reduced Per User Access Fee. Specifically, the Exchange proposes that Redistributors of NYSE BBO and NYSE Trades that do not subscribe to any other market data product listed on the Fee Schedule other than NYSE BQT and/or NYSE OpenBook, and use such market data products for external distribution only, would be eligible for the reduced Per User Access Fee. A Redistributor that receives such data feeds and uses the market data products for any other purpose (such as internal use) would continue to pay the $1,500 per month General Access Fee. And, as currently set forth in footnote 8 to the Fee Schedule, a subscriber would be charged only one access fee for each of the NYSE BBO and NYSE Trades products, depending on the use of that product.

To effect this change, the Exchange proposes to modify footnote 8 to the Fee Schedule as follows (proposed text italicized, proposed deletions bracketed):

The Per User Access Fee is charged to: (i) a subscriber that receives a data feed and uses the market data product only for Professional Users and Non-Professional Users in a display-only format, including for internal use and external redistribution in a display-only format, and (ii) a Redistributor that subscribes [only] to the NYSE BBO and NYSE Trades data feeds, and does not subscribe to any other Products listed on this Fee Schedule other than NYSE BQT *and/or the NYSE OpenBook data feed,* and uses these market data products for external distribution only. A subscriber that receives a data feed and uses the market data product for any other purpose, including if combined with Per User use, will be charged the General Access Fee. A subscriber will be charged only one access fee for each of the NYSE BBO and NYSE Trades products, depending on the use of that product.

The proposed rule change would result in lower fees for Redistributors that receive NYSE BBO, NYSE Trades, and NYSE OpenBook data feeds, and use such market data products for external distribution only.[20] The Exchange believes that the proposed expansion of the reduced Per User Access Fee would provide an incentive for Redistributors that currently subscribe to NYSE OpenBook to also subscribe to the NYSE BQT data feeds so that such product would be available to their customers, which have expressed an interest in subscribing to NYSE BQT.

The proposed rule change is intended to encourage greater use of NYSE BQT by making it more affordable for Redistributors that subscribe to NYSE OpenBook and also have customers interested in subscribing to NYSE BQT. The proposed fee change would allow the Exchange to compete more effectively with Nasdaq Basic and Cboe One Feed by expanding the number of Redistributors that would subscribe to NYSE BQT, and therefore make the product more widely available to data subscribers interested in NYSE BQT.

Applicability of Proposed Rule Change

As noted above, the proposed rule change is designed to reduce the overall cost for Redistributors of NYSE BQT that also redistribute NYSE OpenBook by expanding the applicability of the Per User Access Fee. Today, the Exchange has thirty-one data feed subscribers, two of whom became Redistributors as a direct result of the Second BQT Fee Reduction Filing and currently pay the reduced Per User Access Fee. The Exchange believes that the proposed rule change would provide a further incentive for Redistributors that already subscribe to NYSE OpenBook to subscribe to NYSE BQT for purposes of providing external distribution of NYSE BQT to potential data recipients interested in the product.

real-time market data'' and provides a ''unified view of the market from all four Cboe equity exchanges: BZX Exchange, BYX Exchange, EDGX Exchange, and EDGA Exchange.''

[14] *See* Securities Exchange Act Release Nos. 72750 (August 4, 2014), 79 FR 46494 (August 8, 2014) (notice—NYSE BQT); and 73553 (November 6, 2014), 79 FR 67491 (November 13, 2014) (approval order—NYSE BQT) (SR–NYSE–2014–40) (''NYSE BQT Filing'').

[15] In 2019, NYSE BQT was amended to include NYSE Chicago BBO and NYSE Chicago Trades. *See* Securities Exchange Act Release No. 87511 (November 12, 2019), 84 FR 63689 (November 18, 2019) (SR–NYSE–2019–60).

[16] In 2018, NYSE BQT was amended to include NYSE National BBO and NYSE National Trades. *See* Securities Exchange Act Release No. 83359 (June 1, 2018), 83 FR 26507 (June 7, 2018) (SR–NYSE–2018–22).

[17] *See* NYSE BQT Filing, *supra* note 14.

[18] *See* BQT Fee Reduction Filing, *supra,* note 4.

[19] *See* Second BQT Fee Reduction Filing, *supra,* note 4.

[20] The Per User Access Fee is 93% lower than the General Access Fee. Together with the corresponding proposed rule changes by NYSE American and NYSE Arca to similarly reduce the access fees to their BBO and Trades products for Redistributors, such Redistributors would be eligible for significantly lower access fees for NYSE BQT, from $6,250 per month to $850 per month ($250 + $200 + $200 +$200), a reduction of more than 86%.

Because the proposed rule change is targeted to potential Redistributors of NYSE BQT that also subscribe to NYSE OpenBook, the proposed change to the availability of the NYSE BBO and NYSE Trades Per User Access Fees, together with the proposed changes on NYSE American and NYSE Arca, are narrowly tailored with that purpose in mind. Accordingly, this proposed fee change is not designed for Redistributors that are existing customers of NYSE market data products (other than NYSE OpenBook) or that engage in internal use of NYSE BQT. This proposed rule change would not result in any changes to the market data fees for NYSE BBO and NYSE Trades for such data subscribers.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with the provisions of Section 6 of the Act,[21] in general, and Sections 6(b)(4) and 6(b)(5) of the Act,[22] in particular, in that it provides an equitable allocation of reasonable fees among users and recipients of the data and is not designed to permit unfair discrimination among customers, issuers, and brokers.

The Proposed Rule Change Is Reasonable

In adopting Regulation NMS, the Commission granted SROs and broker-dealers increased authority and flexibility to offer new and unique market data to the public. The Commission has repeatedly expressed its preference for competition over regulatory intervention in determining prices, products, and services in the securities markets. Specifically, in Regulation NMS, the Commission highlighted the importance of market forces in determining prices and SRO revenues, and also recognized that current regulation of the market system ''has been remarkably successful in promoting market competition in its broader forms that are most important to investors and listed companies.'' [23]

With respect to market data, the decision of the United States Court of Appeals for the District of Columbia Circuit in *NetCoalition* v. *SEC* upheld the Commission's reliance on the existence of competitive market mechanisms to evaluate the reasonableness and fairness of fees for proprietary market data:

> In fact, the legislative history indicates that the Congress intended that the market system ''evolve through the interplay of competitive forces as unnecessary regulatory restrictions are removed'' and that the SEC wield its regulatory power ''in those situations where competition may not be sufficient,'' such as in the creation of a ''consolidated transactional reporting system.'' [24]

The court agreed with the Commission's conclusion that ''Congress intended that 'competitive forces should dictate the services and practices that constitute the U.S. national market system for trading equity securities.' '' [25]

More recently, the Commission confirmed that it applies a ''market-based'' test in its assessment of market data fees, and that under that test:

> the Commission considers whether the exchange was subject to significant competitive forces in setting the terms of its proposal for [market data], including the level of any fees. If an exchange meets this burden, the Commission will find that its fee rule is consistent with the Act unless there is a substantial countervailing basis to find that the terms of the rule violate the Act or the rules thereunder.[26]

1. The Proposed Fees Are Constrained by Significant Competitive Forces

An exchange may demonstrate that its fees are constrained by competitive forces by showing that platform competition applies.

As the United States Supreme Court recognized in *Ohio* v. *American Express,* platforms are firms that act as intermediaries between two or more sets of agents, and typically the choices made on one side of the platform affect the results on the other side of the platform via externalities, or ''indirect network effects.'' [27] Externalities are linkages between the different ''sides'' of a platform such that one cannot understand pricing and competition for goods or services on one side of the platform in isolation; one must also account for the influence of the other side. As the Supreme Court explained:

> To ensure sufficient participation, two-sided platforms must be sensitive to the prices that they charge each side. . . . Raising the price on side A risks losing participation on that side, which decreases the value of the platform to side B. If the participants on side B leave due to this loss in value, then the platform has even less value to side A—risking a feedback loop of declining demand. . . . Two-sided platforms therefore must take these indirect network effects into account before making a change in price on either side.[28]

The Exchange and its affiliated exchanges have long maintained that they function as platforms between consumers of market data and consumers of trading services. Proving the existence of linkages between the two sides of this platform requires an in-depth economic analysis of both public data and confidential Exchange data about particular customers' trading activities and market data purchases. Exchanges, however, are prohibited from sharing details about these specific customer activities and purchases. For example, pursuant to Exchange Rule 7.41E, transactions executed on the Exchange are processed anonymously.

Exchanges function as platforms for market data and transaction services mean that exchanges do not set fees for market data products without considering, and being constrained by, the effect the fees will have on the order-flow side of the platform. And as the D.C. Circuit recognized in *NetCoalition I,* ''[n]o one disputes that competition for order flow is fierce.'' [29] The court further noted that ''no exchange possesses a monopoly, regulatory or otherwise, in the execution of order flow from broker dealers,'' and that an exchange ''must compete vigorously for order flow to maintain its share of trading volume.'' [30]

As noted above, while Regulation NMS has enhanced competition, it has also fostered a ''fragmented'' market structure where trading in a single stock can occur across multiple trading centers. When multiple trading centers compete for order flow in the same stock, the Commission has recognized that ''such competition can lead to the fragmentation of order flow in that stock.'' [31] The Commission's Division of Trading and Markets has also recognized that with so many ''operating equities exchanges and dozens of ATSs, there is vigorous price competition among the U.S. equity markets and, as a result, [transaction] fees are tailored and frequently modified to attract particular types of order flow, some of which is highly

[21] 15 U.S.C. 78f(b).

[22] 15 U.S.C. 78f(b)(4), (5).

[23] *See* Regulation NMS Adopting Release, 70 FR 37495, at 37499.

[24] *NetCoalition* v. *SEC,* 615 F.3d 525, 535 (D.C. Cir. 2010) (''*NetCoalition I*'') (quoting H.R. Rep. No. 94–229 at 92 (1975), *as reprinted in* 1975 U.S.C.C.A.N. 323).

[25] *Id.* at 535.

[26] *See* Securities Exchange Act Release No. 34–90217 (October 16, 2020), 85 FR 67392 (October 22, 2020) (SR–NYSENAT–2020–05) (''National IF Approval Order'') (internal quotation marks omitted), quoting Securities Exchange Act Release No. 59039 (December 2, 2008), 73 FR 74770, 74781 (December 9, 2008) (''2008 ArcaBook Approval Order'').

[27] *Ohio* v. *American Express,* 138 S. Ct. 2274, 2280–81 (2018).

[28] *Id.* at 2281.

[29] *NetCoalition I,* 615 F.3d at 544 (internal quotation omitted).

[30] *Id.*

[31] *See* Securities Exchange Act Release No. 61358, 75 3594, 3597 (January 21, 2010) (File No. S7–02–10) (Concept Release on Equity Market Structure).

fluid and price sensitive.'' [32] Indeed, today, equity trading is currently dispersed across 16 exchanges,[33] numerous alternative trading systems,[34] broker-dealer internalizers and wholesalers, all competing for order flow. Based on publicly-available information, no single exchange currently has more than 17% market share.[35]

Further, low barriers to entry mean that new exchanges may, and do, rapidly and inexpensively enter the market and offer additional substitute platforms to compete with the Exchange. For example, since 2020, three new exchanges have entered the market: Long Term Stock Exchange (LTSE), which began operations as an exchange on August 28, 2020; [36] Members Exchange (MEMX), which began operations as an exchange on September 29, 2020; [37] and Miami International Holdings (MIAX), which began operations of its first equities exchange on September 29, 2020.[38]

These low barriers enable existing exchange customers to disintermediate and start their own exchanges if they think the prices charged for exchange proprietary market data products are too high. This is precisely the rationale behind the creation of MEMX, which was formed by some of the largest and most well capitalized financial firms that are also Exchange customers (including Bank of America, BlackRock, Charles Schwab, Citadel, Citi, E*Trade, Fidelity, Goldman Sachs, J.P. Morgan, Jane Street, Morgan Stanley, TD Ameritrade, and others).[39]

For example, one of MEMX's founding principles is that exchange proprietary market data prices are too high, and that MEMX will benefit its members by offering ''[l]ower pricing on market data.'' [40] Nor is this a new phenomenon: exchange customers formed BATS to compete with incumbent exchanges and once registered as an exchange in 2008, BATS did not initially charge for market data. The BATS venture was a financial success for its founders, first through recouping their investment in its initial public offering and then in the subsequent sale of BATS to Cboe, which now charges for market data from those exchanges. Notably, MEMX has some of the same founding broker-dealer customers, leading some to dub MEMX ''BATS 2.0.'' [41]

The fact that this cycle is viable and repeatable by entities that both trade on and compete with existing exchanges confirms that barriers to entry are low and that these markets are competitive and contestable.[42] And low barriers to entry act as a market check on high prices.[43]

In sum, the fierce competition for order flow thus constrains any exchange from pricing its market data at a supracompetitive price and constrains the Exchange in setting its fees at issue here.

The proposed expansion of the Per User Access Fee is therefore reasonable because in setting it, the Exchange is constrained by the availability of numerous substitute platforms offering market data products and trading. Such substitutes need not be identical, but only substantially similar to the product at hand.

More specifically, in expanding the applicability of the Per User Access Fee to Redistributors of NYSE OpenBook, the Exchange is constrained by the fact that, if its pricing across the platform is unattractive to customers, customers have their pick of an increasing number of alternative platforms to use instead of the Exchange. The Exchange believes that it has considered all relevant factors and has not considered irrelevant factors in order to establish reasonable fees. The existence of numerous alternative platforms to the Exchange's platform ensures that the Exchange cannot set unreasonable market data fees without suffering the negative effects of that decision in the fiercely competitive market for trading order flow.

Even putting aside the facts that exchanges are platforms and that pricing decisions on the two sides of the platform are intertwined, the Exchange is constrained in setting the proposed market data fees by the availability of numerous substitute market data products. The Commission has been clear that substitute products need not be identical, but only substantially similar to the product at hand.[44]

The NYSE BQT market data product is subject to significant competitive forces that constrain its pricing. Specifically, as described above, NYSE BQT competes head-to-head with the Nasdaq Basic product and the Cboe One Feed. These products each serve as reasonable substitutes for one another as they are each designed to provide investors with a unified view of real-

[32] Commission Division of Trading and Markets, Memorandum to EMSAC, dated October 20, 2015, available here: *https://www.sec.gov/spotlight/emsac/memo-maker-taker-fees-on-equities-exchanges.pdf.*

[33] *See* Cboe Global Markets, U.S. Equities Market Volume Summary, available at *http://markets.cboe.com/us/equities/market_share/.*

[34] *See* FINRA ATS Transparency Data, *available at https://otctransparency.finra.org/otctransparency/AtsIssueData.* A list of alternative trading systems registered with the Commission is *available at https://www.sec.gov/foia/docs/atslist.htm.*

[35] *See* Cboe Global Markets, U.S. Equities Market Volume Summary, available at *http://markets.cboe.com/us/equities/market_share/.*

[36] *See* LTSE Market Announcement: MA–2020–020, dated August 14, 2020, announcing LTSE production securities phase-in planned for August 28, available here: *https://assets-global.website-files.com/6462417e8db99f8baa06952c/6462417e8db99f8baa0698e7_MA-2020-020__Production_Securities_Launching_August_28_-_Google_Docs.pdf and LTSE Market Announcement: MA–2020–025,* available here: *https://assets-global.website-files.com/6462417e8db99f8baa06952c/6462417e8db99f8baa069873_MA-2020-025.pdf.*

[37] As of October 29, 2020, MEMX is trading all NMS symbols. *See https://info.memxtrading.com/trader-alert-20-10-memx-trading-symbols-update/.*

[38] *See* MIAX Pearl Press release, dated September 29, 2020, available here: *https://www.miaxoptions.com/sites/default/files/alert-files/MIAX_Press_Release_09292020.pdf.*

[39] MEMX Home Page (''Founded by members and investors, MEMX aims to drive simplicity, efficiency, and competition in equity markets.''), available at *https://memx.com/.*

[40] MEMX home page, available at *https://memx.com/.*

[41] *See* ''MEMX turns up the heat on US stock exchanges,'' Financial Times, January 9, 2019, available at *https://www.ft.com/content/4908c8b0-1418-11e9-a581-4ff78404524e; see also* ''US equities exchanges: If you can't beat them, join them,'' Euromoney, February 13, 2019, available at *https://www.euromoney.com/article/b1d3tfby4p3y4v/us-equities-exchanges-if-you-cant-beat-them-join-them.*

[42] *United States* v. *SunGard Data Sys.,* 172 F. Supp. 2d 172, 186 (D.D.C. 2001) (recognizing that ''[a]s a matter of law, courts have generally recognized that when a customer can replace the services of an external product with an internally-created system, this captive output (*i.e.* the self-production of all or part of the relevant product) should be included in the same market.''). In *SunGard,* the court rejected the Antitrust Division's attempt to block SunGuard's acquisition of the disaster recovery assets of Comdisco on the basis that the acquisition would ''substantially lessen competition in the market for shared hotsite disaster recovery services,'' when the evidence showed that ''internal hotsites'' created by customers competed with the ''external shared hotsite business'' engaged in by the merging parties. *Id.* at 173–74, 187.

[43] *United States* v. *Baker Hughes,* 908 F.2d 981, 987 (1990) (''In the absence of significant barriers [to entry], a company probably cannot maintain supracompetitive pricing for any length of time.''); *see also* David S. Evans and Richard Schmalensee, Markets with Two-Sided Platforms, in 1 Issues In Competition Law and Policy 667, 685 (ABA Section of Antitrust Law 2008) (noting that exchange mergers in 2005 and 2006 were approved by competition authorities in part in reliance on planned and likely entry of other firms).

[44] For example, in the National IF Approval Order, the Commission recognized that for some customers, the best bid and offer information from consolidated data feeds may function as a substitute for the NYSE National Integrated Feed product, which contains order by order information. *See* National IF Approval Order, *supra* note 26, at 67397 [release p. 21] (''[I]nformation provided by NYSE National demonstrates that a number of executing broker-dealers do not subscribe to the NYSE National Integrated Feed and executing broker-dealers can otherwise obtain NYSE National best bid and offer information from the consolidated data feeds.'' (internal quotations omitted)).

time quotes and last-sale prices in all Tape A, B, and C securities. Each product provides subscribers with consolidated top-of-book quotes and trades from multiple U.S. equities markets. In the case of NYSE BQT, this product provides top-of-book quotes and trades data from five NYSE-affiliated U.S. equities exchanges, which together account for approximately 20% of consolidated U.S. equities trading volume as of October 2023.[45] Cboe One Feed similarly provides top-of-book quotes and trades data from Cboe's four U.S. equities exchanges. NYSE BQT, Nasdaq Basic, and Cboe One Feed are all intended to provide indicative pricing and are not intended to be used for order routing or trading decisions.

In addition to competing with proprietary data products from Nasdaq and Cboe, NYSE BQT also competes with the consolidated data feed. However, the Exchange does not claim that NYSE BQT is a substitute for consolidated data with respect to requirements under the Vendor Display Rule, which is Regulation NMS Rule 603(c).

The fact that this filing is proposing to further expand the application of the reduced Per User Access Fee is itself confirmation of the inherently competitive nature of the market for the sale of proprietary market data. For example, in August 2019, Cboe filed proposed rule changes to reduce certain of its Cboe One Feed fees and noted that it attracted two additional customers because of the reduced fees.[46] More recently, Nasdaq filed a proposed rule change to lower the enterprise license fee for broker-dealers distributing Nasdaq Basic to internal Professional subscribers and the enterprise license fee for broker-dealers distributing Nasdaq Last Sale to Professional subscribers.[47]

The Exchange notes that NYSE proprietary market data products are entirely optional. The Exchange is not required to make the proprietary data products that are the subject of this proposed rule change available or to offer any specific pricing alternatives to any customers, nor is any firm or investor required to purchase the Exchange's data products. Unlike some other data products (*e.g.,* the consolidated quotation and last-sale information feeds) that firms are required to purchase in order to fulfil regulatory obligations,[48] a customer's decision whether to purchase any of the Exchange's proprietary market data feeds is entirely discretionary. Most firms that choose to subscribe to proprietary market data feeds from the Exchange and its affiliates do so for the primary goals of using them to increase their revenues, reduce their expenses, and in some instances compete directly with the Exchange's trading services. Such firms are able to determine for themselves whether or not the products in question or any other similar products are attractively priced. If market data feeds from the Exchange and its affiliates do not provide sufficient value to firms based on the uses those firms may have for it, such firms may simply choose to conduct their business operations in ways that do not use the products.

In addition, in the case of products that are also redistributed through market data vendors, such as Bloomberg and Refinitiv, the vendors themselves provide additional price discipline for proprietary data products because they control the primary means of access to certain end users. These vendors impose price discipline based upon their business models. For example, vendors that assess a surcharge on data they sell are able to refuse to offer proprietary products that their end users do not or will not purchase in sufficient numbers. This competitive constraint is precisely what is driving the proposed fee changes here, which are designed to attract new market data vendors, and through them new subscribers, to the NYSE BQT product. Currently, only seven data feed vendors subscribe to NYSE BQT, and each vendor has limited redistribution of NYSE BQT. No other vendors currently subscribe to NYSE BQT and likely will not unless their customers request it, and customers will not elect to pay the proposed fees unless such product can provide value by sufficiently increasing revenues or reducing costs in the customer's business in a manner that will offset the fees. All of these factors operate as constraints on pricing proprietary data products.

Because of the availability of substitutes, an exchange that overprices

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[45] *See* Cboe Global Markets U.S. Equities Market Volume Summary, available at *https://www.cboe.com/us/equities/market_share/.*

[46] *See* Securities Exchange Act Release Nos. 86667 (August 14, 2019) (SR–CboeBZX–2019–069); 86670 (August 14, 2019) (SR–CboeBYX–2019–012); 86676 (August 14, 2019) (SR–CboeEDGA–2019–013); and 86678 (August 14, 2019) (SR–CboeEDGX–2019–048) (Notices of filing and Immediate effectiveness of proposed rule change to reduce fees for the Cboe One Feed) (collectively ''Cboe One Fee Filings''). The Cboe One Fee Filings were in effect from August 1, 2019 until September 30, 2019, when the Commission suspended them and instituted proceedings to determine whether to approve or disapprove those proposals. *See, e.g.,* Securities Exchange Act Release No. 87164 (September 30, 2019), 84 FR 53208 (October 4, 2019) (SR–CboeBZX–2019–069). On October 1, 2019, the Cboe equities exchanges refiled the Cboe One Fee Filings on the basis that they had new customers subscribe as a result of the Cboe One Fee Filings, and therefore its fee proposal had increased competition for top-of-book market data. *See* Securities Exchange Act Release Nos. 87312 (October 15, 2019), 84 FR 56235 (October 21, 2019) (SR–CboeBZX–2019–086); 87305 (October 14, 2019), 84 FR 56210 (October 21, 2019) (SR–CboeBYX–2019–015); 87295 (October 11, 2019), 84 FR 55624 (October 17, 2019) (SR–CboeEDGX–2019–059); and 87294 (October 11, 2019), 84 FR 55638 (October 17, 2019) (SR–CboeEDGA–2019–015) (Notices of filing and immediate effectiveness of proposed rule changes to re-file the Small Retail Broker Distribution Program) (''Cboe One Fee Re-Filings''). On November 26, 2019, the Commission suspended the Cboe One Fee Re-Filings and instituted proceedings to determine whether to approve or disapprove those proposals. *See, e.g.,* Securities Exchange Act Release No. 87629 (November 26, 2019), 84 FR 66245 (December 3, 2019) (SR–CboeBZX–2019–086). On November 27, 2019, the Cboe equities exchanges refiled the Cboe One Fee Filings with one revision to the requirements for participating in the Small Retail Broker Distribution Program and additional information about the basis for the proposed fee changes. *See* Securities Exchange Act Release Nos. 87712 (December 10, 2019), 84 FR 68508 (December 16, 2019) (SR–CboeBZX–2019–101); 88713 (December 10, 2019), 84 FR 68530 (December 16, 2019) (SR–CboeBYX–2019–023); 87709 (December 10, 2019), 84 FR 68523 (December 16, 2019) (SR–CboeEDGA–2019–021); and 87711 (December 10, 2019), 84 FR 68501 (December 16, 2019) (SR–Cboe–EDGX–2019–071) (Notices of filing and immediate effectiveness of proposed rule changes to introduce a Small Retail Broker Distribution Program) (''Cboe One Third Fee Re-Filings''). On February 4, 2020, the Cboe equities exchanges withdrew the Cboe One Third Fee Re-Filings and, on the same date, refiled the Cboe One Fee Filings. *See* Securities Exchange Act Release Nos. 88221 (February 14, 2020), 85 FR 9904 (February 20, 2020) (SR–CboeBYX–2020–007); 88218 (February 14, 2020), 85 FR 9827 (February 20, 2020) (SR–CboeBZX–2020–014); 88220 (February 14, 2020), 85 FR 9912 (February 20, 2020) (SR–CboeEDGA–2020–004); and 88219 (February 14, 2020), 85 FR 9872 (February 20, 2020) (SR–CboeEDGX–2020–008) (Notices of filing and immediate effectiveness of proposed rule changes to introduce a Small Retail Broker Distribution Program) (''Cboe One Fourth Fee Re-Filings''). On April 15, 2020, the Cboe equities exchanges withdrew the Cboe One Fee Filings and the Cboe One Fee Re-Filings. Pursuant to the Cboe One Fourth Fee Re-Filings, the Small Retail Broker Distribution Program is currently in effect at the Cboe equities exchanges.

[47] *See* Securities Exchange Act Release No. 90177 (October 14, 2020), 85 FR 66620 (October 20, 2020) (SR–NASDAQ–2020–065) (Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Lower the Enterprise License Fee for Broker-Dealers Distributing Nasdaq Basic to Internal Professional Subscribers as Set Forth in the Equity 7 Pricing Schedule, Section 147, and the Enterprise License Fee for Broker-Dealers Distributing Nasdaq Last Sale to Professional Subscribers at Equity 7, Section 139).

[48] The Exchange notes that broker-dealers are not required to purchase proprietary market data to comply with their best execution obligations. *See In the Matter of the Application of Securities Industry and Financial Markets Association for Review of Actions Taken by Self-Regulatory Organizations,* Release Nos. 34–72182; AP–3–15350; AP–3–15351 (May 16, 2014). Similarly, there is no requirement in Regulation NMS or any other rule that proprietary data be utilized for order routing decisions, and some broker-dealers and ATSs have chosen not to do so.

its market data products stands a high risk that users may substitute another source of market data information for its own. Those competitive pressures imposed by available alternatives are evident in the Exchange's proposed pricing.

In setting the proposed fees, the Exchange considered the competitiveness of the market for proprietary data and all of the implications of that competition. The Exchange believes that it has considered all relevant factors and has not considered irrelevant factors in order to establish reasonable fees. The existence of numerous alternatives to the Exchange's platform and, more specifically, alternatives to the market data products, including proprietary data from other sources, ensures that the Exchange cannot set unreasonable fees when vendors and subscribers can elect these alternatives or choose not to purchase a specific proprietary data product if the attendant fees are not justified by the returns that any particular vendor or data recipient would achieve through the purchase.

The proposed expansion of the Per User Access Fee is reasonable, for the following additional reasons.

Overall. This proposed fee change is a result of the competitive environment, as the Exchange seeks to decrease certain of its fees to attract Redistributors that do not currently subscribe to the NYSE BQT market data product. The Exchange is proposing the fee reduction at issue to make the Exchange's fees more competitive for a specific segment of market participants, thereby increasing the availability of the Exchange's data products, and expanding the options available to firms making data purchasing decisions based on their business needs. The Exchange believes that this is consistent with the principles contained in Regulation NMS to ''promote the wide availability of market data and to allocate revenues to SROs that produce the most useful data for investors.'' [49]

Access Fee. By making the reduced Per User Access Fee available to Redistributors of NYSE OpenBook for external distribution who do not subscribe to any other products listed on the Fee Schedule other than NYSE BBO and NYSE Trades, the Exchange believes that more Redistributors may choose to subscribe to these products, thereby expanding the distribution of this market data for the benefit of investors that participate in the national market system and increasing competition generally. The Exchange also believes that offering the Per User Access Fee to these Redistributors would expand the availability of NYSE BQT to potential data recipients that are interested in subscribing to NYSE BQT but do not have access to a Redistributor who subscribes to the data feeds.

The Exchange determined to make the reduced Per User Access Fee available to these Redistributors because it constitutes a substantial reduction of the current fee, with the intended purpose of increasing use of NYSE BQT by Redistributors. NYSE BQT has been in place since 2014 but has a very small number of subscribers. The Exchange believes that in order to compete with other indicative pricing products such as Nasdaq Basic and Cboe One Feed, it needs to provide a meaningful financial incentive for more Redistributors to choose to subscribe to NYSE BQT so that they can make it available to their customers. Accordingly, the proposed expansion of the Per User Access Fee, together with the proposed expansion of the Per User Access Fee by the Exchange's affiliates, is reasonable because the reductions will make NYSE BQT a more attractive offering for Redistributors that do not currently subscribe to any NYSE market data products other than NYSE OpenBook and make it more competitive with Nasdaq Basic and Cboe One Feed.

Evidence of the competition among exchange groups for these products has previously been demonstrated via fee changes. For example, following the introduction of the Cboe One Feed, Nasdaq responded by reducing its fees for the Nasdaq Basic product.[50] With the proposed changes by the Exchange, NYSE American, and NYSE Arca, the Exchange is similarly seeking to compete by decreasing the total access fees for NYSE BQT from $6,250 to $850 for Redistributors that do not currently subscribe to any NYSE market data products other than NYSE OpenBook and have customers that are interested in subscribing to NYSE BQT but cannot do so until their Redistributor also subscribes. This proposed rule change therefore demonstrates the existence of an effective, competitive market because this proposal resulted from a need to generate innovative approaches in response to competition from other exchanges that offer market data for a specific segment of market participants.

For all of the foregoing reasons, the Exchange believes that the proposed fees are reasonable.

The Proposed Fees Are Equitably Allocated

The Exchange believes the proposed expansion of the Per User Access Fee is allocated fairly and equitably among the various categories of users of the Exchange's market data feed, and any differences among categories of users are justified.

Overall. As noted above, this proposed fee change is a result of the competitive environment for market data products that provide indicative pricing information across a family of exchanges. To respond to this competitive environment, the Exchange seeks to expand the application of the Per User Access Fee for Redistributors that would be subscribing to the NYSE BBO, NYSE Trades and NYSE OpenBook data feeds and would use these market data products for external distribution only, which the Exchange hopes will attract new Redistributor subscribers for the NYSE BQT market data product so that the product can be made available to prospective market data recipients. The Exchange is proposing to expand the application of the reduced Per User Access Fee to make the Exchange's fees more competitive for a specific segment of market participants, thereby increasing the availability of the Exchange's data products, expanding the options available to firms making data purchasing decisions based on their business needs, and generally increasing competition.

Access Fee. The Exchange believes that making the Per User Access Fee available to Redistributors that would be subscribing to the NYSE BBO, NYSE Trades and NYSE OpenBook data feeds and would use these market data products for external distribution only is equitable as the reduced fee would apply equally to all data recipients that choose to subscribe to NYSE BBO, NYSE Trades and NYSE OpenBook for external distribution only. Because NYSE BBO, NYSE Trades and NYSE OpenBook are optional products, any data recipient could choose to subscribe to such data feeds to distribute externally and be eligible for the Per User Access Fee. The Exchange does not believe that it is inequitable that the Per User Access Fee would be available only to data recipients that subscribe to

[49] *See* Regulation NMS Adopting Release, 70 FR 37495, at 37503.

[50] *See e.g.,* Securities Exchange Act Release No. 83751 (July 31, 2018), 83 FR 38428 (August 6, 2018) (SR–NASDAQ–2018–058) (Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Lower Fees and Administrative Costs for Distributors of Nasdaq Basic, Nasdaq Last Sale, NLS Plus and the Nasdaq Depth-of-Book Products Through a Consolidated Enterprise License). Nasdaq filed the proposed fee change to lower the Enterprise Fee for Nasdaq Basic and other market data products in response to the Enterprise Fee for the Cboe One Feed adopted by Cboe family of exchanges.

NYSE BBO, NYSE Trades and NYSE OpenBook and only for external distribution. Internal use of data represents a different set of use cases than a Redistributor that is engaged only in external distribution of data. For example, non-display data can be used by data recipients for a wide variety of profit-generating purposes, including proprietary and agency trading and smart order routing, as well as by data recipients that operate order matching and execution platforms that compete directly with the Exchange for order flow. The data also can be used for a variety of non-trading purposes that indirectly support trading, such as risk management and compliance. Although some of these non-trading uses do not directly generate revenues, they can nonetheless substantially reduce the recipient's costs by automating such functions so that they can be carried out in a more efficient and accurate manner and reduce errors and labor costs, thereby benefiting end users. The Exchange believes that charging a different access fee for a Redistributor that is engaged solely in external distribution of only the NYSE BBO, NYSE Trades and NYSE OpenBook products is equitable because it would make NYSE BQT available to more data recipients that are customers of such Redistributors and who would not otherwise be able to access NYSE BQT if their Redistributor did not subscribe to and redistribute NYSE BQT.

For all of the foregoing reasons, the Exchange believes that the proposed fees for the NYSE market data products are equitably allocated.

The Proposed Fees Are Not Unfairly Discriminatory

The Exchange believes the proposed fees are not unfairly discriminatory because any differences in the application of the fees are based on meaningful distinctions between customers, and those meaningful distinctions are not unfairly discriminatory between customers.

Overall. As noted above, this proposed fee change is a result of the competitive environment for market data products that provide indicative pricing information across a family of exchanges. To respond to this competitive environment, the Exchange seeks to amend its fees to provide a financial incentive for Redistributors of NYSE OpenBook that do not currently subscribe to any NYSE market data products that decide to subscribe to NYSE BQT, which the Exchange hopes will attract more subscribers for the NYSE BQT market data product. The Exchange is proposing to expand the application of the Per User Access Fee to make the Exchange's fees more competitive for a specific segment of market participants, thereby increasing the availability of the Exchange's data products, expanding the options available to firms making data purchasing decisions based on their business needs, and generally increasing competition.

Access Fee. The Exchange believes that making the Per User Access Fee available to Redistributors that would be subscribing to the NYSE BBO, NYSE Trades and NYSE OpenBook data feeds and would use these market data products for external distribution only is not unfairly discriminatory as the reduced fee would apply equally to all Redistributors that choose to subscribe to NYSE BBO, NYSE Trades and NYSE OpenBook for external distribution only. Because NYSE BBO, NYSE Trades and NYSE OpenBook are optional products, any data recipient could choose to subscribe to such data feeds to distribute externally and be eligible for the Per User Access Fee. The Exchange does not believe that it is unfairly discriminatory that the Per User Access Fee would be available only to data recipients that subscribe to NYSE BBO, NYSE Trades and NYSE OpenBook and only for external distribution. Internal use of data represents a different set of use cases than a Redistributor that is engaged only in external distribution of data. For example, non-display data can be used by data recipients for a wide variety of profit-generating purposes, including proprietary and agency trading and smart order routing, as well as by data recipients that operate order matching and execution platforms that compete directly with the Exchange for order flow. The data also can be used for a variety of non-trading purposes that indirectly support trading, such as risk management and compliance. While some of these non-trading uses do not directly generate revenues, they can nonetheless substantially reduce the recipient's costs by automating such functions so that they can be carried out in a more efficient and accurate manner and reduce errors and labor costs, thereby benefiting end users. The Exchange therefore believes that there is a meaningful distinction between internal use and redistribution of market data and that charging a different access fee to a Redistributor that is engaged solely in external distribution of only the NYSE BBO, NYSE Trades and NYSE OpenBook products is not unfairly discriminatory because it would make NYSE BQT available to more data recipients that are customers of such Redistributors and who would not otherwise be able to access NYSE BQT if their Redistributor did not subscribe to and redistribute NYSE BQT.

Moreover, the Exchange does not believe that it is unfairly discriminatory to offer the Per User Access Fee only to those Redistributors that would subscribe to the NYSE BBO, NYSE Trades and NYSE OpenBook data feeds, and only for external distribution. This proposed rule change is designed to provide an incentive for Redistributors that currently subscribe to NYSE OpenBook, but do not subscribe to NYSE BQT, and may have customers that are interested in subscribing to NYSE BQT, to subscribe to the NYSE BBO and NYSE Trades data feeds so that they can make NYSE BQT available to their customers. This fee incentive is not necessary for Redistributors that currently subscribe to the NYSE BBO and NYSE Trades data feeds because such Redistributors could already subscribe to NYSE BQT, but have chosen not to, and a reduction in their existing access fees would likely not result in such Redistributors choosing to subscribe to NYSE BQT.

For all of the foregoing reasons, the Exchange believes that the proposed fees are not unfairly discriminatory.

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. Indeed, as demonstrated above, the Exchange believes the proposed rule changes are pro-competitive.

Intramarket Competition. The Exchange believes that the proposed fees do not put any market participants at a relative disadvantage compared to other market participants. As noted above, the proposed fee schedule would apply to all subscribers of NYSE market data products, and customers may not only choose whether to subscribe to the products at all, but also may tailor their subscriptions to include only the products and uses that they deem suitable for their business needs. The Exchange also believes that the proposed fees neither favor nor penalize one or more categories of market participants in a manner that would impose an undue market on competition. As shown above, to the extent that particular proposed fees apply to only a subset of subscribers, those distinctions are not unfairly discriminatory and do unfairly burden one set of customers over another.

Intermarket Competition. The Exchange believes that the proposed fees do not impose a burden on competition on other exchanges that is not necessary or appropriate; indeed, the Exchange believes the proposed fee changes would have the effect of increasing competition. As described above, exchanges are platforms for market data and trading. In setting the proposed fees, the Exchange is constrained by the availability of substitute platforms also offering market data products and trading, and low barriers to entry mean new exchange platforms are frequently introduced. The fact that exchanges are platforms ensures that no exchange can make pricing decisions for one side of its platform without considering, and being constrained by, the effects that price will have on the other side of the platform. In setting fees at issue here, the Exchange is constrained by the fact that, if its pricing across the platform is unattractive to customers, customers will have its pick of an increasing number of alternative platforms to use instead of the Exchange. Given this intense competition between platforms, no one exchange's market data fees can impose an unnecessary burden on competition, and the Exchange's proposed fees do not do so here.

In addition, the Exchange believes that the proposed fees do not impose a burden on competition or on other exchanges that is not necessary or appropriate because of the availability of numerous substitute market data products. Specifically, as described above, NYSE BQT competes head-to-head with the Nasdaq Basic product and the Cboe One Feed. These products each serve as reasonable substitutes for one another as they are each designed to provide investors with a unified view of real-time quotes and last-sale prices in all Tape A, B, and C securities. Each product provides subscribers with consolidated top-of-book quotes and trades from multiple U.S. equities markets. NYSE BQT provides top-of-book quotes and trades data from five NYSE-affiliated U.S. equities exchanges, while Cboe One Feed similarly provides top-of-book quotes and trades data from Cboe's four U.S. equities exchanges. NYSE BQT, Nasdaq Basic, and Cboe One Feed are all intended to provide indicative pricing and therefore, are reasonable substitutes for one another. Additionally, market data vendors are also able to offer close substitutes to NYSE BQT. Because market data users can find suitable substitute feeds, an exchange that overprices its market data products stands a high risk that users may substitute another source of market data information for its own. These competitive pressures ensure that no one exchange's market data fees can impose an unnecessary burden on competition, and the Exchange's proposed fees do not do so here.

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 has become effective upon filing pursuant to Section 19(b)(3)(A) [51] of the Act and paragraph (f) of Rule 19b–4 thereunder.[52] 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.

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 (*https://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include file number SR–NYSE–2023–42 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–2023–42. 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 (*https://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 a.m. and 3 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. Do not include personal identifiable information in submissions; you should submit only information that you wish to make available publicly. We may redact in part or withhold entirely from publication submitted material that is obscene or subject to copyright protection. All submissions should refer to file number SR–NYSE–2023–42 and should be submitted on or before December 13, 2023.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[53]

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2023–25788 Filed 11–21–23; 8:45 am]

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[51] 15 U.S.C. 78s(b)(3)(A).

[52] 17 CFR 240.19b–4(f).

[53] 17 CFR 200.30–3(a)(12).

SURFACE TRANSPORTATION BOARD

[Docket No. FD 35544]

Desertxpress Enterprises, LLC, and Desertxpress HSR Corporation—Construction and Operation Exemption—In Victorville, Cal., and Las Vegas, Nev.

In 2019, DesertXpress Enterprises, LLC, (DesertXpress) [1] filed a petition to reopen this proceeding, seeking modification of a 2011 condition concerning the construction of an approximately 190-mile rail line for high-speed passenger rail service between Victorville, Cal., and Las Vegas, Nev. (the LV Line). That condition authorized construction of a designated alignment. DesertXpress seeks authority

[1] On September 17, 2018, DesertXpress' ownership group entered into an agreement to sell the company to Brightline Holdings LLC (Brightline). *Fortress Inv. Grp. LLC—Continuance in Control—Cent. Me. & Que. Ry.,* FD 36225, slip op. at 1–2 (STB served Oct. 11, 2018). Brightline's acquisition of DesertXpress was consummated on March 4, 2019. (Pet. to Reopen 4.)

for modifications to the previously approved alignment.

Environmental review of the modified route had been ongoing and was recently completed. Specifically, the Board's Office of Environmental Analysis (OEA) has worked with the Federal Railroad Administration (FRA), the lead agency on the environmental and historic review for this project under the National Environmental Policy Act (NEPA) and related environmental laws, including Section 106 of the National Historic Preservation Act (NHPA). As part of this process, OEA has reviewed a 2020 reevaluation by FRA (FRA 2020 Reevaluation) of the modified alignment, as well as a subsequent reevaluation by FRA (FRA 2023 Reevaluation) considering further route modifications proposed by DesertXpress in 2022. OEA concludes that FRA adequately assessed the potential environmental and historic impacts associated with the project modifications and concurs with FRA's determination that a Supplemental Environmental Impact Statement (EIS) is not necessary. OEA also recommends that the Board impose the revised mitigation measures in Appendix D of the FRA 2023 Reevaluation. Historic review of the project modifications had also been ongoing and was completed this year. A Programmatic Agreement (PA) setting out the final terms for compliance with Section 106 was executed on August 15, 2023.

As discussed below, the Board will reopen this proceeding and grant DesertXpress' petition for exemption seeking authority for the modified alignment. The Board will also adopt FRA's 2020 and 2023 Reevaluations and impose the environmental mitigation measures listed in Appendix D of the FRA 2023 Reevaluation.

Background

On July 28, 2011, DesertXpress and its wholly owned subsidiary, DesertXpress HSR Corporation (collectively, DXE), filed a petition under 49 U.S.C. 10502 for an exemption from the prior approval requirements of 49 U.S.C. 10901 to construct and operate the LV Line. FRA, with OEA's participation as a cooperating agency, conducted an environmental review of the proposed project by preparing an EIS.[2] Following an examination of the entire record on both the transportation merits and potential environmental impacts, the Board granted the petition for a construction and operation exemption, subject to environmental conditions and the condition that DXE construct the 2011 Selected Alternative. *See DesertXpress Enters.—Constr. & Operation Exemption—in Victorville, Cal., & Las Vegas, Nev.* (*October 2011 Decision*), FD 35544, slip op. at 8 (STB served Oct. 25, 2011).[3]

On March 27, 2019, DesertXpress filed a petition to reopen this proceeding, seeking modification of the condition authorizing construction of the 2011 Selected Alternative to permit the LV Line to be constructed along a modified route, referred to as the ''I–15 median'' alignment. (Pet. to Reopen 1, 5.) DesertXpress stated that it had determined that it would be more efficient to construct the LV Line primarily in the median between the northbound and southbound lanes of the I–15 freeway and to utilize a single-track configuration with passing sidings. (*Id.* at 5.)

In a notice served on June 24, 2019, the Director of the Board's Office of Proceedings (Director) explained that FRA had agreed to reevaluate the environmental analysis relied upon by the Board in the *October 2011 Decision* in light of the alignment changes proposed by DesertXpress and that OEA would participate in that process as a cooperating agency. *See DesertXpress Enters.—Constr. & Operation Exemption—in Victorville, Cal., & Las Vegas, Nev.,* FD 35544, slip op. at 2 (STB served June 24, 2019). The Director added that the petition to reopen would be addressed after the FRA 2020 Reevaluation was completed. *DesertXpress Enters.—Constr. & Operation Exemption—in Victorville, Cal., & Las Vegas, Nev.,* FD 35544, slip op. at 2 (STB served June 24, 2019).

On September 15, 2020, DesertXpress filed a letter stating that FRA had completed the FRA 2020 Reevaluation[4] and concluded that a Supplemental EIS was not required for the proposed modifications to the alignment. (DesertXpress Letter 2, Sept. 15, 2020.) DesertXpress also asserted that ''[t]he Board need not revisit the [*October 2011 Decision's*] findings with respect to the transportation merits of the Line,'' as ''[n]one of those findings would be affected by substituting the modified I–15 median alignment for the side-running alignment previously designated by FRA.'' (DesertXpress Letter 2 n.4, Sept. 15, 2020.) Accordingly, DesertXpress asked the Board to grant its petition to reopen the *October 2011 Decision* to revise the routing condition to authorize it to build the modified alignment and project design specified in the FRA 2020 Reevaluation. (DesertXpress Letter 3, Sept. 5, 2020.)[5]

OEA then prepared an Environmental Memorandum (OEA 2020 Memo) concurring with the conclusions reached in the FRA 2020 Reevaluation. The Board also recommended that the Board consider FRA's 2020 Reevaluation, along with the EIS, when determining whether to authorize the LV Line as modified, and that it impose revised mitigation measures recommended by FRA in the FRA 2020 Reevaluation. OEA 2020 Memo 2. OEA further explained that FRA was working with appropriate consulting parties to complete the historic review under Section 106. *Id.*

The Board provided an opportunity for the public to comment in a decision served on December 3, 2020. *See DesertXpress Enters.—Constr. & Operation Exemption—in Victorville, Cal., & Las Vegas, Nev.,* FD 35544 (STB served Dec. 3, 2020). The Board did not receive any comments. In that decision, the Board also noted that review of historic and cultural resources was ongoing pursuant to Section 106 and that it could not issue a final decision modifying the routing condition, if appropriate, until that process was complete.

In 2022, DesertXpress proposed additional modifications, which were developed through the final design phase for the LV Line. DesertXpress' further modifications include, among other things, moving ''additional miles of track along the Las Vegas-Victorville route (as well as the Victor Valley station building) into the median between the northbound and southbound lanes'' of the I–15 freeway, relocating certain facilities, and adding temporary construction areas. (DesertXpress Letter 2, Sept. 19, 2023.) It asks the Board to modify the routing condition again to reflect those modifications. (*Id.* at 3.) After evaluating these additional modifications, FRA

[2] On July 8, 2011, FRA published its Record of Decision (ROD) approving the environmentally preferred alternative for the route, facilities, and technology (2011 Selected Alternative), subject to mitigation measures to avoid or minimize potential adverse environmental impacts. (*See* Pet. for Exemption, Ex. D.)

[3] The 2011 Selected Alternative contemplated a double-track rail line to be located almost entirely on the north/west side of the I–15 freeway travel lanes. (DesertXpress Letter 1, Sept. 15, 2020; Pet. for Exemption, Ex. D, 34–35, 63–64.)

[4] The FRA 2020 Reevaluation is available on FRA's website at *https://railroads.dot.gov/rail-network-development/environment/environmental-reviews/brightline-west-las-vegas-victor-valley.*

[5] In addition to locating the LV Line primarily within the I–15 freeway median, the modified alignment would also relocate the LV Line's southern terminus in Victor Valley from the City of Victorville to the Town of Apple Valley. (FRA 2020 Reevaluation, Summary 1 n1.)

issued the 2023 FRA Reevaluation,[6] concluding that a Supplemental EIS is not necessary and updating the mitigation measures. OEA then prepared the OEA 2023 Environmental Memorandum (OEA 2023 Memo) (appended to this decision) concurring with FRA's conclusions and recommending that the Board consider FRA's 2023 Reevaluation, along with the 2020 Reevaluation and the EIS, in deciding whether to authorize the LV Line as modified, and that it impose the updated mitigation measures contained in Appendix D of the FRA 2023 Reevaluation. OEA 2023 Memo 5. As noted above, a PA was executed on August 15, 2023, completing the Section 106 historic review process for this proceeding.

Discussion and Conclusions

Reopening the Proceeding

A party may seek to reopen a Board proceeding by submitting a petition that (1) presents new evidence or substantially changed circumstances that would materially affect the case or (2) demonstrates material error in a prior decision. 49 U.S.C. 1322(c); 49 CFR 1115.4. ''To warrant reopening, the new evidence must be newly available, and the new evidence or substantially changed circumstances must materially affect the prior decision.'' *Port of Moses Lake—Constr. Exemption—Moses Lake, Wash.,* FD 34936, slip op. at 2 (STB served Jan. 28, 2019) citing *Riffin—Pet. for Declaratory Ord.,* FD 34997 et al., slip op. at 6 (STB served, Oct. 29, 2012).

Here, DesertXpress has proposed to construct the LV Line along a modified alignment somewhat different from that which the Board authorized in the *October 2011 Decision.* The modifications led to the 2020 and 2023 FRA Reevaluations and the updated mitigation measures in Appendix D of the 2023 FRA Reevaluation. These developments constitute new evidence and changed circumstances that warrant reopening the *October 2011 Decision* to consider the modified alignment and revised mitigation.

Rail Transportation Analysis

The construction of new railroad lines requires prior Board authorization, through either a certificate under section 10901 or, as requested here, an exemption under section 10502 from the prior approval requirements of section 10901. Section 10901(c) directs the Board to grant authority for rail line construction proposals unless it finds the proposal ''inconsistent with the public convenience and necessity.'' *See Alaska R.R.—Constr. & Operation Exemption—A Rail Line Extension to Port MacKenzie, Alaska,* FD 35095, slip op. at 5 (STB served Nov. 21, 2011), *aff'd sub nom. Alaska Survival* v. *STB,* 705 F.3d 1073 (9th Cir. 2013). Under section 10502(a), the Board shall, to the maximum extent permissible, exempt a proposed rail line construction from the prior approval requirements of section 10901 when it finds that: (1) those procedures are not necessary to carry out the rail transportation policy of 49 U.S.C. 10101 and (2) either (a) the proposal is of limited scope or (b) the full application procedures are not needed to protect shippers from an abuse of market power.

In the *October 2011 Decision,* the Board concluded that DesertXpress met the standards of section 10502 for an exemption to construct and operate the LV Line. The Board found that the LV Line would provide additional transportation options and alleviate both automobile congestion on the I–15 freeway as well as constraints on the expansion of air travel in Southern California. *See Oct. 2011 Decision,* FD 35544, slip op. at 3. The Board further found that the LV Line would reduce air pollution and overall fuel consumption and noted the expected multi-billion-dollar beneficial impact on the economies of Nevada and California. *See id.* at 2 n.4 & 3 (referencing forecasts of LV Line ridership and automobile diversions, jobs, and economic impacts). The Board concluded that the requested exemption would reduce the need for federal regulation (49 U.S.C. 10101(2)), ensure the development of a sound rail transportation system with effective competition to meet the needs of the shipping public (49 U.S.C. 10101(4)), foster sound economic conditions in transportation (49 U.S.C. 10101(5)), reduce regulatory barriers to entry (49 U.S.C. 10101(7)), and promote energy conservation and reduce congestion consistent with 49 U.S.C. 10101(14). *See Oct. 2011 Decision,* FD 35544, slip op. at 3–4. The Board also found that other aspects of the rail transportation policy would not be affected. Finally, the Board found that regulation of the proposed construction is not necessary to protect shippers from the abuse of market power. *Id.*

No party challenged in this proceeding the Board's 2011 conclusions on the transportation merits of the proposal,[7] and nothing in the record developed since then, including the environmental analysis discussed in the next section, calls those conclusions into question. The LV Line, with a modified median alignment, would reduce highway congestion by diverting vehicle traffic from the I–15 freeway to a faster and more efficient rail option. As previously noted, diversions would also benefit the environment, in part due to the far lower emissions associated with rail. (*See also* Titus Letter 2, July 27, 2023 (''Estimates show that over 700 million vehicle miles traveled will be removed annually from the highway which will eliminate more than 400,000 tons of CO_2 emissions from the atmosphere.'').) And, as previously noted, construction of the LV Line is anticipated to generate billions of dollars in economic activity and tax revenue, and lead to the creation of thousands of jobs. (*See also id.* at 1–2.) Simply put, the benefits to the traveling public and, ultimately, the environment of adding a high-speed passenger rail option between Southern California and Las Vegas are considerable, and the project modifications do not change this conclusion. Moreover, the merits are enhanced by the Victor Valley-to-Rancho Cucamonga extension (RC Line), which would connect passengers on the LV Line to the Southern California commuter rail network.[8] The Board therefore reaffirms its 2011 conclusions regarding the transportation merits of the LV Line.

Environmental Analysis

NEPA requires that the Board examine the environmental effects of proposed federal actions and inform the public concerning those effects. *Balt. Gas & Elec. Co.* v. *Nat. Res. Def. Council,* 462 U.S. 87, 97 (1983). Under NEPA, the Board must consider potential beneficial and adverse environmental effects in reaching its decision. The two-fold purpose of NEPA is to ensure that the agency's decision-making process includes environmental considerations and to inform the public about those considerations. *Citizens Against Rails-to-Trails* v. *STB,* 267 F.3d 1144, 1151 (D.C. Cir. 2001). While NEPA prescribes the process that must

[6] The FRA 2023 Reevaluation is also available on FRA's website at *https://railroads.dot.gov/rail-network-development/environment/environmental-reviews/brightline-west-las-vegas-victor-valley.*

[7] See note 10, *infra.*

[8] In Docket No. FD 36488, DesertXpress filed a petition for exemption to construct and operate the RC Line, an approximately 50-mile high-speed passenger rail line, between the Victor Valley and Rancho Cucamonga in Southern California. The RC Line would connect with the southern terminal of the LV Line at the Victor Valley. The Board instituted a proceeding in Docket No. FD 36488 on July 12, 2021. *DesertXpress Enters.—Constr. & Operation Exemption—Passenger Rail Line Between Victor Valley & Rancho Cucamonga, Cal.,* FD 36488 (STB served July 12, 2021). The Board issued a decision today authorizing DesertXpress to construct and operate the RC Line.

be followed, it does not mandate a particular result. *Robertson* v. *Methow Valley Citizens Council,* 490 U.S. 332, 350–51 (1989). Thus, once the adverse environmental effects of a proposed action have been adequately identified and evaluated, the Board may conclude that ''other values outweigh the environmental costs.'' *Id.*

The FRA 2020 Reevaluation reassessed the project modifications alongside the proposed action described in the EIS and ROD. OEA 2020 Memo 3. FRA also updated and revised certain mitigation measures developed in the EIS to address changes in the affected environment and project changes since publication of the EIS. OEA 2020 Memo 3. FRA determined that, with mitigation, the project modifications would result in similar impacts to those evaluated in the EIS and concluded that the project modifications would reduce certain environmental impacts of the LV Line. OEA 2020 Memo 3. For example, the modified alignment assessed in the FRA 2020 Reevaluation, which would be single track and primarily in an existing median, would reduce the project's impact on land use, visual resources, air quality and climate change, and biological resources. *Id.* at 5, 7, 10, 12.

As part of FRA's review, it also identified regulatory changes that had taken effect since the issuance of the EIS and analyzed the affected environment to ensure that the conclusions of the EIS remained valid. OEA 2020 Memo 3. Based on the analysis and findings in the FRA 2020 Reevaluation, FRA concluded that the project modifications, with the implementation of the proposed mitigation, did not constitute changes to the proposed action that would result in significant environmental impacts that were not evaluated in the EIS and that a Supplemental EIS was not necessary. *Id.*

OEA concluded that FRA had adequately assessed the potential environmental impacts associated with the project modifications and concurred with FRA's determination that a Supplemental EIS was not necessary. OEA 2020 Memo 13. Accordingly, OEA recommended that the Board consider the FRA 2020 Reevaluation, along with the EIS, in deciding whether to authorize the project as modified. OEA 2020 Memo 13–14. OEA also recommended that the Board impose the revised mitigation measures recommended in the FRA 2020 Reevaluation. OEA 2020 Memo 14. As noted above, the Board provided an opportunity for public comment, and no comments were filed.[9]

Likewise, in the FRA 2023 Reevaluation, FRA determined that (1) the additional modifications proposed by DesertXpress in 2022, with the imposition of final proposed mitigation, would not result in substantial changes in the evaluation of impacts disclosed in the EIS or the FRA 2020 Reevaluation and (2) no Supplemental EIS is required. OEA 2023 Memo 4. FRA also determined that the modifications would generally avoid or minimize the overall effects of the project. *Id.* For example, FRA concluded that placement of additional components of the rail alignment and a greater portion of ancillary facilities within the I–15 freeway right-of-way would reduce biological resource impacts compared to the EIS or the FRA 2020 Reevaluation. OEA 2023 Memo 4 n.7. Similarly, constructing along the modified route would result in fewer air emissions compared to the route examined in the EIS because there would be no tunneling and less of a need to elevate the alignment. *Id.*

OEA further concluded that the FRA 2023 Reevaluation adequately assessed the potential environmental impacts associated with DesertXpress' additional modifications and concurred with FRA's determination that a Supplemental EIS is not necessary. OEA 2023 Memo 5. Accordingly, OEA recommends that the Board consider the FRA 2023 Reevaluation, along with the FRA 2020 Reevaluation and the EIS, when it decides whether to authorize the LV Line as modified. OEA 2023 Memo 5. OEA also recommends that, in any decision granting an exemption for construction and operation of the LV Line modified as described in the FRA 2020 and 2023 Reevaluations, the Board should impose all the mitigation measures included in Appendix D of the FRA 2023 Reevaluation. OEA 2023 Memo 5.

NHPA

Section 106 of NHPA requires federal agencies to ''take into account the effect of'' their licensing decisions (in this case, whether to grant DesertXpress' request to modify the LV Line alignment) on properties included in, or eligible for inclusion in, the National Register of Historic Places and, prior to the approval of an undertaking, to afford ACHP a reasonable opportunity to comment. *See* 54 U.S.C. 306108. Consultation with the SHPO is also required. *See* 36 CFR 800.2(a)(4) & (c)(1), 800.3(c)(3).

FRA determined that the project modifications would not result in substantial changes to the evaluation of cultural resource impacts from those identified in the EIS. OEA 2020 Memo 8. However, FRA concluded that the modified project would encounter new archaeological resources and historic built environment resources that were not previously evaluated. OEA 2020 Memo 8. In accordance with 36 CFR part 800, FRA moved the Section 106 process forward in consultation with the appropriate parties, including ACHP, the California and Nevada SHPOs, and federally recognized Native American tribes with an interest in the project area. OEA 2020 Memo 8. In response to requests from several consulting parties after FRA completed the FRA 2020 Reevaluation, FRA decided to resolve any adverse effects to historic archeological and built environment resources through the execution of a new PA. OEA 2020 Memo 8–9.

As noted in the PA executed on August 15, 2023, FRA identified 197 historic properties, assessed the adverse effects to those properties, and prepared a Historic Properties Treatment Plan that provides detailed methodology for implementing mitigation prescribed by the agreement and resolves adverse effects to all known historic properties. (2023 PA 6, 20.)[10] OEA concludes, and the Board agrees, that execution of the PA satisfies the requirements of Section

[9] In response to DesertXpress' petition for exemption to construct and operate the RC Line, see note 9, *supra,* the San Manuel Band of Mission Indians (San Manuel Band, now the Yuhaaviatam of San Manuel Nation) and Morongo Band of Mission Indians (Morongo Band), filed comments challenging the sufficiency of FRA's historic review process with respect to the modified alignment of the LV Line. (San Manuel Band Comments 1–2, FD 36488, May 5, 2021; Morongo Band Comments 1–2, FD 36488, June 4, 2021). Since those comments were filed, a new PA has been executed between (among others) FRA, STB, the California State Historic Preservation Office (SHPO), the Nevada SHPO, and the Advisory Council on Historic Preservation (ACHP). *See* note 11, *infra.* Execution of the PA satisfies the requirements of Section 106 for the modified route of the LV Line.

Also in the docket for the RC Line, the National Parks Conservation Association (NPCA) filed a comment suggesting that the LV Line was not adequately assessed under NEPA. (NPCA Comments 1, FD 36488 June 8, 2021.) NPCA further argued that the LV Line should have been considered simultaneously with the RC Line because, according to NPCA, ''there is no viable project'' absent the RC Line. (*Id.*) The Board disagrees. As explained above, both the LV Line's and RC Line's environmental and historic impacts have been thoroughly evaluated under NEPA and NHPA. And, as the Board found in 2011, the LV Line has considerable merit—including ridership demand—even without the RC Line. *See Oct. 2011 Decision,* FD 35544, slip op. at 2–3.

[10] The PA is available on FRA's website at *https://railroads.dot.gov/rail-network-development/environment/environmental-reviews/brightline-west-las-vegas-victor-valley.*

106 for the modified route. OEA 2023 Memo 4.

The Board's Analysis of the Environmental Issues

The Board will adopt the analyses and conclusions in the FRA 2020 and 2023 Reevaluations. The Board will also impose the final recommended mitigation measures listed in Appendix D of the FRA 2023 Reevaluation, which would lessen impacts from constructing and operating the modified alignment. The Board is satisfied that the FRA 2020 and 2023 Reevaluations took the requisite ''hard look'' at the potential environmental and historic impacts associated with modifications to the LV Line and properly determined that, with the mitigation in Appendix D of FRA's 2023 Reevaluation, the proposed modifications would not have potentially significant environmental impacts, and that preparation of a Supplemental EIS is unnecessary.

Conclusions

The Board already authorized construction and operation of the LV Line by exemption in 2011, and the modified alignment would lessen or avoid a number of potential environmental impacts by placing much of the routing in the I–15 median. As noted above, the merits of a high-speed rail passenger line connecting Las Vegas and Southern California are substantial, and are strengthened by the RC Line and its connection to the greater Southern California commuter rail network. Moreover, providing a rail alternative along the I–15 corridor would not only create a transportation benefit for passengers; it would also create environmental benefits in replacing highway vehicle traffic, and its associated emissions, with more environmentally-friendly rail travel. Therefore, after considering the transportation merits, the environmental issues, and the entire record, the Board will grant the petition for exemption and authorize the modified alignment of the LV Line by modifying the 2011 routing condition, subject to compliance with the mitigation measures listed in Appendix D of the FRA 2023 Reevaluation.

This action, as conditioned, will not significantly impact the quality of the human environment or the conservation of energy resources.

It is ordered:

1. DesertXpress' petition to reopen and modify the 2011 routing condition is granted.

2. Under 49 U.S.C. 10502, the Board exempts construction of the LV Line from the prior approval requirements of 4 U.S.C. 10901, with the modifications evaluated in the FRA 2020 and 2023 Reevaluations.

3. The Board adopts the environmental mitigation measures set forth in Appendix D of the FRA 2023 Reevaluation and imposes them as conditions to the exemption granted here.

4. Notice will be published in the **Federal Register**.

5. Petitions for reconsideration must be filed by December 6, 2023.

6. This decision is effective December 16, 2023.

Decided: November 15, 2023.

By the Board, Board Members Fuchs, Hedlund, Oberman, Primus, and Schultz.

Jeffrey Herzig,

Clearance Clerk.

Appendix

Surface Transportation Board

Washington, DC 20423

Office of Environmental Analysis

MEMORANDUM

TO: Martin Oberman, Chairman; Karen Hedlund, Vice Chairman; Patrick Fuchs, Member; Michelle Schultz, Member; Robert Primus, Member

Cc: Mai Dinh, Director, Office of Proceedings

FROM: Danielle Gosselin, Director, Office of Environmental Analysis

DATE: October 30, 2023

SUBJECT: Docket No. FD 35544, DesertXpress Enterprises, LLC and DesertXpress HSR Corporation—Construction and Operation Exemption—in Victorville, Cal. and Las Vegas, Nev.: Environmental Memorandum

This memorandum summarizes a second reevaluation undertaken by the Federal Railroad Administration (FRA) in 2023 (2023 Reevaluation) of additional proposed project modifications to DesertXpress Enterprises, LLC's, d/b/a Brightline West (the Applicant), construction and operation of a high-speed passenger rail line between Southern California and Las Vegas, Nevada. This memorandum also presents the Office of Environmental Analysis' (OEA) final recommendations to the Board based on FRA's 2023 Reevaluation, including a recommendation that the Board impose the revised environmental mitigation in FRA's 2023 Reevaluation in any decision authorizing the project, as modified.

Introduction

On July 28, 2011, the Applicant submitted a petition for exemption under 49 U.S.C. 10502 for the construction and operation of an approximately 190-mile high-speed passenger rail line between the Victor Valley, in Southern California, and Las Vegas, Nevada (Line). The purpose of the Line was to create an alternative transportation option (in addition to auto and air) from Southern California to Las Vegas. The Applicant plans to provide passenger rail service on the Line.

The Board, through OEA, participated in the environmental review as a cooperating agency under the lead of FRA.[1] A number of other agencies, including the Bureau of Land Management (BLM), the Federal Highway Administration, the National Park Service, the California Department of Transportation (Caltrans), and the Nevada Department of Transportation (NDOT), participated in the environmental review process as cooperating agencies or consulting parties. FRA, with the assistance of the cooperating agencies, prepared a Draft Environmental Impact Statement (Draft EIS) in March 2009, a Supplemental Draft EIS in August 2010, and a Final Environmental Impact Statement (Final EIS) in March 2011.[2]

The EIS identified a preferred alternative and developed environmental mitigation conditions to avoid or minimize potential environmental impacts. Following the issuance of a Record of Decision (ROD) by FRA, the Board, on October 20, 2011, granted the Applicant's petition for exemption, subject to environmental conditions and the condition that the Applicant build the route designated in the EIS and ROD as environmentally preferable (2011 Decision).[3] Despite having the requisite agency approvals to construct and operate the Line, construction did not immediately proceed.

In 2018, the Applicant proposed design modifications to the Line, including modifying the rail alignment between the Victor Valley and Las Vegas so that it was located primarily within the I–15 freeway median with portions following the east side of the I–15 freeway; relocating the Southern California terminus from Victorville to the Town of Apple Valley (both located in the Victor Valley); collocating an operations maintenance storage facility with the passenger station in Apple Valley; and constructing certain ancillary facilities not previously evaluated in the EIS.

FRA prepared a written reevaluation[4] of the design modifications (2020

[1] FRA was the lead agency in the environmental review because of its jurisdiction and expertise related to high-speed train operations and railroad safety. *See DesertXpress Enters., LLC & DesertXpress HSR Corp.—Constr. & Operation Exemption—in Victorville, Cal. & Las Vegas, Nev.,* Docket No. FD 35544, slip op. at 4 n.6 (STB served Oct. 25, 2011).

[2] The DEIS, Supplemental DEIS, and FEIS are referred to collectively as the EIS.

[3] See *2011 Decision* at 1, 8.

[4] FRA's Procedures for Considering Environmental Impacts (64 FR 28545, May 26, 1999), provide that if major steps toward implementation of the proposed action have not occurred within the time frame, if any, set forth in the Final EIS, or within five years from the date of approval of the Final EIS, a written reevaluation of the adequacy, accuracy, and validity of the Final EIS is prepared, to determine if a new or supplemental EIS is necessary.

Reevaluation), in which it determined that the project modifications would reduce certain environmental impacts; updated and revised some mitigation measures developed in the EIS to address changes in the affected environment and project modifications since publication of the EIS; and concluded that a Supplemental EIS was not required and that the proposed project modifications are consistent with the proposed action described in FRA's EIS and ROD. The Board, through OEA, participated as a cooperating agency in FRA's reevaluation process.

On March 27, 2019, the Applicant filed a petition with the Board to reopen this proceeding, seeking modification to the condition in the *2011 Decision* authorizing construction of the Line along the previously selected preferred alternative route due to the Applicant's proposed design modifications and other changes. OEA prepared an Environmental Memorandum to the Board agreeing with FRA's conclusions in the 2020 Reevaluation that no Supplemental EIS was required, and recommending that, in any decision approving the proposed project, the Board impose the revised mitigation measures in FRA's 2020 Reevaluation. The Board then issued a decision on December 3, 2020 attaching the OEA memorandum, seeking public comment, and noting that the review of historic and cultural resources pursuant to Section 106 of the National Historic Preservation Act was still ongoing and that, therefore, the Board could not issue a final decision addressing the modified route and other changes until that process was complete. No comments were received.

FRA'S 2023 Reevaluation

In 2022, the Applicant proposed additional modifications, which were developed through the final design phase for the Line. These modifications included relocating the rail alignment on certain portions of the Line from the east side of the I–15 freeway to the median; revising the design of the Apple Valley station to include the passenger boarding and alighting platforms in the median of the I–15 freeway; raising and moving east a portion of the existing I–15 northbound lanes to provide the necessary footprint and access for these passenger platforms; adding or modifying certain ancillary features not previously evaluated in the EIS or 2020 Reevaluation, such as highway ramps, state highway patrol emergency crossovers, and culverts; and locating a vehicle maintenance facility and connecting freight track corridor at a site that had not previously been evaluated in Sloan, Nevada (Sloan VMF). A detailed table from the 2023 Reevaluation describing all of the additional modifications is attached to this memorandum.

FRA evaluated the additional modifications and issued a memorandum on September 15, 2023, concluding that a Supplemental EIS is not necessary. The 2023 Reevaluation focused on the modifications to the project footprint and facilities proposed since the issuance of FRA's 2020 Reevaluation, and also reflected changes since then to the affected environment, regulatory setting, and project effects. FRA reassessed each of the environmental resource areas analyzed in the EIS and 2020 Reevaluation: land use, community, and environmental justice communities; growth; farmlands and grazing lands; utilities/emergency services; traffic and transportation; visual resources; cultural resources; hydrology and water quality; geology and soils; paleontological resources; hazardous materials; air quality and global climate change; noise and vibration; energy; biological resources; [5] and cumulative impacts.[6] FRA determined that the additional modifications, with the imposition of final proposed mitigation (including, in most cases, mitigation that had already been proposed in the EIS and 2020 Reevaluation), would not result in substantial changes in the evaluation of impacts disclosed in the EIS or 2020 Reevaluation, that the modifications would generally avoid or minimize the overall effects of the project, and that no Supplemental EIS is required.[7]

Mitigation Measures

FRA has updated the mitigation measures included in the 2011 ROD and the 2020 Reevaluation to account for the additional project modifications, and principally to mitigate impacts on the desert tortoise and the desert tortoise habitat from the Sloan VMF footprint. The mitigation measures are described in detail in Attachment D of the 2023 Reevaluation.[8] The 2023 Reevaluation concludes that the mitigation measures developed in the EIS and the 2020 Reevaluation, as updated in the 2023 Reevaluation, would avoid or minimize potential environmental impacts and that no Supplemental EIS is required.

Section 106 Process

A Programmatic Agreement (PA) to govern the approach for ongoing compliance with Section 106 and implementation of the resolution of adverse effects was executed on August 15, 2023. This completed the Section 106 process for the proceeding.

OEA'S Final Environmental Recommendations

After participating in the reevaluation process and reviewing FRA's 2023 Reevaluation, OEA concludes that the 2023 Reevaluation adequately assesses the potential environmental impacts associated with the Applicant's additional modifications and concurs with FRA's determination that a Supplemental EIS is not necessary. Accordingly, OEA recommends that the Board consider FRA's 2023 Reevaluation, along with the 2020 Reevaluation and the EIS, when it decides whether to authorize the Line as modified. Mitigation measures imposed in FRA's ROD and the Board's prior decision, and refined in the 2020 Revaluation, were further refined in the 2023 Reevaluation. Therefore, OEA recommends that, in any decision approving the Line as modified in the 2020 and 2023 Reevaluations, the Board impose all the mitigation measures included in Appendix D of the 2023 Reevaluation.

Attachment

[5] FRA reinitiated consultation with the U.S. Fish and Wildlife Service (USFWS), under Section 7 of the Endangered Species Act for the additional modifications. USFWS recommended updates to the mitigation measures described in the project's Biological Opinion prepared in 2011, specifically mitigation for impacts from the Sloan VMF on the desert tortoise and desert tortoise habitat. FRA incorporated the revised mitigation measures into the 2023 Reevaluation. On September 1, 2023, USFWS concluded re-initiation of Section 7 consultation and determined that formal consultation was not required for the Line.

[6] With the exception of biological resources and cultural resources, FRA performed a desktop/qualitative evaluation for the above-listed resources as changes to the affected environment for those resources would be unlikely to occur or were easily assessed using publicly available resources. FRA performed more detailed evaluations to assess impacts to cultural resources and biological resources, which it documented in technical reports/memoranda. To facilitate review by BLM, FRA included a separate analysis for the Sloan VMF in the 2023 Reevaluation because the Sloan VMF has been proposed on land owned and managed by BLM. FRA's determination as to whether a Supplemental EIS is required considered all project modifications, including the Sloan VMF.

[7] For example, FRA concluded that placement of additional components of the rail alignment and a greater portion of ancillary facilities within the I–15 freeway right-of-way would reduce biological resource impacts compared to the EIS or the FRA 2020 Reevaluation. (FRA 2023 Reevaluation 51–54.) Similarly, constructing along the modified route would result in fewer air emissions compared to the route examined in the EIS because there would be no tunneling and less of a need to elevate the alignment. (*Id.* at 45.)

[8] The 2023 Reevaluation, including its attachments, is available on FRA's website at *https://railroads.dot.gov/rail-network-development/environment/environmental-reviews/brightline-west-las-vegas-victor-valley*.

PROJECT MODIFICATIONS (SINCE THE SEPTEMBER 2020 REEVALUATION) [9]

Project feature	Description of modification
Segment 1 Alignment (Apple Valley to Lenwood)	The Project modifications involve relocating the rail alignment between the Victor Valley Station and Sidewinder Road from east side of the I–15 freeway to the median. As such, the entirety of the Segment 1 rail alignment is now within the I–15 freeway median, which would result in reduced impacts and increase the efficiency of train operations. This design change is also favorable with Caltrans and FHWA as it would improve constructability of potential future I–15 freeway improvements in either the northbound or southbound directions. Additionally, the Segment 1 rail alignment would be extended less than one mile south of the Victor Valley Station to access a maintenance of way track that will be constructed to move equipment from the median rail mainline to the maintenance of way facility. Construction of a median-running rail alignment in this area, south of the Dale Evans Parkway intersection, would require realignment of the existing I–15 northbound travel lanes approximately 50 feet east, and reconstruction of the Dale Evans Parkway interchange including the overpass.[10] This is discussed further under the Victor Valley Station description below. Additionally, the I–15 northbound travel lanes would be elevated approximately 25 feet south of the interchange to allow the maintenance of way track to pass from the median to the maintenance of way facility. All roadway work would occur within existing Caltrans/NDOT ROW.
Segment 5 Alignment (PRIMM to Sloan Road)	Project modifications would relocate the rail alignment, between Primm and north of Goodsprings Road near Jean, from the east side of the I–15 freeway to the freeway median. As such, the entirety of the Segment 5 rail alignment is now located within the I–15 freeway median, which would result in reduced impacts, increase the safety and efficiency of train operations, and improve constructability for future I–15 widening in this portion of the alignment. Additionally, the previously considered Braid Structures near Primm and the Union Pacific Railroad (UPRR) crossing are no longer needed and have been removed.
Victor Valley Station (Previously Referred to as Dale Evans Station)	The Project design evaluated in September 2020 considered collocating an operations, maintenance, and storage facility (OMSF) with the Victor Valley Station, with a permanent footprint of approximately 300 acres. As discussed below, the current Project modifications include a relocation of the Vehicle Maintenance Facility (VMF) to a site on the west side of I–15 in Sloan. The Victor Valley Station permanent footprint would remain unchanged. As noted above, under Segment 1, the Project Modifications include relocating the rail alignment into the median of the I–15 freeway. To accommodate this new rail alignment, the Victor Valley Station layout has been revised to include the passenger boarding and alighting platforms in the median of the I–15 freeway. In order to provide the necessary footprint and access for these platforms, the existing I–15 northbound lanes would be raised and moved east within the Caltrans ROW south of the Dale Evans Parkway interchange. Passengers would access station platforms using a walkway underneath the relocated I–15 freeway northbound lanes.
Highway Ramp Realignments/Modifications	The Project design evaluated in September 2020 included realignment of portions of approximately 17 existing freeway on and off- ramps to accommodate the rail line within the I–15 freeway ROW. The current Project modifications include extending these on and off ramp realignments and ramp modifications and changing the location where these ramp realignment/reconstructions transition to the existing roadway/pavement. There are locations where these proposed freeway ramp modifications occur (from south to north): • The I–15 southbound ramps at Dale Evans Parkway. • The I–15 northbound ramps at Main Street in Barstow. • The I–15 northbound ramps and southbound ramps at East Primm Boulevard. • The I–15 southbound ramps at Goodsprings Road. • The I–15 southbound ramps at Sloan Road. These modifications would be located primarily on previously evaluated Project footprint within existing Caltrans/NDOT, and local ROW along the I–15 freeway. These modifications are the result of coordination with Caltrans and NDOT on final design details, in order to update the modified median-running alignment to adhere to current safety design standards.

PROJECT MODIFICATIONS (SINCE THE SEPTEMBER 2020 REEVALUATION) [9]—Continued

Project feature	Description of modification
California Highway Patrol (CHP) Emergency Crossovers	The Project design evaluated in September 2020 included eight emergency crossovers along the alignment in California. The current Project modifications include two new emergency crossovers at Zzyzx Road and Halloran Springs. Additionally, five previously evaluated emergency crossovers in Segment 3 would be relocated. These are located near Coyote Lake Road, Basin Road, Baker, and both north and south of Halloran Springs. Emergency crossovers would be located mainly on previously evaluated Project footprint within the existing Caltrans ROW. In total, the modified Project would include 10 emergency crossovers in California, located in Segment 3 between Yermo and Mountain Pass, and one emergency crossover in Nevada approximately 1.5-miles south of Sloan.
Roadwork	The Project design evaluated in September 2020 included roadwork at local interchanges and along the I–15 freeway at various locations. The current Project modifications include: • Realigning the I–15 freeway northbound lane approximately 50 feet east and raising the lane approximately 25 feet, to accommodate the passenger platforms in the I–15 median, tail track for train storage, a pedestrian underpass for access to/from the platforms, and a maintenance of way access track for trains. These roadwork improvements would occur along a 60-foot portion of the I–15 freeway northbound lane adjacent to the Victor Valley Station. • Additional roadwork at the Dale Evans Parkway interchange accessing the I–15 freeway southbound ramps. • I–15 freeway median widening at Segment 5 to accommodate the modified median-running alignment. • Raising of I–15 southbound lanes just south of the Sloan Road interchange to allow for tracks to exit the I–15 median under the southbound lanes and into the Sloan VMF site. The Project modifications also include small, on-road lane realignments along the I–15 freeway at Segment 6, near Silverado Ranch Boulevard and Blue Diamond Road.
Culverts	The Project design evaluated in September 2020 included drainage and culvert work throughout the Project limits. The current Project modifications include revised designs for three culverts and the addition of four culverts within Segment 5. The associated drainage and grading activities have also been modified accordingly.
Cemex Facility and Rail Connection	A new connection to the existing Cemex industrial rail track is proposed on the north side of Apple Valley, CA near the proposed Victor Valley Station. The connection would consist of a turnout off the existing Cemex track and approximately 2 miles of new track along the east side of I–15 freeway heading north, all within the Caltrans ROW limit. This connection would allow rail transportation of construction materials such as track ballast to the Project area. This reduces the need for trucking construction materials to the Project area.
Ivanpah Traction Power Substation (TPSS)	The Ivanpah modified TPSS 3-mile utility line and 3.5-mile redundant utility line would travel north of the existing solar field to connect to a Southern California Edison (SCE) substation adjacent to the BrightSource Ivanpah Electrical Generating System, west of the I–15 freeway, resulting in the reduction of approximately 0.18 acres of permanent footprint. These modifications are the result of coordination with SCE, BLM and USFWS.
California Maintenance Of Way (MOW) Facility	The Project design evaluated in September 2020 considered the relocation of the California MOW Facility from Baker, California, to the I–15 freeway median approximately six miles south of the California/Nevada state line, adjacent to the existing California Agricultural Inspection Station (CAIS). The 25-acre facility was proposed to be utilized for passive equipment storage. The MOW is no longer located adjacent to the CAIS and will be divided between the new site at Sloan and the Victor Valley Station area.

PROJECT MODIFICATIONS (SINCE THE SEPTEMBER 2020 REEVALUATION) [9]—Continued

Project feature	Description of modification
Sloan Vehicle Maintenance Facility (VMF)	The Project design evaluated in the DesertXpress EIS included an OMSF in close proximity to the original Victorville Station west of the I–15 freeway and included facilities for maintaining and storing trains. Project modifications evaluated in 2020 included relocating the Victorville Station to the south side of the I–15 freeway at Dale Evans Parkway in Apple Valley. At that time, it was proposed the OMSF would be collocated with the Victorville Station, and a separate location for vehicle maintenance and storage had not been identified. The current Project modifications include locating the vehicle maintenance and storage activities at a site located in Segment 6 west of and within 1.5 miles of the I–15 freeway, and south of Sloan Road; the Victor Valley Station permanent footprint would remain unchanged. An additional freight track corridor will be constructed to connect the VMF to the adjacent UPRR. Brightline West have filed a connection request and are coordinating with UPRR regarding the connection design and operational concepts. UPRR have granted preliminary approval of this rail connection, which would be subject to additional design development. The Sloan VMF and adjacent UPRR connection would require 246 acres of permanent footprint and 105 acres of temporary footprint,6 and includes: • Storage and staging tracks and overhead catenary system from which trains would be mobilized for daily operations. • Equipment and operations associated with the Sloan VMF, including but not limited to a train car wash station, a train performance monitoring station, an Operations Control Center, a power substation and distribution lines, utility connections, circulation system, site control, fencing, and parking. The Sloan VMF will be a permanent workplace for approximately 100 employees related to either the maintenance of the Brightline West train fleet or performing other functions such as driving the trains. These facilities would be located on land under BLM jurisdiction and would therefore require a ROW grant lease from BLM.
Temporary Construction Areas (TCAS)	TCAs are areas that would be utilized for construction staging and storage. No permanent project features would be installed in these areas, and they would be restored/vacated upon completion of construction. The modified Project includes an additional 202 TCAs located within Caltrans/NDOT ROW along the I–15 freeway corridor for construction of the rail alignment. These are in addition to TCAs previously identified in the original project description and the September 2020 Reevaluation. Most of these additional TCAs are areas located within the existing I–15 freeway ROW. The addition of these TCAs adds 1,492 acres of temporary footprint to the project [11] The Sloan VMF facility footprint includes 105 acres of temporary footprint required for constructing the Sloan VMF and UPRR Connection.

[9] Brightline West Victor Valley, CA to Las Vegas, NV High-Speed Rail Project Reevaluation (September 15, 2023) pgs. 4–7.
[10] This Reevaluation has assumed full reconstruction and replacement of the overpass. Caltrans will determine the necessary modifications to the I–15/Dale Evans interchange which may not include full reconstruction and replacement of the overpass.
[11] As more of the alignment has been shifted to be within the I–15 freeway median, additional TCAs are proposed since room for construction within the I–15 freeway median is more limited and needs to be spread out throughout the alignment.

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BILLING CODE 4915–01–P

SURFACE TRANSPORTATION BOARD

[Docket No. FD 36488]

Desertxpress Enterprises, LLC—Authority To Construct and Operate—Petition for Exemption From 49 U.S.C. 10901—Passenger Rail Line Between the Victor Valley, Cal. and Rancho Cucamonga, Cal.

On April 13, 2021, DesertXpress Enterprises, LLC, a Nevada limited liability company, d/b/a Brightline West (DesertXpress),[1] filed a petition under 49 U.S.C. 10502 for an exemption from the prior approval requirements of 49 U.S.C. 10901 to construct and operate an approximately 50-mile high-speed passenger rail line between the Victor Valley, in Southern California, and Rancho Cucamonga, Cal. (the RC Line). DesertXpress plans to operate as a common carrier providing passenger rail service on the rail line to be constructed. DesertXpress does not plan to provide freight rail service. No comments opposing the transportation merits of DesertXpress' petition were filed.

On July 12, 2021, the Board instituted a proceeding under 49 U.S.C. 10502.[2] As discussed below, the Board, through the Office of Environmental Analysis (OEA), participated in the environmental and historic review of the RC Line as a cooperating agency

[1] On September 17, 2018, DesertXpress' ownership group entered into an agreement to sell the company to Brightline Holdings LLC (Brightline). *Fortress Inv. Grp. LLC—Continuance in Control—Cent. Me. & Que. Ry.,* FD 36225, slip op. at 1–2 (STB served Oct. 11, 2018). Brightline's acquisition of DesertXpress was consummated on March 4, 2019. (DesertXpress Pet. 2 n.2.)

[2] On July 21, 2023, DesertXpress filed a letter requesting that the Board expedite a final decision in this proceeding. On July 27, 2023, U.S. Representative Dina Titus filed a letter urging the Board to expeditiously consider DesertXpress' petition.

under the lead of the Federal Railroad Administration (FRA). This thorough environmental review took a ''hard look'' at environmental impacts, selected a preferred alternative, and recommended environmental mitigation conditions to avoid or minimize the selected alternative's potential environmental impacts. After considering the entire record on both the transportation and the environmental issues, the Board will grant DesertXpress' petition for exemption, subject to environmental conditions.

Background

In *DesertXpress Enterprises, LLC—Construction & Operation Exemption—in Victorville, Cal. and Las Vegas, Nev.,* FD 35544 (STB served Oct. 25, 2011), the Board exempted from the prior approval requirements of 49 U.S.C. 10901 DesertXpress' proposal to construct and operate an approximately 190-mile high-speed passenger rail line between Las Vegas, Nev., and the Victor Valley (the LV Line).[3] The RC Line will extend from a point of connection with the southern terminus of the LV Line in the Victor Valley to Rancho Cucamonga. (DesertXpress Pet. 4.) The RC Line's alignment will be entirely within the I–15 right-of-way except for the final mile at Rancho Cucamonga, which will exit the I–15 right-of-way, proceed west along 8th Street and terminate adjacent to the Southern California Regional Rail Authority's (Metrolink's) Rancho Cucamonga train station on the south side of 8th Street west of Milliken Avenue.[4] (*Id.* at 5.) DesertXpress' Rancho Cucamonga station will link DesertXpress' train services with the passenger services operated by Metrolink and the bus rapid transit system. (*Id.* at 6.) DesertXpress states that connecting its service to Metrolink's rail system in this manner will create a seamless all-rail option for travel between Las Vegas and points throughout the greater Los Angeles, Cal., Orange County, Cal., and San Bernardino, Cal. metropolitan areas. (*Id.* at 14.) The RC Line will be built and operated on a dedicated, fully grade-separated right-of-way with no at-grade crossings. (*Id.* at 4.) It will consist of a single main-line track with passing sidings and will be dedicated exclusively to high-speed passenger service. (*Id.* at 4, 18.)

DesertXpress currently plans to operate 50 trains per day (25 in each direction) between Las Vegas and Rancho Cucamonga. (*Id.* at 7.) Trains will depart from both Las Vegas and Rancho Cucamonga at 45-minute intervals and will operate at speeds up to 180 miles per hour. (*Id.*) The first trains will depart Rancho Cucamonga and Las Vegas at 5:30 a.m. with the final trains arriving in Rancho Cucamonga and Las Vegas at approximately 11:30 p.m. and 1:00 a.m., respectively. (*Id.*)

The RC Line is forecasted to attract approximately 1.5 million additional passengers to DesertXpress' train service, compared to the LV Line standing alone, by the third year of revenue operations. (*Id.* at 6.) Travelers on the RC Line will include both passengers traveling between Las Vegas and Southern California and passengers traveling between the Victor Valley and Rancho Cucamonga stations. (*Id.*) According to DesertXpress, the service between Victor Valley and Rancho Cucamonga is expected to attract more than half a million riders annually by the second year of service and the RC Line is expected to double the number of westbound passengers who choose DesertXpress train service for their travel from Las Vegas to Southern California. (*Id.*)

DesertXpress plans to commence construction of the RC Line as soon as practicable following approval of its petition. (*Id.* at 11.) According to DesertXpress, the estimated cost of constructing the RC Line is approximately $2 billion and Brightline plans to finance the construction with a blend of tax-exempt bonds, taxable debt, and equity. (*Id.*)

Several parties filed comments in response to DesertXpress' petition. The only comment on the transportation merits was filed on May 13, 2021 by the Allied Rail Unions[5] stating that they support DesertXpress' petition. On May 5, 2021, the San Manuel Band of Mission Indians (San Manuel Band) filed comments on environmental issues and a request for an extension of time to file further comments. The Board granted that request in a decision served on May 19, 2021. In addition, the San Manuel Band, Morongo Band of Mission Indians (Morongo Band), and the National Parks Conservation Association (NPCA) filed comments regarding environmental issues on June 3, 2021, June 4, 2021, and June 8, 2021, respectively. On June 22, 2021, DesertXpress filed a reply to the comments of San Manuel Band, Morongo Band, and NPCA.

Discussion and Conclusions

Rail Transportation Analysis. The construction of new rail lines requires prior Board authorization through issuance of a certificate under 49 U.S.C. 10901 or, as requested here, through an exemption under 49 U.S.C. 10502 from the prior approval requirements of section 10901. Section 10901(c) directs the Board to authorize rail line construction proposals unless it finds the proposal ''inconsistent with the public convenience and necessity.'' *See Alaska R.R.—Constr. & Operation Exemption—a Rail Line Extension to Port MacKenzie, Alaska,* FD 35095, slip op. at 5 (STB served Nov. 21, 2011), *aff'd sub nom. Alaska Survival* v. *STB,* 705 F.3d 1073 (9th Cir. 2013). Thus, Congress has established a presumption that rail construction projects are in the public interest unless shown otherwise. *See N. Plains Res. Council* v. *STB,* 668 F.3d 1067, 1091–92 (9th Cir. 2011); *Mid States Coal. for Progress* v. *STB,* 345 F.3d 520, 557 (8th Cir. 2003).

Under section 10502(a), the Board ''shall exempt'' a proposed rail line construction from the detailed application procedures of section 10901 when it finds that: (1) those procedures are not necessary to carry out the rail transportation policy of 49 U.S.C. 10101 (RTP); and (2) either (a) the proposal is of limited scope, or (b) the full application procedures are not necessary to protect shippers from an abuse of market power.

Based on the record in this proceeding, the Board concludes that the proposed construction qualifies for an exemption from the section 10901 prior approval requirements. Simply put, this is a project with a lot of upside and little, if any, downside, one that has the potential for broad public benefits, and one for which no issues about the project's current or future financial viability, including any negative effects of financial nonviability, have been raised.[6] Extending DesertXpress' previously approved service between Las Vegas and Victor Valley further south to Rancho Cucamonga and

[3] The LV Line has not yet been constructed. On March 27, 2019, DesertXpress filed a petition to reopen the Board's October 25, 2011 decision, in which DesertXpress requested that the Board approve changes to the alignment of the LV Line, including moving the proposed terminus approximately four miles from the City of Victorville to the Town of Apple Valley, both situated in the Victor Valley. The Board will address the proposed alignment changes to the LV Line in a separate decision.

[4] An additional DesertXpress station in the City of Hesperia, Cal. (south of Victorville) is also planned. (DesertXpress Pet. 5.)

[5] The Allied Rail Unions is a group of unions composed of the Brotherhood of Maintenance of Way Employes Division/IBT; Brotherhood of Railroad Signalmen; International Association of Sheet Metal, Air, Rail and Transportation Workers-Mechanical Division; and National Conference of Firemen and Oilers, 32BJ/SEIU.

[6] *See Mid States Coal. for Progress* v. *Surface Transp. Bd.,* 345 F.3d 520, 552 (8th Cir. 2003).

providing a connection to Metrolink's rail service there supports the RTP. It will provide additional transportation options for travelers throughout the greater Los Angeles, Orange County and San Bernardino metropolitan areas, thereby reducing congestion on the I–15 freeway, while also reducing air pollution and overall fuel consumption. Thus, the RC Line will help ''to ensure the development and continuation of a sound rail transportation system with effective competition among rail carriers and with other modes,'' 49 U.S.C. 10101(4), and will ''encourage and promote energy conservation.'' 49 U.S.C. 10101(14). In addition, constructing the RC line to extend DesertXpress' service will help ''foster sound economic conditions in transportation,'' 49 U.S.C. 10101(5), by increasing demand for DesertXpress' service. As noted above, it is projected that the RC Line will attract an additional 1.5 million passengers to DesertXpress' train service annually. An exemption will also minimize the time and administrative expense associated with obtaining Board approval and expedite the introduction of a new rail service for millions of travelers and will therefore both ''reduce regulatory barriers to entry into and exit from the industry,'' 49 U.S.C. 10101(7), and ''provide for the expeditious handling and resolution of . . . proceedings required or permitted to be brought [before the Board].'' 49 U.S.C. 10101(15). Other aspects of the RTP would not be adversely affected.

In addition, consideration of the RC Line under section 10901 here is not necessary to protect shippers from an abuse of market power. The RC Line will not be used to provide freight rail transportation to shippers, nor will it cause any shipper to lose access to any rail options.[7]

Environmental Analysis. The National Environmental Policy Act (NEPA) requires federal agencies to examine the environmental effects of proposed federal actions and to inform the public concerning those effects. *Balt. Gas & Elec. Co.* v. *Nat. Res. Def. Council,* 462 U.S. 87, 97 (1983). Under NEPA and related environmental laws, the Board must consider significant potential beneficial and adverse environmental impacts in deciding whether to authorize a railroad construction project as proposed, deny the proposal, or grant it with conditions (including environmental mitigation conditions). *Lone Star R.R. Track Constr. & Operation Exemption—in Howard Cnty., Tex.,* FD 35874, slip op at 4 (STB served Mar. 3, 2016). While NEPA prescribes the process that must be followed, it does not mandate a particular result. *Robertson* v. *Methow Valley Citizens Council,* 490 U.S. 332, 350 (1989). Once the adverse environmental effects have been adequately identified and evaluated, an agency may conclude that ''other values outweigh the environmental costs.'' *Id.*

In every exemption case, the Board considers both the transportation merits and the environmental impacts in deciding whether to authorize the proposed action. With respect to environmental issues, the Board, through OEA, participated in the environmental and historic review of the RC Line as a cooperating agency under the lead of FRA. FRA prepared an Environmental Assessment (EA) in accordance with NEPA, the National Historic Preservation Act (NHPA), and related environmental laws to evaluate the potential environmental and historic impacts of the RC Line. The EA analyzed both a Build Alternative and No-Build Alternative (*i.e.,* No-Action Alternative), and FRA identified the Build Alternative as the preferred alternative. (EA xv, 10–14.) The EA also identified mitigation measures to reduce potential environmental impacts. (EA 57–58, 61–63, 67, 90–102, 137–38, 173–76, 192, 198–200.) The EA was made available for public review and comment between October 28, 2022, and November 28, 2022.

On July 12, 2023, FRA issued a Finding of No Significant Impact (FONSI), which incorporated the EA by reference. The FONSI concluded that the Build Alternative would not significantly impact the quality of the human environment and should be authorized subject to appropriate environmental mitigation (FONSI 15 & Attach. A). The FONSI also addressed the public comments on the EA. The comments received on the EA were minor and the responses to the comments were limited to factual corrections or explanations of why the comments did not warrant further response. (FONSI 2.)

Concurrently with preparation of the EA, FRA initiated consultation under Section 106 of NHPA, which included efforts to identify, evaluate, and assess effects to historic properties that could be impacted by the RC Line.[8] (EA 138–58.) FRA concluded that construction and operation of the RC Line would have no adverse effects on resources listed in or eligible for listing in the National Register of Historic Places. (*Id.*) The California State Historic Preservation Officer (SHPO) did not object to FRA's finding of no adverse effect for the RC Line. FRA issued a final Finding of Effect report and made a finding of no adverse effect for the RC Line on June 30, 2023. (*Id.* at 13–14.) Accordingly, no historic mitigation was imposed. (*Id.* at 8, 10 & Attach. A.)

OEA prepared a memorandum making final environmental recommendations for this proceeding (Environmental Memo), which is attached to this decision. The Environmental Memo summarizes the environmental and historic review process, the potential environmental impacts of the construction and operation of the RC Line, and FRA's mitigation measures to minimize those impacts. (Environmental Memo 3–8.) The Environmental Memo recommends that the Board adopt FRA's EA and the conclusions in the FONSI, and that it impose the environmental mitigation measures set forth in Attachment A to the FONSI as conditions to any decision authorizing construction and operation of the RC Line. (Environmental Memo 8–9.)

The Board's Analysis of the Environmental Issues. The Board adopts FRA's analysis and conclusions in both the EA and FONSI. The Board is satisfied that OEA, together with FRA and the cooperating agencies, has taken the requisite ''hard look'' at the potential environmental impacts associated with DesertXpress' proposal and properly determined that, with the recommended environmental mitigation in the FONSI, the RC Line will not have potentially significant environmental impacts and that preparation of an Environmental Impact Statement is unnecessary.

As noted above, San Manuel Band, Morongo Band, and NPCA filed comments regarding environmental issues. However, those comments raise concerns regarding FRA's

[7] Because regulation of the proposed construction and operation is not needed to protect shippers from the abuse of market power, the Board need not determine whether the transaction is limited in scope. 49 U.S.C. 10502(a)(2).

[8] The Board participated as a consulting party in FRA's Section 106 consultation process, along with the Advisory Council on Historic Preservation, DesertXpress, Caltrans, City of Fontana, City of Ontario, City of Rancho Cucamonga, City of Rialto, City of Victorville, Federal Highway Administration, U.S. Army Corps of Engineers, and the United States Forest Service. (FONSI 13). As part of that process, FRA consulted with the Chairpersons of and/or Tribal Historic Preservation Officers for the Chemheuvi Indian Tribes, the Colorado River Indian Tribes, the Morongo Band of Mission Indians, the San Fernando Band of Mission Indians, the Soboba Band of Luiseno Indians, and the Twenty-Nine Palms Band of Mission Indians, and identified tribal contacts for the Yuhaaviatam of San Manuel Nation (formerly the San Manuel Band). (*Id.*)

environmental and historic review process with respect to the proposed modified alignment of the LV Line. (San Manuel Band Comments 1–2, May 5, 2021; Morongo Band Comments 1–2; NPCA Comments 1.) The LV Line is not at issue in this proceeding and parties were given the opportunity in *DesertXpress Enterprises, LLC,* Docket No. FD 35544, to provide comments in the LV Line proceeding. *See DesertXpress Enters., LLC,* FD 35544, slip op. 1–2 (STB served Dec. 3, 2020) (providing 20-day period for filing of public comments). Accordingly, comments regarding the modified alignment of the LV Line will not be considered in this proceeding.

In addition, San Manuel Band and NPCA urge the Board not to permit an exemption from review under the California Environmental Quality Act (CEQA). (San Manuel Band Comments 2–3, June 3, 2021; NPCA Comments 2.) However, the only issue for the Board in this case is whether to grant DesertXpress' petition seeking an exemption from 49 U.S.C. 10901. Moreover, state permitting or preclearance requirements like CEQA are categorically preempted under 49 U.S.C. 10501(b) as to any lines and facilities that are an integral part of the national rail transportation system. *EPA—Pet. for Declaratory Ord.,* FD 35803, slip op. at 7 (STB served Dec. 30, 2014); *see also City of Auburn* v. *United States,* 154 F.3d 1025, 1031 (9th Cir. 1998). Indeed, the Board previously found that section 10501 preempted the application of CEQA to the LV Line.[9] *DesertXpress Enters., LLC—Pet. for Declaratory Ord.,* FD 34914, slip op. at 5 (STB served June 27, 2007). Because CEQA's permitting requirements could be used to deny or significantly delay construction of the RC Line, CEQA review is preempted in this proceeding as well.[10]

The project's transportation merits—expanding the broader DesertXpress passenger service to provide more seamless transportation to and from Southern California and Las Vegas, as well as providing a passenger rail option between Rancho Cucamonga and Victor Valley—are manifest. And the environmental and historic impacts have been thoroughly analyzed as required under NEPA and NHPA, with environmental mitigation imposed as appropriate. Accordingly, the Board grants DesertXpress' petition for exemption.

This action, as conditioned, will not significantly impact the quality of the human environment or the conservation of energy resources.

It is ordered:

1. Under 49 U.S.C. 10502, the Board exempts DesertXpress' construction and operation of the RC Line from the prior approval requirements of 49 U.S.C. 10901, subject to the requirement that DesertXpress build the FRA-preferred Build Alternative.

2. The Board adopts the environmental mitigation measures set forth in Attachment A to the FONSI and imposes them as conditions to the exemption granted here.

3. Notice will be published in the **Federal Register**.

4. Petitions for reconsideration must be filed by December 6, 2023.

5. This decision is effective, December 16, 2023.

Decided: November 15, 2023.

By the Board, Board Members Fuchs, Hedlund, Oberman, Primus, and Schultz.

Jeffrey Herzig,

Clearance Clerk.

Appendix

Surface Transportation Board

Washington, DC 20423

Office of Environmental Analysis

MEMORANDUM

TO: Martin Oberman, Chairman; Karen Hedlund, Vice Chairman; Patrick Fuchs, Member; Michelle Schultz, Member; Robert Primus, Member

Cc: Mai Dinh, Director, Office of Proceedings

FROM: Danielle Gosselin, Director, Office of Environmental Analysis

DATE: October 20, 2023

SUBJECT: Docket No. FD 36488, DesertXpress Enterprises, LLC—Construction and Operation Exemption—Passenger Rail Line Between Victor Valley and Rancho Cucamonga, Cal.: Environmental Memorandum

This memorandum summarizes the environmental and historic review conducted for the proposed 49-mile high-speed rail line between the Victor Valley and Rancho Cucamonga, California (RC Line or Project). The proposed RC Line would be part of the electrified high-speed passenger railroad system that DesertXpress Enterprises, LLC, d/b/a Brightline West (Brightline West) intends to construct and operate between Southern California and Las Vegas, Nevada. The memorandum also presents the Office of Environmental Analysis' (OEA) final recommendations to the Board regarding adoption of the Environmental Assessment (EA) for the Project, including the selection of the build alternative as the preferred alternative, and the environmental mitigation that should be imposed if the Board authorizes the RC Line.

Introduction

The Board, through OEA, participated in the environmental review of the RC Line as a cooperating agency under the lead of the Federal Railroad Administration (FRA). FRA prepared an EA in accordance with the National Environmental Policy Act (NEPA), the National Historic Preservation Act (NHPA), and related environmental laws to evaluate the potential environmental and historic impacts of the RC Line. The EA analyzed both a Build Alternative and No-Build Alternative (*i.e.,* No-Action Alternative), and FRA identified the Build Alternative as the Preferred Alternative. (EA xv, 10–14.) The EA also identified mitigation measures to reduce potential environmental impacts. (EA 57–58, 61–63, 67, 90–102, 137–38, 173–76, 192, 198–200.) The EA was made available for public review and comment between October 28, 2022, and November 28, 2022.

On July 12, 2023, FRA issued a Finding of No Significant Impact (FONSI), which incorporated the EA by reference,[1] and which concluded that the Build-Alternative would not significantly impact the quality of the human environment and should be authorized subject to appropriate

[9] Although the California High-Speed Rail Authority conducted an environmental review under CEQA as well as NEPA for the California High-Speed Train System—a project within the Board's jurisdiction—it ''elected'' to apply CEQA on its own volition and, in its environmental documentation, reserved the right to assert federal preemption in response to any potential legal challenge to its CEQA compliance. *Cal. High-Speed Rail Auth.—Pet. for Declaratory Ord.,* FD 35861, slip op. at 1–2, 11 (STB served Dec. 12, 2014); *see also Cal. High-Speed Rail Auth.—Constr. Exemption—in Merced, Madera, & Fresno Cntys., Cal.,* FD 35724 et al., slip op. at 3 n.6 (STB served Dec. 20, 2022) (finding that the ''Board is only required to comply with NEPA'' and related federal environmental laws despite FRA and California High-Speed Rail Authority conducting joint NEPA and CEQA review).

[10] While the RC Line will be an intrastate line located completely within California, it will connect to the LV Line, which will extend into Nevada. Therefore, the RC Line will be part of the interstate rail network and will be subject to the Board's jurisdiction. *See e.g.,* 49 U.S.C. 10501(a)(2)(A) (stating that the Board has jurisdiction over rail transportation between a place in ''a State and a place in the same or another State as part of the interstate rail network''); *Cal. High-Speed Rail Auth.—Pet. for Declaratory Ord.,* FD 35724, slip op. at 13–14 (STB served June 13, 2013) (finding that a rail line to be located completely within California was subject to Board jurisdiction because it would have extensive interconnectivity with Amtrak, an interstate passenger rail carrier).

[1] The FONSI attached an errata sheet making certain corrections to the EA. (FONSI, Attachment B.) FRA used an errata sheet in lieu of a Final EA because the comments received on the EA were minor and the responses to the comments were limited to factual corrections or explanations of why the comments did not warrant further response. (FONSI 2.)

environmental mitigation. (FONSI 15, 17 & Attachment A.) The FONSI summarized the Project's potential construction and operations impacts, as well as FRA's proposed mitigation measures, and addressed the public comments on the EA. (FONSI 7–13 & Attachment C.)

OEA has independently reviewed the EA and FONSI and agrees with FRA's analysis and conclusions. Further, OEA has determined that the EA adequately assesses the potential environmental and historic impacts of the RC Line and complies with the Board's responsibilities under NEPA, NHPA, and related environmental laws. OEA also concurs with FRA's selection of the Build-Alternative as the Preferred Alternative. Therefore, in any decision authorizing construction and operation of the RC Line, OEA recommends that the Board: (1) adopt the EA and FRA's conclusions in the FONSI; (2) approve construction and operation of FRA's Build-Alternative for the RC Line; and (3) impose the environmental mitigation in Attachment A to the FONSI.

Background

On April 13, 2021, Brightline West filed a petition for exemption with the Board under 49 U.S.C. 10502 to construct and operate the RC Line. Brightline West proposes to construct the RC Line within the Interstate-15 (I–15) right-of way for 48 miles and on existing transportation corridors for the last mile into the proposed Rancho Cucamonga station. (FONSI 1.) The RC Line would include two new rail stations—one in Hesperia and one in Rancho Cucamonga, both in California.[2] (*Id.*)

The purpose of the RC Line is to provide an alternative transportation option (in addition to cars) between the Los Angeles metropolitan region and the High Desert of San Bernardino County. (FONSI 3.) Trains are expected to operate daily every 60 minutes between the Victor Valley and Rancho Cucamonga. (*Id.* at 1.) The trip between the Victor Valley and Rancho Cucamonga will be approximately 35 minutes. Service will be coordinated with existing and planned Metrolink service at the Rancho Cucamonga station to provide a convenient connection between the RC Line and commuter rail systems. (*Id.*) Trains traversing over the RC Line would be capable of reaching a top speed of approximately 140 miles per hour. (*Id.*)

Summary of Environmental Impacts and Mitigation Measures

The charts below from FRA's FONSI provide an overview of the potential construction and operations impacts of the RC Line, and the associated mitigation measures to minimize these impacts.

Analysis area	Long-term operational impacts of the selected alternative	Mitigation
Transportation	The Rancho Cucamonga station will result in traffic impacts to three intersections that are projected to operate at unacceptable level of service during the 2025 Opening Year conditions during peak periods and will also degrade the level of service at the Milliken Avenue/7th Street Intersection compared to the 2045 No Build scenario.	During Project design, Brightline West will coordinate with SBCTA, Caltrans, Rancho Cucamonga, and Hesperia to incorporate intersection improvements to lessen or avoid adverse impacts to traffic to the extent feasible, including optimizing signal timing to reflect changes in traffic flows in station areas during operation of the Project.
	Operation of the Project would increase demand for local transit at the Hesperia station, such that the hourly volume of passengers desiring to depart the station via bus will likely exceed the available bus capacity during any single hour. At the Rancho Cucamonga station, the Project will impact passengers utilizing regional rail on Sunday, when there is a 5-hour period in the late afternoon/early evening with only one train in each direction.	Brightline West will coordinate with local transit agencies to identify opportunities to best serve the needs of transit users at the Hesperia and Rancho Cucamonga stations without significantly affecting other transit services.
	Based on ridership estimates, parking at the Hesperia and Rancho Cucamonga stations will exceed the amount of existing and planned spaces at the station in the 2045 Horizon Year.	Brightline West will develop and implement a parking demand management plan prior to operation of the Project to manage increasing parking demand at the Hesperia and Rancho Cucamonga stations.
Land Use and Community Facilities.	None	None.
Socioeconomic Environment.	None	None.
Cultural Resources	None	None.
Aesthetics	The Project would have a permanent impact on views of the San Gabriel and San Bernardino Mountains, as well as the Southern California Edison Boulder Dam-San Bernardino transmission lines from northbound I–15, looking north toward the split of northbound and southbound I–15 as it climbs toward the summit of Cajon Pass.	During the design phase, Brightline West will design rail features, including bridge pillars/columns, raised tracks, trains, catenary structures, crash barriers, retaining walls, abutments, fencing, and embankments to blend with or represent the surrounding desert or urban environment. Features will be created or stained in muted desert colors. Bright colors and highly reflective materials will be avoided, as feasible. Project elements defined in the design process will include visual elements that contribute to a sense of place and a memorable experience for motorists, pedestrians, and rail passengers. Concrete will be embossed with patterns, where appropriate, that are indicative of the surrounding environment and that create a visual link between the railway features and their surroundings and will be similar in character to recent nearby freeway projects.
Water Quality	The Project will result in permanent increased impervious surface along the rail alignment and the proposed Hesperia station, which will increase the amount of stormwater runoff and nonpoint-source pollution in some areas, affecting 48 ephemeral or intermittent drainage features.	To protect water quality, Brightline West will install permanent water quality treatment devices in accordance with the National Pollutant Discharge Elimination System (NPDES) permit obtained for the Project (Mitigation Measure WQ–7).
		Brightline West will redesign and resize the existing drainage features to accommodate the potential increase in runoff along the rail alignment. Additionally, stormwater treatment will be designed in accordance with the Caltrans Project Planning and Design Guide (PPDG). The 100-year, 24-hour storm event will be used to determine the appropriate size of drainage facilities need for the Project (Mitigation Measure WQ–8).

[2] A station at Victorville connecting the RC Line to the separate high-speed passenger rail project between the Victor Valley and Las Vegas, Nevada, was approved by the Board in 2011. *DesertXpress Enters., LLC, et al.—Constr. & Operation Exemption—in Victorville, Cal. & Las Vegas, Nev.,* FD 35544, slip op. at 2, 5 (STB served Oct. 25, 2011). On March 27, 2019, Brightline West petitioned the Board to reopen the 2011 decision to permit construction of the Victor Valley-Las Vegas line along a different route than what had been previously approved. The project modifications also include moving the Victorville station to within the Town of Apple Valley. The Victor Valley-Las Vegas line has involved a separate environmental review and is currently pending before the Board.

Analysis area	Long-term operational impacts of the selected alternative	Mitigation
Wetlands and Stream Areas.	During Project operation, railway crossings over Debris Cone Creek, Cajon Wash/Creek, and Lytle Creek will require new structures in the channels. All crossings will result in less than 0.1 acre of permanent fill. The Project will have no permanent impacts on the Mojave River itself, but a small portion (less than 0.01 acre) of wetlands associated with the Mojave River will be permanently impacted.	Prior to construction, Brightline West will coordinate with USACE to obtain a jurisdictional determination for aquatic resources. If applicable, Brightline West will obtain any required permits and implement all required permit conditions.
Floodplains	None	None.
Biological Resources	Approximately 64 acres of native vegetation habitat types will be permanently converted to transportation uses by the Project. Permanent impacts occur in a wide variety of habitat types; most permanent impacts would occur in Desert Scrub habitats (37 acres).	Brightline West will implement mitigation and compensation strategies identified during consultation with USFWS and documented in USFWS' Biological Opinion. Brightline West will also obtain an Incidental Take Permit for Endangered Species Act (ESA)-listed species. Refer to Attachment A, for a list and description of Mitigation Measures BIO–1 through BIO–57.
Geology, Soils, and Seismicity.	Seismic activity during operation could result in impacts related to surface fault rupture, ground shaking, and liquefaction because the Project alignment crosses or comes within 1,000 feet of four major faults: the Sierra Madre, the San Jacinto, the San Andreas, and the Cleghorn faults.	Brightline West will hire qualified geologists and geotechnical engineers to conduct geotechnical investigations along the Project alignment for potential hazards related to geology, soils, seismicity. Brightline West will incorporate recommendations of the evaluation that avoid or minimize hazardous impacts and will be implemented prior to design and construction. Refer to Attachment A for a list and description of Mitigation Measures GEO–2 through GEO–8.
Air Quality and Greenhouse Gas.	None. The Project will not result in exceedances of the de minimis thresholds for criteria pollutants in the applicable air basins. As ridership increases during the operation period, the Project will reduce emissions of both criteria pollutants and GHGs by providing an alternative to passenger car travel and reducing vehicle miles traveled within the South Coast Air Basin and Mojave Desert Air Basin, resulting in a beneficial impact to air quality and reductions in greenhouse gas emissions.	None.
Energy Resources	None	None.
Noise and Vibration	None	None.
Safety and Security	None	None.
Environmental Justice	The Project will not result in disproportionately high and adverse human health or environmental effects on minority populations and low-income populations.	None.

Analysis area	Temporary construction-related impacts of the selected alternative	Mitigation
Transportation	None	None.
Land Use and Community Facilities.	None	None.
Socioeconomic Environment.	None	None.
Cultural Resources	None	None.
Aesthetics	Changes in visual quality from construction will result from implementation of standard industry practices, including the use of temporary lighting, fences, barriers, stockpiling of materials, and the use of heavy equipment, and will result in temporary visual disturbances to natural visual resources.	Brightline West will implement measures to minimize nighttime light spillover onto adjacent properties, to reduce glare for freeway motorists, and to prevent visible lighting overflow into the natural dark sky of the desert at night. Visual screening, such as fences, will be erected along construction and staging areas as appropriate. Landscaping and native vegetation that is cleared for temporary construction areas (TCA) will be replaced by Brightline West within one year of the completion of construction at any location along the alignment.
Water Quality	Construction of the Project will impact water quality from activities involving soil disturbance, excavation, cutting/filling, stockpiling, and grading. Grading could result in increased erosion and sedimentation of surface waters. Stormwater runoff from TCAs could contain sediment and other contaminants, and could carry contaminants to drainages, groundwater, and impaired water bodies.	Brightline West will implement Best Management Practices (BMP) during construction and operation of the Project to minimize impacts on aquatic resources (Mitigation Measure WQ–1), comply with the statewide National Pollutant Discharge Elimination System (Mitigation Measure WQ–2), implement a stormwater pollution prevention program (SWPPP) (Mitigation Measure WQ–3), implement a spill prevention, control and countermeasures plan (SPCC) (Mitigation Measure WQ–4), locate TCAs to avoid key water features (Mitigation Measure WQ–5), and obtain water from existing, commercially available water sources (Mitigation Measure WQ–6).
Wetlands and Streams	Construction of bridges over the Bell Mountain Wash, Mojave River, Brush Creek, Cleghorn Creek, Cajon Wash/Creek and Lytle Creek, will involve work in the Ordinary High Water Mark (OHWM). The Project may require temporary soil disturbance and vegetation clearing within the Mojave River riparian area and in and around other drainages along the corridor.	Brightline West will contract with a qualified biologist, who will be on site prior to and during construction of the Project to identify and protect aquatic resources. The biologist will define the boundaries of the aquatic resources and will supervise the placement of exclusion fencing to protect those areas during all project activities. Additionally, a silt fence around the construction areas adjacent to aquatic resources will protect the resources, including waters of the United States (WOTUS), from runoff and spills associated with construction activities, if any. Aquatic resources that are affected by construction activities (e.g., clearing, ground disturbance) will be restored by Brightline West with native vegetation within one year of the completion of construction at any location along the alignment.

Analysis area	Temporary construction-related impacts of the selected alternative	Mitigation
Floodplains	Project construction will involve the use of heavy, earth-moving equipment in the floodplains of the Mojave River and Lytle Creek, and near the floodplains of Etiwanda Channel and Hawker-Crawford Channel Construction activities within floodplains will likely result in temporary impacts such and minor erosion and runoff on floodplains.	Brightline West will implement BMPs prior to construction to minimize the temporary effects on floodplains, and construction equipment and materials will not be stored within the floodplain. Brightline West will return any temporary effects on floodplains to preconstruction conditions.
Biological Resources	Construction of the project would have temporary impacts on approximately 2,206 acres of various types of wildlife habitat. The most common habitat types would be Urban (1,787 acres), Desert Scrub (168 acres), and Mixed Chaparral (128 acres). Construction impacts would include disturbance of vegetation and soils, construction noise, hydrologic modifications, facilitation of invasive species, and changes in habitat elements that increase or decrease populations of predators or prey species.	Brightline West will implement mitigation and compensation strategies identified during consultation with USFWS and documented in USFWS' Biological Opinion. Brightline West will also obtain an Incidental Take Permit for ESA-listed species. Refer to Attachment A, for a list and description of Mitigation Measures BIO–1 through BIO–57.
Geology, Soils, and Seismicity.	Construction of the Project may result in impacts related to ground fissures due to pile driving.	Brightline West will retain qualified geologists and geotechnical engineers to conduct geotechnical investigations along the Project alignment for potential hazards related to geology, soils, seismicity. Recommendations of the evaluation that avoid or minimize hazardous impacts will be implemented prior to design and construction (Mitigation Measure GEO–1).
Air Quality and Greenhouse Gas.	Construction of the Project will temporarily generate emissions of both criteria pollutants and GHGs. However, the Project will not result in exceedances of the de minimis thresholds for criteria pollutants in the applicable air basins. The Project will result in short-term increases in GHG emissions from construction activities.	Prior to construction activities, Brightline West will develop and implement a fugitive dust control plan and utilize additional means to reduce construction period emissions of air pollutants, such as solar powered signal boards.
Energy Resources	None	None.
Noise and Vibration	Construction of the Project will result in short-term noise impacts to resources due to elevated noise levels associated with construction activities, including construction equipment, diesel engines, impact pile driving and jackhammering.	Brightline West will require the contractors to prepare a detailed Noise Control Plan (Mitigation Measure NOI–1) in coordination with a qualified noise monitor prior to construction. Brightline West will comply with all applicable local noise regulations to minimize temporary construction noise and vibration impacts (Mitigation Measure NOI–2).
Hazardous Materials	Construction of the Project may result in the release of hazardous materials through disturbance of identified hazardous materials sites and using hazardous materials, either of which may result in impacts on human health. There is also the potential to encounter previously unidentified hazardous materials along the Project footprint.	Brightline West will prepare a Hazardous Materials Management Plan (HMMP) prior to application for permits for demolition, grading, or construction, as required by the State of California (Mitigation Measure HAZ–1). The HMMP shall be reviewed and approved by either the office of the State Fire Marshall or the San Bernardino County Certified Unified Program Agency (CUPA). Activities identified in the HMMP will be implemented by Brightline West throughout the construction period.
Safety	Construction of the Project will involve use of heavy equipment on site, earthwork, and other major construction activities, including the transportation of overweight and oversized materials. Throughout construction, workers and nearby community members could be exposed to hazards, which could affect human health or present to safety from construction site hazards and accidents, associated with construction site equipment and activities. Project construction could temporarily increase fire risks in the high fire hazard severity zones (FHSZ) due to the storage and use of flammable or combustible materials, operation of vehicles and heavy machinery. The Rancho Cucamonga and Hesperia stations will not be located within FSHZ zones.	Brightline West will implement construction safety requirements during construction, per regulatory requirements, including California Division of Occupational Safety and Health (Cal OSHA) Construction Safety Orders and California Public Utilities Commission (CPUC) General Order No. 176.
Environmental Justice	The Project will not result in disproportionately high and adverse human health or environmental effects on minority populations and low-income populations.	None.

Historic Review Under Section 106

Concurrently with preparation of the EA, FRA initiated consultation under Section 106 of the NHPA, which included efforts to identify, evaluate, and assess effects to historic properties that could be impacted by the RC Line. (EA 138–58.) As part of that process, FRA consulted with the Chairpersons of and/or Tribal Historic Preservation Officers for the Chemheuvi Indian Tribes, the Colorado River Indian Tribes, the Morongo Band of Mission Indians, the San Fernando Band of Mission Indians, the Soboba Band of Luiseno Indians, and the Twenty-Nine Palms Band of Mission Indians, and identified tribal contacts for the Yuhaaviatam of San Manuel Nation. (FONSI 13.) The Board participated as a consulting party in FRA's Section 106 consultation process, along with the Advisory Council on Historic Preservation, Brightline West, Caltrans, City of Fontana, City of Ontario, City of Rancho Cucamonga, City of Rialto, City of Victorville, Federal Highway Administration, United States Army Corps of Engineers, and the United States Forest Service. (*Id.*)

FRA concluded that construction and operation of the RC Line would have no adverse effects on resources listed in or eligible for listing in the National Register of Historic Places. (*Id.*) On May 22, 2023, the California State Historic Preservation Officer did not object to FRA's finding of no adverse effect for the RC Line. FRA issued a final Finding of Effect report and made a finding of no adverse effect for the Project on June 30, 2023. (*Id.* at 13–14.) Accordingly, no historic mitigation was imposed. (*Id.* at 8, 10 & Attachment A.)

OEA's Final Environmental Recommendations

After participating in FRA's environmental review, OEA concludes that the EA adequately assesses the potential environmental and historic impacts associated with the RC Line and concurs with the conclusions reached by FRA in the FONSI. Accordingly, OEA recommends that the Board adopt FRA's EA and the conclusions in the FONSI, and that it impose the environmental mitigation attached to the FONSI at Attachment A as conditions to any decision authorizing construction and operation of the RC Line. OEA concludes that FRA's mitigation measures are adequate to address the potential environmental and historic impacts of the RC Line. Therefore,

OEA does not recommend any additional environmental or historic mitigation.

[FR Doc. 2023–25786 Filed 11–21–23; 8:45 am]

BILLING CODE 4915–01–P

OFFICE OF THE UNITED STATES TRADE REPRESENTATIVE

[Docket Number USTR–2023–0012; Dispute Number WT/DS617]

WTO Dispute Settlement Proceeding Regarding a United States Anti-Dumping Measure on Oil Country Tubular Goods From Argentina

AGENCY: Office of the United States Trade Representative.

ACTION: Notice with request for comments.

SUMMARY: The Office of the United States Trade Representative (USTR) invites public comments concerning the issues raised in this World Trade Organization (WTO) dispute settlement proceeding regarding a United States anti-dumping measure on oil country tubular goods from Argentina.

DATES: Although USTR will accept any comments submitted during the course of the dispute settlement proceedings, you should submit your comment on or before December 22, 2023, to be assured of timely consideration by USTR.

ADDRESSES: USTR strongly prefers electronic submissions made through the Federal eRulemaking Portal: *http://www.regulations.gov.* Follow the instructions for submitting comments in sections III and IV below. The Docket Number is USTR–2023–0012. For alternatives to on-line submissions, please contact Sandy McKinzy at (202) 395–9483 in advance of the deadline.

FOR FURTHER INFORMATION CONTACT: Michael Gagain, Senior Associate General Counsel, (202) 395–9529, or Matthew Jaffe, Senior Associate General Counsel, (202) 395–9512.

SUPPLEMENTARY INFORMATION:

I. Background

Section 127(b)(1) of the Uruguay Round Agreements Act (URAA) (19 U.S.C. 3537(b)(1)) requires notice and opportunity for comment after the United States submits or receives a request for the establishment of a WTO dispute settlement panel. Accordingly, USTR is providing notice that Argentina has requested a dispute settlement panel pursuant to the WTO Understanding on Rules Procedures Governing the Settlement of Disputes (DSU). The panel established by the WTO will hold its meetings in Geneva Switzerland.

II. Major Issues Raised by Argentina

On May 17, 2023, Argentina requested consultations with the United States concerning the imposition of antidumping duties on oil country tubular goods from Argentina, following final determinations by the U.S. Department of Commerce (DOC) and U.S. International Trade Commission (ITC) in *Oil Country Tubular Goods From Argentina: Final Affirmative Determination of Sales at Less Than Fair Value and Final Negative Determination of Critical Circumstances* (DOC investigation number A–357–824), and *Oil Country Tubular Goods From Argentina, Mexico, Russia, and South Korea* (ITC investigation numbers 701–TA–671–672 and 731–TA–1571–1573), and section 771(7)(G) of the Tariff Act of 1930 (19 U.S.C. 1677(7)(G)). The consultation request can be found at *www.wto.org* in a document designated as WT/DS617/1. The United States and Argentina held consultations on July 6, 2023. On September 1, 2023, Argentina made its request to the WTO to establish a dispute settlement panel under the Marrakesh Agreement Establishing the World Trade Organization (WTO Agreement). That request may be found at *www.wto.org* in a document designated as WT/DS617/3. On October 26, 2023, the WTO established a panel to examine Argentina's complaint.

Argentina's panel request appears to be concerned with the DOC's examination of whether there was sufficient domestic industry support to justify initiation of its investigation; the ITC's cumulation analysis in its material injury investigation; aspects of the ITC's analyses of volume and imports and price effects in its investigation; and aspects of the ITC's analyses of injury and causation. Argentina claims that the imposition of duties is inconsistent with Article VI of the WTO *General Agreement on Tariffs and Trade 1994* (GATT 1994); and Articles 1, 3.1, 3.2, 3.3, 3.4, 3.5, 5.1, 5.2, 5.3, 5.4, 6.6, and 18.1 of the WTO *Agreement on Implementation of Article VI of the General Agreement on Tariffs and Trade 1994* (Antidumping Agreement). Argentina further alleges that section 771(7)(G) of the Tariff Act of 1930 is inconsistent with Articles 3.1, 3.2, 3.3, 3.4, and 3.5 of the Antidumping Agreement.

III. Public Comments: Requirements for Submissions

To be assured of consideration, submit your written comments by the December 22, 2023 deadline. All submissions must be in English. USTR strongly encourages submissions via *Regulations.gov*, using Docket Number USTR–2023–0012.

To make a submission via *Regulations.gov*, enter Docket Number USTR–2023–0012 in the 'search for' field on the home page and click 'search.' The site will provide a search results page listing all documents associated with this docket. Find a reference to this notice by selecting 'notice' under 'document type' in the 'refine documents results' section on the left side of the screen and click on the link entitled 'comment.' *Regulations.gov* allows users to make submissions by filling in a 'type comment' field, or by attaching a document using the 'upload file' field. USTR prefers that you provide submissions in an attached document and, in such cases, that you write 'see attached' in the 'type comment' field. USTR prefers submissions in Microsoft Word (.doc) or Adobe Acrobat (.pdf). If you use an application other than those two, please indicate the name of the application in the 'type comment' field.

Please do not attach separate cover letters, exhibits, annexes, or other attachments to electronic submissions; rather, include any in the same file as the submission itself, not as separate files. You will receive a tracking number upon completion of the submission procedure at *Regulations.gov*. The tracking number is confirmation that *Regulations.gov* received your submission. Keep the confirmation for your records. USTR is not able to provide technical assistance for *Regulations.gov*.

For further information on using *Regulations.gov*, please consult the resources provided on the website by clicking on 'How to Use *Regulations.gov*' on the bottom of the home page. Contact the *Regulations.gov* help desk with technical questions on submitting comments at *regulationshelpdesk@gsa.gov* or 1–866–498–2945.

If you are unable to provide submissions as requested, please contact Sandy McKinzy at (202) 395–9483 in advance of the deadline to arrange for an alternative method of transmission. USTR may not consider submissions that you do not make in accordance with these instructions.

IV. Confidential Submissions

If you ask USTR to treat information you submit as business confidential information (BCI), you must certify that the information is business confidential and you would not customarily release it to the public. For any comments submitted electronically containing BCI, the file name of the business

confidential version should begin with the characters 'BCI.' You must clearly mark any page containing BCI with 'BUSINESS CONFIDENTIAL' at the top of that page. Filers of submissions containing BCI also must submit a public version of their submission that will be placed in the docket for public inspection. The file name of the public version should begin with the character 'P.' The 'BCI' and 'P' should be followed by the name of the person or entity submitting the comments. If this is not sufficient to protect BCI or otherwise protect business interests, please contact Sandy McKinzy at (202) 395–9483 in advance of the deadline to discuss whether alternative arrangements are possible.

USTR may determine that information or advice contained in a comment, other than BCI, is confidential in accordance with section 135(g)(2) of the Trade Act of 1974 (19 U.S.C. 2155(g)(2)). If a submitter believes that information or advice is confidential, they must clearly designate the information or advice as confidential and mark it as 'SUBMITTED IN CONFIDENCE' at the top and bottom of the cover page and each succeeding page, and provide a non-confidential summary of the information or advice.

V. Public Viewing of Comments

Pursuant to section 127(e) of the URAA (19 U.S.C. 3537(e)), USTR will maintain a docket on this dispute settlement proceeding. USTR will post written submissions in the docket for public inspection, except properly designated BCI and other confidential information. You can view submissions at *Regulations.gov* by entering Docket Number USTR–2023–0012 in the search field on the home page.

If a dispute settlement panel is convened, or in the event of an appeal from a panel, USTR will make the following documents publicly available at *www.ustr.gov:* the U.S. submissions and any non-confidential summaries of submissions received from other participants in the dispute. If a dispute settlement panel is convened, or in the event of an appeal from a panel, the report of the panel, and, if applicable, the report of the Appellate Body, will also be available on the website of the World Trade Organization, at *www.wto.org.*

Juan Millan,

Deputy General Counsel for Monitoring and Enforcement, Office of the United States Trade Representative.

[FR Doc. 2023–25802 Filed 11–21–23; 8:45 am]

BILLING CODE 3390–F4–P

OFFICE OF THE UNITED STATES TRADE REPRESENTATIVE

[Docket Number USTR–2023–0013]

Request for Comments and Notice of Public Hearing Concerning the Operation of the United States-Mexico-Canada Agreement With Respect To Trade in Automotive Goods

AGENCY: Office of the United States Trade Representative (USTR).

ACTION: Request for comments and notice of public hearing.

SUMMARY: The U.S. Trade Representative must conduct a review of trade in automotive goods under the United States-Mexico-Canada Agreement (USMCA) and submit a report to the Committee on Finance of the Senate and the Committee on Ways and Means of the House of Representatives no later than July 1, 2024. USTR invites comments concerning the operation of the USMCA with respect to automotive goods, including the implementation and enforcement of the USMCA rules of origin for automotive goods, as well as whether the automotive provisions of the USMCA are effective in light of technological and production advances.

DATES: January 17, 2024 at 11:59 p.m. EST: Deadline for submission of written comments, request to testify, and written testimony.

February 7, 2024 at 10:00 a.m. EST: USTR and the Interagency Committee on Trade in Automotive Goods will convene a public hearing to receive oral testimony.

ADDRESSES: USTR strongly prefers electronic submissions made through the Federal rulemaking Portal: *https://www.regulations.gov/* (*Regulations.gov*). Follow the instructions for submitting written comments, testimony, and requests to testify in sections III through V below, using docket number USTR–2023–0013. For alternatives to on-line submissions, please contact Justin Hoffmann, Deputy Assistant U.S. Trade Representative for Market Access and Industrial Competitiveness, in advance of the deadline at (202) 395–2990 or *Justin.D.Hoffmann@ustr.eop.gov.*

FOR FURTHER INFORMATION CONTACT: Justin Hoffmann, Deputy Assistant U.S. Trade Representative for Market Access and Industrial Competitiveness at (202) 395–2990 or *Justin.D.Hoffmann@ustr.eop.gov.*

SUPPLEMENTARY INFORMATION:

I. USMCA Background

On January 29, 2020, the President signed into law the USMCA Implementation Act (Pub. L. 116–113), which implements the USMCA between the United States, the United Mexican States, and Canada attached as an Annex to the Protocol Replacing the North American Free Trade Agreement. The USMCA entered into force on July 1, 2020.

The USMCA includes new rules of origin to claim preferential treatment for automotive goods, including higher Regional Value Content (RVC) thresholds, mandatory requirements to produce core parts in the region, mandatory steel and aluminum purchasing requirements, and a Labor Value Content (LVC) requirement. The USMCA allows vehicle producers to request an alternative staging regime for these requirements that would permit a longer period of transition to help ensure that future production is able to meet the new rules. The standard staging regime is specified under the Automotive Appendix to Chapter 4 of the USMCA, with the exception of Article 8, which specifies provisions relating to the alternative staging regime.

The USMCA Implementation Act and Executive Order 13908 established the Interagency Committee on Trade in Automotive Goods (Committee) to advise the President and the U.S. Trade Representative on the implementation, enforcement and modification of the USMCA provisions related to automotive goods. In addition, the Committee reviews the operation of the USMCA with respect to trade in automotive goods, including the economic effects of the USMCA automotive rules of origin on the U.S. economy, workers and consumers, and the impact of new technology on such rules.

II. Report to Congress

Section 202A(g) of the USMCA Implementation Act requires the U.S. Trade Representative, in consultation with the Committee, to conduct a biennial review of the operation of the USMCA with respect to trade in automotive goods, including:

(a) To the extent practicable, a summary of actions taken by producers to demonstrate compliance with the automotive rules of origin, use of the alternative staging regime, enforcement of such rules of origin, and other relevant matters.

(b) Whether the automotive rules of origin are effective and relevant in light of new technology and changes in content, production processes and character of automotive goods.

USTR submitted its first report to Congress on June 30, 2022. No later than

July 1, 2024, USTR will submit the results of the second biennial review to the Committee on Finance of the Senate and the Committee on Ways and Means of the House of Representatives and post a public version of the report to its website at *https://www.ustr.gov.* The 2022 report is available on USTR's website at *https://ustr.gov/sites/default/files/2022%20USMCA%20Autos%20Report%20to%20Congress.pdf.*

III. Request for Public Input

In accordance with the USMCA Implementation Act, USTR and the Committee seek views from producers of automotive goods, labor organizations and other interested parties regarding:

1. The overall operation of the USMCA with respect to automotive goods.

2. Actions taken by automotive and parts producers to demonstrate compliance with the USMCA automotive rules of origin, including:

a. The applicable RVC requirements for passenger vehicles, light trucks, heavy trucks, other vehicles and parts thereof.

b. The North American steel and aluminum purchase requirements.

c. The LVC requirements.

3. The use of alternative staging regimes by vehicle producers to meet the USMCA automotive rules of origin.

4. Enforcement of the USMCA automotive rules of origin, including the alternative staging regimes and the automotive certification process for steel and aluminum content, LVC and RVC.

5. Whether the current USMCA automotive rules of origin are effective in light of new technology and changes in the content, production processes and character of automotive goods. In particular, whether the rules of origin remain effective for:

a. The large-scale transition towards electric and other clean-energy vehicles;

b. The transition away from internal combustion and diesel vehicles;

c. The automotive parts applicable to electric and clean-energy vehicles and internal combustion or diesel vehicles; or

d. Any other vehicle and part subject to the USMCA automotive rules of origin.

6. Whether the USMCA rules of origin are effective in supporting the competitiveness of the North American automotive industry in light of global challenges, such as excess capacity of electric vehicles.

7. An update on the supply chain challenges identified in the 2022 report (*e.g.,* semiconductor shortage, war in Ukraine) and the impact the USMCA had on overcoming those supply chain challenges.

8. The impact of the 2022 Inflation Reduction Act and similar legislation, *e.g.,* the CHIPS and Science Act of 2022, and the Infrastructure Investment and Jobs Act, on the overall trade in automotive goods under the USMCA and those goods' ability to meet the USMCA rules of origin.

9. Specific issues faced by producers of heavy-duty trucks and other automotive goods not specifically addressed above.

10. Any other topics relevant to the trade in automotive goods under the USMCA.

IV. Hearing Participation

USTR will convene a public hearing on February 7, 2024 related to the operation of the USMCA with respect to autos. Persons wishing to observe the public hearing will find a link on USTR's web page for the USMCA on the day of the hearing at *https://ustr.gov/trade-agreements/free-trade-agreements/united-states-mexico-canada-agreement.* To ensure participation, you must submit requests to present oral testimony at the hearing and written testimony by 11:59 p.m. EST on January 17, 2024, via *Regulations.gov*, using Docket Number USTR–2023–0013. Instructions for submission are in section V below. Remarks at the hearing will be limited to no more than five minutes to allow for possible questions from the Committee. Because it is a public hearing, testimony should not include any business confidential information (BCI).

V. Procedures for Written Submissions

To be assured of consideration, submit your written comments, requests to testify, and written testimony by the January 17, 2024, 11:59 p.m. EST deadline. All submissions must be in English. USTR strongly encourages submissions via *Regulations.gov*, using Docket Number USTR–2023–0013.

To make a submission via *Regulations.gov*, enter Docket Number USTR–2023–0013 in the 'search for' field on the home page and click 'search.' The site will provide a search results page listing all documents associated with this docket. Find a reference to this notice by selecting 'notice' under 'document type' in the 'refine documents results' section on the left side of the screen and click on the link entitled 'comment.' *Regulations.gov* allows users to make submissions by filling in a 'type comment' field, or by attaching a document using the 'upload file' field. USTR prefers that you provide submissions in an attached document and, in such cases, that you write 'see attached' in the 'type comment' field. USTR prefers submissions in Microsoft Word (.doc) or Adobe Acrobat (.pdf). If you use an application other than those two, please indicate the name of the application in the 'type comment' field.

At the beginning of your submission or on the first page (if an attachment), include the following text: (1) 2024 USMCA Autos Report; (2) your organization's name; and (3) whether the submission is a comment, request to testify, or written testimony. Please do not attach separate cover letters, exhibits, annexes, or other attachments to electronic submissions; rather, include any in the same file as the submission itself, not as separate files. You will receive a tracking number upon completion of the submission procedure at *Regulations.gov*. The tracking number is confirmation that *Regulations.gov* received your submission. Keep the confirmation for your records. USTR is not able to provide technical assistance for *Regulations.gov*.

For further information on using *Regulations.gov*, please consult the resources provided on the website by clicking on 'How to Use *Regulations.gov*' on the bottom of the home page. USTR may not consider submissions that you do not make in accordance with these instructions.

If you are unable to provide submissions as requested, please contact Justin Hoffmann, Deputy Assistant U.S. Trade Representative for Market Access and Industrial Competitiveness, in advance of the deadline at *Justin.D.Hoffmann@ustr.eop.gov* or (202) 395–2990, to arrange for an alternative method of transmission. USTR will not accept hand-delivered submissions. General information concerning USTR is available at *www.ustr.gov*.

If you ask USTR to treat information you submit as BCI, you must certify that the information is business confidential and you would not customarily release it to the public. For any comments submitted electronically containing BCI, the file name of the business confidential version should begin with the characters 'BCI.' You must clearly mark any page containing BCI with 'BUSINESS CONFIDENTIAL' at the top of that page. Filers of submissions containing BCI also must submit a public version of their submission that will be placed in the docket for public inspection. The file name of the public version should begin with the character 'P.'

USTR will post written submissions in the docket for public inspection,

except properly designated BCI. You can view submissions at *Regulations.gov* by entering Docket Number USTR–2023–0013 in the search field on the home page.

Greta Peisch,

General Counsel, Office of the United States Trade Representative.

[FR Doc. 2023–25765 Filed 11–21–23; 8:45 am]

BILLING CODE 3390–F4–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

[Docket No. FAA–2023–2226]

Notice of Intent To Designate as Abandoned Supplemental Type Certificate No. SA3–483

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of intent to Designate Supplemental Type Certificate as abandoned; request for comments.

SUMMARY: This Notice announces the FAA's intent to designate Supplemental Type Certificate (STC) No. SA3–483 as abandoned and make the related engineering data available upon request. The FAA has received a request to provide engineering data concerning this STC. The FAA has been unsuccessful in contacting the STC holder concerning the STC. This action is intended to enhance aviation safety.

DATES: We must receive all comments by May 20, 2024.

ADDRESSES: You may send comments on this notice by any of the following methods:

- *Federal eRulemaking Portal:* Go to *regulations.gov.* Follow the instructions for submitting comments.
- *Mail:* JoWanna Jenkins, Program Management Specialist, Central Certification Branch (Chicago), 2300 East Devon Avenue, Room 107, Des Plaines, IL 60018.
- *Email: jowanna.jenkins@faa.gov.* Include ''Docket No. FAA–2023–2226'' in the subject line of the message.
- *Hand Delivery:* Deliver to Mail address above between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: JoWanna Jenkins, Program Management Specialist, Central Certification Branch (Chicago), 2300 East Devon Avenue, Room 107, Des Plaines, IL 60018; telephone 847–294–7145; email *jowanna.jenkins@faa.gov.*

SUPPLEMENTARY INFORMATION:

Comments Invited

The FAA invites interested parties to provide comments, written data, views, or arguments relating to this notice. Send your comments to an address listed under the **ADDRESSES** section. Include ''Docket No. FAA–2023–2226'' at the beginning of your comments. The FAA will consider all comments received on or before the closing date. All comments received will be available in the docket for examination by interested persons.

Background

The FAA is posting this notice to inform the public of the intent to designate as abandoned STC No. SA3–483, which installs a Continental Model C85–12 engine on a Mooney Model M–18C 55 airplane, and subsequently release the related engineering data.

The FAA has received a third-party request for the release of the aforementioned engineering data under the provisions of the Freedom of Information Act (FOIA), 5 U.S.C. 552. The FAA cannot release commercial or financial information under FOIA without the permission of the data owner. However, in accordance with title 49 of the United States Code section 44704(a)(5), the FAA can provide STC ''engineering data'' it possesses for STC maintenance or improvement, upon request, if the following conditions are met:

1. The FAA determines the STC has been inactive for three years or more;
2. Using due diligence, the FAA is unable to locate the owner of record or the owner of record's heir; and
3. The availability of such data will enhance aviation safety.

There has been no activity with this STC holder for more than three years.

On August 24, 2023, the FAA sent a registered letter to the STC holder, Donna R. Sparks, at her last known address, 6414 East 86th Street, Kansas City, MO 64138. The letter informed Ms. Sparks that the FAA had received a request for engineering data related to STC No. SA3–483 and was conducting a due diligence search to determine whether the STC was inactive and may be considered abandoned. The letter further requested Ms. Sparks to respond in writing within 60 days and state whether she is the holder of the STC. The FAA also attempted to contact Ms. Sparks by other means, including telephone communication, email, and certified mail, without success.

Information Requested

If you are the owner or heir or a transferee of STC No. SA3–483 or have any knowledge regarding who may now hold STC No. SA3–483, please contact JoWanna Jenkins using a method described in this notice under **FOR FURTHER INFORMATION CONTACT**. If you are the heir of the owner, or the owner by transfer, of STC No. SA3–483, you must provide a notarized copy of your government-issued identification with a letter and background establishing your ownership of the STC and, if applicable, your relationship as the heir to the deceased holder of the STC.

Conclusion

If the FAA does not receive any response by May 20, 2024, the FAA will consider STC No. SA3–483 abandoned, and the FAA will proceed with the release of the requested data. This action is for the purpose of maintaining the airworthiness of an aircraft and enhancing aviation safety.

Issued on November 16, 2023.

Ross Landes,

Deputy Director for Regulatory Operations, Compliance & Airworthiness Division, Aircraft Certification Service.

[FR Doc. 2023–25764 Filed 11–21–23; 8:45 am]

BILLING CODE 4910–10–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

[Docket No. FAA–2023–2183; Summary Notice No. 2023–46]

Petition for Exemption; Summary of Petition Received; Gulfstream

AGENCY: Federal Aviation Administration (FAA), 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 December 12, 2023.

ADDRESSES: Send comments identified by docket number FAA–2023–2183 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: Deana Stedman, AIR–646, Federal Aviation Administration, phone (209) 231–3187, email *deana.stedman@faa.gov.* This notice is published pursuant to 14 CFR 11.85.

Issued in Washington, DC, on November 17, 2023.

Daniel J. Commins,

Manager, Integration and Performance.

PETITION FOR EXEMPTION

Docket No.: FAA–2023–2183.

Petitioner: Gulfstream.

Section(s) of 14 CFR Affected: §§ 25.951(c), 25.952(a), and 25.901(d).

Description of Relief Sought: The petitioner has requested a partial exemption from the affected sections of 14 CFR for a period of 3 years, in order to develop and conduct a full-scale test of the fuel system to show that the fuel system icing threat has been adequately mitigated for the Model GVIII–G700 and Model GVIII–G800 airplanes.

[FR Doc. 2023–25862 Filed 11–21–23; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

[Docket No. FAA–2023–2327]

Agency Information Collection Activities: Requests for Comments; Clearance of a Renewed Approval of Information Collection: Unmanned Aircraft Remote Identification Message Elements

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice and request for comments.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, FAA invites public comments about our intention to request the Office of Management and Budget (OMB) approval to renew an information collection. The collection involves electronic information that is broadcast directly from certain unmanned aircraft, specifically standard remote identification unmanned aircraft and unmanned aircraft equipped with a remote identification broadcast module. With certain limited exceptions, the Remote Identification of Unmanned Aircraft rule prohibits the operation of unmanned aircraft within the airspace of the United States unless the unmanned aircraft are broadcasting certain remote identification message elements throughout their operation. An exception to the general rule is when an unmanned aircraft is not equipped with remote identification equipment but is operated within visual line of sight and within an FAA-recognized identification area.

DATES: Written comments should be submitted by January 22, 2024.

ADDRESSES: Please send written comments:

By Electronic Docket: www.regulations.gov (Enter docket number into search field).

By mail: Benjamin Walsh, FAA Flight Standards Service, Emerging Technologies Division, AFS–700, 800 Independence Ave SW, Washington, DC 20591.

By fax: 202–267–8233.

FOR FURTHER INFORMATION CONTACT: Benjamin Walsh by email at: *ben.walsh@faa.gov;* phone: 202–267–8233.

SUPPLEMENTARY INFORMATION:

Public Comments Invited: You are asked to comment on any aspect of this information collection, including (a) Whether the proposed collection of information is necessary for FAA's performance; (b) the accuracy of the estimated burden; (c) ways for FAA to enhance the quality, utility and clarity of the information collection; and (d) ways that the burden could be minimized without reducing the quality of the collected information. The agency will summarize and/or include your comments in the request for OMB's clearance of this information collection.

OMB Control Number: 2120–0783.

Title: Unmanned Aircraft Remote Identification Message Elements.

Form Numbers: N/A.

Type of Review: Renewal of an information collection.

Background: Regulations for the Remote Identification of Unmanned Aircraft were published on January 15, 2021, and are contained in 14 Code of Federal Regulations (14 CFR), part 89. Requirements for the operation of unmanned aircraft with remote identification are contained in part 89, subpart B. The Remote Identification rule requires unmanned aircraft with remote identification equipment to broadcast remote identification message elements directly from the unmanned aircraft using radio frequency spectrum in accordance with 47 CFR part 15, where operations may occur without a Federal Communications Commission (FCC) individual license. These unmanned aircraft include standard remote identification unmanned aircraft and unmanned aircraft equipped with remote identification broadcast modules.

A standard remote identification unmanned aircraft must be capable of broadcasting the following remote identification message elements:

(a) The identity of the unmanned aircraft consisting of:

(1) A serial number assigned to the unmanned aircraft by the person responsible for the production of the standard remote identification unmanned aircraft; or

(2) A session ID.

(b) An indication of the latitude and longitude of the control station.

(c) An indication of the geometric altitude of the control station.

(d) An indication of the latitude and longitude of the unmanned aircraft.

(e) An indication of the geometric altitude of the unmanned aircraft.

(f) An indication of the velocity of the unmanned aircraft.

(g) A time mark identifying the Coordinated Universal Time (UTC) time of applicability of a position source output.

(g) An indication of the emergency status of the unmanned aircraft.

A remote identification broadcast module must be capable of broadcasting the following remote identification message elements:

(a) The identity of the unmanned aircraft consisting of the serial number assigned to the remote identification broadcast module by the person responsible for the production of the remote identification broadcast module.

(b) An indication of the latitude and longitude of the unmanned aircraft.

(c) An indication of the geometric altitude of the unmanned aircraft.

(d) An indication of the velocity of the unmanned aircraft.

(e) An indication of the latitude and longitude of the take-off location of the unmanned aircraft.

(f) An indication of the geometric altitude of the take-off location of the unmanned aircraft.

(g) A time mark identifying the Coordinated Universal Time (UTC) time of applicability of a position source output.

The collection of this information in the remote identification message elements is necessary to comply with the FAA's statutory requirement to develop and implement standards for remotely identifying operators and owners of unmanned aircraft. The collection of this information will also provide airspace awareness to enable the FAA, national security agencies, and law enforcement entities to distinguish compliant airspace users from those potentially posing a safety or security risk.

The remote identification message elements that unmanned aircraft operators are required to broadcast under Part 89 are considered publicly available information. The remote identification message elements broadcast directly from the unmanned can be received by anyone who has the appropriate equipment, such as a personal wireless device, that can receive broadcast messages.

Respondents: The collection of information through the broadcasting of message elements from a standard remote identification unmanned aircraft or remote identification broadcast module is entirely automatic. The collection uses automated, electronic, and related technological collection techniques. This framework makes it relatively simple and straightforward for individuals to comply with the broadcast requirements by operating unmanned aircraft that are standard remote identification unmanned aircraft or unmanned aircraft equipped with a remote identification broadcast module.

Frequency: Operators of unmanned aircraft with remote identification are required to broadcast the remote identification message elements addressed in this information collection on occasion (when the unmanned aircraft with remote identification is operated in the airspace of the United States).

Estimated Average Burden per Response: To transmit remote identification message elements, each remote pilot is required to operate either a standard remote identification unmanned aircraft or unmanned aircraft equipped with a remote identification broadcast module. The collection of information through the broadcasting of the remote identification message elements is entirely automatic, therefore there is no average burden associated with the broadcast of the remote identification message elements.

Estimated Total Annual Burden: The collection of information through the broadcasting of the remote identification message elements is entirely automatic, therefore there is no annual burden associated with the broadcast of the remote identification message elements.

Issued in Washington, DC, on November 17, 2023.

Joseph Morra,

Manager, Emerging Technologies Division, AFS–700.

[FR Doc. 2023–25839 Filed 11–21–23; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF THE TREASURY

Alcohol and Tobacco Tax and Trade Bureau

[Docket No. TTB–2023–0005]

Proposed Information Collections; Comment Request (No. 91)

AGENCY: Alcohol and Tobacco Tax and Trade Bureau (TTB); Treasury.

ACTION: Notice and request for comments.

SUMMARY: As part of our continuing effort to reduce paperwork and respondent burden, and as required by the Paperwork Reduction Act of 1995, we invite comments on the continuing or proposed information collections listed below in this document.

DATES: We must receive your written comments on or before January 22, 2024.

ADDRESSES: You may send comments on the information collections described in this document using one of these two methods:

- *Internet*—To submit comments electronically, use the comment form for this document posted on the ''*Regulations.gov*'' e-rulemaking website at *https://www.regulations.gov* within Docket No. TTB–2023–0005.
- *Mail*—Send comments to the Paperwork Reduction Act Officer, Regulations and Rulings Division, Alcohol and Tobacco Tax and Trade Bureau, 1310 G Street NW, Box 12, Washington, DC 20005.

Please submit separate comments for each specific information collection described in this document. You must reference the information collection's title, form or recordkeeping requirement number (if any), and OMB control number in your comment.

You may view copies of this document, the relevant TTB forms, and any comments received at *https://www.regulations.gov* within Docket No. TTB–2023–0005. TTB has posted a link to that docket on its website at *https://www.ttb.gov/rrd/information-collection-notices.* You also may obtain paper copies of this document, the listed forms, and any comments received by contacting TTB's Paperwork Reduction Act Officer at the addresses or telephone number shown below.

FOR FURTHER INFORMATION CONTACT: Michael Hoover, Regulations and Rulings Division, Alcohol and Tobacco Tax and Trade Bureau, 1310 G Street NW, Box 12, Washington, DC 20005; 202–453–1039, ext. 135; or complete the Regulations and Rulings Division contact form at *https://www.ttb.gov/contact-rrd.*

SUPPLEMENTARY INFORMATION:

Request for Comments

The Department of the Treasury and its Alcohol and Tobacco Tax and Trade Bureau (TTB), as part of a continuing effort to reduce paperwork and respondent burden, invite the general public and other Federal agencies to comment on the proposed or continuing information collections described below, as required by the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

Comments submitted in response to this document will be included or summarized in our request for Office of Management and Budget (OMB) approval of the relevant information collection. All comments are part of the public record and subject to disclosure. Please do not include any confidential or inappropriate material in your comments.

We invite comments on: (a) Whether an information collection is necessary for the proper performance of the agency's functions, including whether the information has practical utility; (b) the accuracy of the agency's estimate of the information collection's burden; (c) ways to enhance the quality, utility, and clarity of the information collected; (d)

ways to minimize the information collection's burden 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 the requested information.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection of information has a valid OMB control number.

Information Collections Open for Comment

Currently, we are seeking comments on the following forms, letterhead applications or notices, recordkeeping requirements, questionnaires, or surveys:

OMB Control No. 1513–0009

Title: Application to Establish and Operate Wine Premises and Wine Bond.

TTB Form Number: TTB F 5120.25, TTB F 5120.36.

Abstract: The Internal Revenue Code (IRC) at 26 U.S.C. 5351 through 5357 provides for the establishment of bonded wine cellars, bonded wineries, and taxpaid wine bottling houses and, to establish such wine premises, these IRC sections require the filing of applications and bonds. Under these authorities, TTB has issued TTB F 5120.25, Application to Establish and Operate Wine Premises, to collect information that TTB uses to determine the qualifications of anyone applying to establish a new wine premises. Proprietors of established wine premises also use TTB F 5120.25 to report subsequent changes to information such as location and ownership. Unless exempted by the IRC at 26 U.S.C. 5551(d), wine premises proprietors use TTB F 5120.36, Wine Bond, to file bond coverage with TTB. The bond may be secured through a surety company, or it may be secured with collateral (cash, Treasury Bonds or Treasury Notes).

Current Actions: There are no program changes to this information collection, and TTB is submitting for extension purposes only. As for adjustments, due to a change in agency estimates, TTB is decreasing the estimated number of annual respondents, total responses, and burden hours associated with this information collection.

Type of Review: Extension of a currently approved collection.

Affected Public: Businesses and other for-profits.

- *Number of Respondents:* 5,800.
- *Average Responses per Respondent:* 1 (one per year).
- *Number of Responses:* 5,800.
- *Average per-response Burden:* 0.97 hours.
- *Total Burden:* 5,626 hours.

OMB Control No. 1513–0015

Title: Brewer's Bond and Brewer's Bond Continuation Certificate; Brewer's Collateral Bond and Brewer's Bond Collateral Bond Continuation Certificate.

TTB Form Number: TTB F 5130.22, TTB F 5130.23, TTB F 5130.25 and TTB F 5130.27.

Abstract: In general, the IRC at 26 U.S.C. 5401(b) requires brewers to execute a bond before starting business, subject to regulations issued by the Secretary of the Treasury (the Secretary) and the exemptions for certain small brewers that are eligible to pay excise taxes on an annual or quarterly basis as provided under 26 U.S.C. 5551(d). Also under section 5401, brewers' bonds expire every four years, and a brewer must provide a new bond or a continuation certificate extending the terms of an existing bond. Additionally, under the IRC at 26 U.S.C. 7101 and subject to regulations prescribed by the Secretary, a brewer may furnish a surety bond under which a surety company guarantees payment of the proprietor's unpaid tax liabilities, or a brewer may submit other obligations, such as United States Treasury securities. Under those IRC authorities, the TTB regulations in 27 CFR part 25 require brewers to file a surety bond using TTB F 5130.22, Brewer's Bond, or a collateral bond backed by U.S. Treasury securities, notes, or cash using TTB F 5130.25, Brewer's Collateral Bond. To continue an existing bond, a brewer may furnish a surety bond continuation certificate using TTB F 5130.23 or a collateral bond continuation certificate using TTB F 5130.27, as appropriate. The collected information is necessary to document the required bonds.

Current Actions: There are no program changes associated with this information collection, and TTB is submitting it for extension purposes only. As for adjustments, due to changes in agency estimates, TTB is decreasing the estimated number of annual respondents and responses to this information collection.

Type of Review: Extension of a currently approved collection.

Affected Public: Businesses or other for-profits.

- *Number of Respondents:* 150.
- *Average Responses per Respondent:* 1 (one) per year.
- *Number of Responses:* 150.
- *Average per-response Burden:* 0.84.
- *Total Burden:* 126 hours.

OMB Control No. 1513–0017

Title: Drawback on Beer Exported.

TTB Form Number: TTB F 5130.6.

Abstract: Under the IRC at 26 U.S.C. 5055, brewers may receive drawback (refund) of the Federal excise tax paid on beer produced in the United States when such beer is subsequently exported or delivered for use as supplies on vessels and aircraft if proof of such action is provided as the Secretary may by regulation require. Under this authority, after taxpaid domestic beer is exported to a foreign country, delivered to the U.S. Armed Forces for export, delivered for use as supplies on vessels or aircraft, or transferred to a foreign trade zone for export, the TTB regulations allow the brewer or exporter to file a claim for drawback of the excise taxes paid on such beer using TTB F 5130.6. The required information is necessary as it provides documentation through which TTB can determine that beer for which export drawback is claimed is eligible for such drawback.

Current Actions: There are no program changes associated with this information collection, and TTB is submitting it for extension purposes only. As for adjustments, due to changes in agency estimates, TTB is decreasing the estimated number of annual respondents and responses to this information collection.

Type of Review: Extension of a currently approved collection.

Affected Public: Businesses and other for-profits.

- *Number of Respondents:* 725.
- *Average Responses per Respondent:* 20 per year.
- *Number of Responses:* 14,500.
- *Average per-response Burden:* 1 hour.
- *Total Burden:* 14,500 hours.

OMB Control No. 1513–0025

Title: Notice of Release of Tobacco Products, Cigarette Papers, or Cigarette Tubes.

TTB Form Number: TTB F 5200.11

Abstract: The IRC at 26 U.S.C. 5704 provides, among other things, that tobacco products and cigarette papers and tubes that have been imported or exported and then returned may be released from customs custody, without payment of tax, for delivery to an export warehouse proprietor or a manufacturer of tobacco products or cigarette papers and tubes, in accordance with regulations issued by the Secretary. Under that IRC authority, the TTB tobacco-related import regulations in 27 CFR part 41 require industry members

who do not file customs entries electronically to use TTB F 5200.11 to give notice of release of tobacco products, cigarette papers, or cigarette tubes. At importation, industry members, TTB, and customs bonded warehouse proprietors or government officials use TTB F 5200.11 to, respectively, request, authorize, and document the release of such products from customs custody, without payment of tax, to a manufacturer or export warehouse proprietor authorized to receive such articles. (The electronic submission of import data and notices of release to TTB through Customs and Border Protection systems is approved under OMB Number 1513–0064, Importer's Records and Reports.)

Current Actions: There are no program changes or adjustments associated with this information collection, and TTB is submitting it for extension purposes only.

Type of Review: Extension of a currently approved collection.

Affected Public: Businesses or other for-profits.

- *Number of Respondents:* 10.
- *Average Responses per Respondent:* 6 (one) per year.
- *Number of Responses:* 60.
- *Average per-response Burden:* 0.25 hours.
- *Total Burden:* 15 hours.

OMB Control No. 1513–0032

Title: Inventory—Manufacturer of Tobacco Products or Processed Tobacco.

TTB Form Number: TTB F 5210.9.

Abstract: The IRC at 26 U.S.C. 5721 requires manufacturers of tobacco products and processed tobacco to complete an inventory at the commencement of business, the conclusion of business, and at any other time the Secretary by regulation prescribes. Under the IRC at 26 U.S.C. 5741, these manufacturers are also required to keep records and make them available for inspection in the manner the Secretary by regulation prescribes. Under these authorities, the TTB regulations in 27 CFR part 40 require manufacturers of tobacco products and processed tobacco to provide inventories on TTB F 5210.9 at the commencement of business, the conclusion of business, when changes in business ownership or factory location occur, and at any other time as directed by the appropriate TTB officer. The use of TTB F 5210.9 provides a uniform format for recording inventories. The collected information is necessary to ensure that manufacturers of tobacco products pay the appropriate amount of Federal excise tax, and that processed tobacco, which is not subject to that tax, is not diverted to the illegal manufacture of otherwise taxable tobacco products.

Current Actions: There are no program changes or adjustments associated with this information collection at this time, and TTB is submitting it for extension purposes only.

Type of Review: Extension of a currently approved collection.

Affected Public: Businesses and other for-profits.

- *Number of Respondents:* 100.
- *Average Responses per Respondent:* 1 (one) per year.
- *Number of Responses:* 100.
- *Average per-response Burden:* 5 hours.
- *Total Burden:* 500 hours.

OMB Control No. 1513–0036

Title: Signing Authority for Corporate and LLC Officials.

TTB Form Number: TTB F 5100.1.

Abstract: Under the IRC at 26 U.S.C. 6061, any return, statement, or other document required to be made under internal revenue laws or regulations ''shall be signed in accordance with forms or regulations'' prescribed by the Secretary. Under that section's authority, TTB provides form TTB F 5100.1, which corporations and limited liability companies (LLCs) may use to identify the specific officials or employees, by name or by position title, authorized by their articles of incorporation, bylaws, or governing officials to act on behalf of, or sign documents for, the entity in TTB matters. This information collection allows TTB to identify the corporate and LLC officials or employees authorized to act on an entity's behalf in TTB matters.

Current Actions: There are no program changes associated with this information collection, and TTB is submitting it for extension purposes only. As for adjustments, due to changes in agency estimates, TTB is decreasing the estimated number of annual respondents, responses, and burden hours associated with this collection.

Type of Review: Extension of a currently approved collection.

Affected Public: Businesses or other for-profits.

- *Number of Respondents:* 2,150.
- *Average Responses per Respondent:* 1 per year.
- *Number of Responses:* 2,150.
- *Average per-response Burden:* 11.47 minutes.
- *Total Burden:* 411 hours.

OMB Control No. 1513–0037

Title: Withdrawal of Spirits, Specially Denatured Spirits, or Wines for Exportation.

TTB Form Number: TTB F 5100.11.

Abstract: The IRC at 26 U.S.C. 5066, 5214, and 5362 provides that distilled spirits, denatured spirits, and wines may be withdrawn from bonded premises, without payment of excise tax, for export, for transfer to a foreign trade zone or a customs bonded warehouse, or for use as supplies on certain vessels or aircraft, subject to regulations prescribed by the Secretary. Under those IRC authorities, the TTB alcohol export regulations in 27 CFR part 28 require exporters to use TTB F 5100.11 to report and document removals of distilled spirits, denatured spirits, and wines, without payment of tax, for export purposes. Those purposes include direct export to a foreign country or United States armed forces stationed overseas; transfer to a foreign trade zone, a customs manufacturing bonded warehouse, or a customs bonded warehouse for subsequent export; or for use as supplies on international vessels or aircraft. The collected information is necessary as it allows TTB to determine that exporters of spirits and wines withdrawn without payment of tax possess the appropriate bond coverage, and the form provides certification that the products in question were, in fact, exported or laden and not diverted into domestic commerce, which would make the products subject to tax.

Current Actions: There are no program changes associated with this information collection, and TTB is submitting it for extension purposes only. As for adjustments, TTB is increasing the estimated number of annual respondents, total responses, and burden hours associated with this information collection.

Type of Review: Extension of a currently approved collection.

Affected Public: Businesses or other for-profits.

- *Number of Respondents:* 370.
- *Average Responses per Respondent:* 20.
- *Number of Responses:* 7,400.
- *Average per-response Burden:* 0.5 hour (30 minutes).
- *Total Burden:* 3,700 hours.

OMB Control No. 1513–0038

Title: Application for Transfer of Spirits and/or Denatured Spirits in Bond.

TTB Form Number: TTB F 5100.16.

Abstract: Under the IRC at 26 U.S.C. 5005(c), when a proprietor of a distilled spirits plant (DSP) or an alcohol fuel plant (AFP, a type of DSP) desires to have spirits or denatured spirits transferred to its plant from another domestic plant, the proprietor must

make an application to receive such spirits in bond. Under that IRC authority, the TTB regulations in 27 CFR part 19 require the receiving proprietor to file an application for the transfer on TTB F 5100.16, Application for Transfer of Spirits and/or Denatured Spirits in Bond. TTB must approve the application before the transfer may occur. The collected information is necessary to ensure that the receiving plant has adequate bond coverage, as required.

Current Actions: There are no program changes to this information collection, and TTB is submitting for extension purposes only. As for adjustments, due to a change in agency estimates resulting from continued growth in the number of DSPs in the United States, TTB is increasing the estimated number of annual respondents, total responses, and burden hours associated with this information collection.

Type of Review: Extension of a currently approved collection.

Affected Public: Businesses and other for-profits.

- *Number of Respondents:* 505.
- *Average Responses per Respondent:* 6 per year.
- *Number of Responses:* 3,030.
- *Average per-response Burden:* 0.152 hours.
- *Total Burden:* 461 hours.

OMB Control No. 1513–0044

Title: Distilled Spirits Plants—Notices of Alternations and Changes in Production Status, and Alternating Premises Records.

Abstract: Under the IRC at 26 U.S.C. 5178(a), a DSP is a delineated place on which only certain authorized activities may be conducted. However, under section 5178(b), the Secretary may authorize other businesses on a DSP's premises upon application under certain circumstances. Also, under the IRC at 26 U.S.C. 5221, DSP proprietors are required to give written notification, in the form and manner prescribed by regulation, when they begin, suspend, or resume production of spirits. In addition, the IRC at 26 U.S.C. 5555 requires those liable for any tax imposed by chapter 51 of the IRC to keep such records, submit such returns and statements, and comply with such rules and regulations as the Secretary may prescribe. Under these authorities, TTB has issued regulations in 27 CFR part 19 requiring DSP proprietors to provide written notification regarding alternations of DSPs between proprietors or for customs purposes, and regarding changes to the production status of spirits. TTB also has issued regulations requiring DSP proprietors to keep alternating premises records when alternating operations at DSPs, including with an adjacent bonded wine cellar, taxpaid wine bottling house or brewery, as a manufacturer of eligible flavors, or as general premises. The collected information is necessary to ensure compliance with the statutory provisions regarding authorized activities and the applicable Federal excise tax.

Current Actions: There are no program changes to this information collection, and TTB is submitting for extension purposes only. As for adjustments, TTB is increasing the estimated number of annual respondents, total responses, and burden hours associated with this information collection.

Type of Review: Extension of a currently approved collection.

Affected Public: Businesses and other for-profits.

- *Number of Respondents:* 1,560.
- *Average Responses per Respondent:* 5 per year.
- *Number of Responses:* 7,800.
- *Average per-response Burden:* 0.5 hours (30 minutes).
- *Total Burden:* 3,900 hours.

OMB Control No. 1513–0048

Title: Registrations and Miscellaneous Requests and Notices for Distilled Spirits Plants; Distilled Spirits Related Requests and Notices.

TTB Form Number: TTB F 5110.41.

Abstract: The IRC at 26 U.S.C. 5171 and 5172, provides than an application to register a DSP must be made in conformity with regulations issued by the Secretary, while 26 U.S.C. 5201 requires DSPs to operate in conformity with such regulations. The IRC at 26 U.S.C. 5312 also authorizes the Secretary to issue regulations regarding the use of distilled spirits by certain educational and scientific institutions for experimental or research use, and that section authorizes the establishment and regulation of experimental DSPs. Under those authorities, the TTB regulations in 27 CFR part 19 prescribe the use of TTB F 5110.41 to register a DSP or to make certain amendments to an existing DSP registration. The TTB regulations in part 19 also require DSP operators to submit various miscellaneous notices or requests to vary their operations from the requirements of that part. In addition, the regulations in part 19 require persons who are neither registered DSPs nor applicants for registration to submit applications or notices related to certain distilled spirits activities, such as the establishment of an experimental DSP or the use of spirits for research purposes. The required information assists TTB in determining a person's eligibility to establish and operate a DSP, whether a variance from TTB's regulatory requirements should be approved, and whether entities that are not DSPs are eligible to engage in certain distilled spirits-related activities.

Current Actions: There are no program changes to this information collection, and TTB is submitting for extension purposes only. As for adjustments, TTB is increasing the estimated number of annual respondents, total responses, and burden hours associated with this information collection.

Type of Review: Extension of a currently approved collection.

Affected Public: Businesses and other for-profits.

- *Number of Respondents:* 4,600.
- *Average Responses per Respondent:* 1.1944 per year.
- *Number of Responses:* 5,495.
- *Average per-response Burden:* 1.7047 hours.
- *Total Burden:* 9,367 hours.

OMB Control No. 1513–0050

Title: Tax Deferral Bond—Distilled Spirits (Puerto Rico).

TTB Form Number: TTB F 5110.50.

Abstract: Under the IRC at 26 U.S.C. 7652, beverage distilled spirits, as well as nonbeverage products containing spirits subject to tax, produced in Puerto Rico and brought into the United States, are subject to a tax equal to that imposed by the IRC on domestically produced spirits. That section also authorizes the Secretary to prescribe regulations regarding the mode and time for the collection of such taxes. In addition, the IRC at 26 U.S.C. 7101 and 7102 authorizes the Secretary to issue regulations regarding bonds required under the IRC or its related regulations. Under those IRC authorities, the TTB regulations in 27 CFR part 26 allow respondents who ship taxable distilled spirits products produced in Puerto Rico to the United States to either pay the required tax prior to shipment or to file a bond to defer payment of the tax due until the submission of the respondent's next excise tax return. The regulations require those who elect to defer tax payment on such shipments to file a bond on TTB F 5110.50 to guarantee payment of the taxes due in case of default. The information collected administers these statutory provisions.

Current Actions: There are no program changes or adjustments to this

information collection, and TTB is submitting for extension purposes only.

Type of Review: Extension of a currently approved collection.

Affected Public: Businesses and other for-profits.

- *Number of Respondents:* 10.
- *Average Responses per Respondent:* 1 (1 per year).
- *Number of Responses:* 10.
- *Average per-response Burden:* 1 hour.
- *Total Burden:* 10 hours.

OMB Control No. 1513–0053

Title: Report of Wine Premises Operations.

TTB Form Number: TTB F 5120.17.

Abstract: The IRC at 26 U.S.C. 5367 authorizes the Secretary to issue regulations requiring the keeping of records and the filing of returns related to wine cellar and bottling house operations. Section 5555 of the IRC also generally requires any person liable for tax under chapter 51 of the IRC to keep records, provide statements, and make returns as the Secretary prescribes by regulation. Under those IRC authorities, the TTB wine regulations in 27 CFR part 24 require wine premises proprietors to file periodic operations reports on form TTB F 5120.17. TTB uses the collected information to verify excise tax liabilities and ensure that respondents operate wine premises in accordance with applicable Federal law and regulations. TTB also uses this report to collect raw data on wine premises activity for its generalized monthly statistical report on wine operations, which TTB makes public on its website.

Current Actions: There are no program changes to this information collection, and TTB is submitting for extension purposes only. As for adjustments, due to changes in agency estimates, TTB is increasing the estimated number of annual respondents, total responses, and burden hours associated with this information collection.

Type of Review: Extension of a currently approved collection.

Affected Public: Businesses and other for-profits.

- *Number of Respondents:* 17,000.
- *Average Responses per Respondent:* 4.34 per year.
- *Number of Responses:* 74,460.
- *Average per-response Burden:* 1.10 hours.
- *Total Burden:* 81,906 hours.

OMB Control No. 1513–0064

Title: Importer's Records and Reports.

TTB REC Number: TTB REC 5170/1.

Abstract: Pursuant to chapters 51 and 52 of the IRC and the Federal Alcohol Administration Act (FAA Act, 27 U.S.C. 201 *et seq.*), TTB regulates, among other things, the importation of alcohol and tobacco products. Under those statutory authorities, TTB has issued regulations in 27 CFR requiring importers of alcohol and tobacco products to provide certain information regarding their permits, the products imported, and the taxes paid on those products or, for products released from customs custody without payment of tax, the transfer of such products to a bonded facility. TTB also uses the collected information to ensure that imported alcohol beverage labels comply with FAA Act labeling requirements. Under this information collection, importers generally submit the required information electronically through Customs and Border Protection's interface during the import entry process, and the required information is then transmitted to TTB. In addition, importers may submit letterhead applications to TTB to request variances from established regulatory provisions. The collected import and letterhead variance information is necessary to ensure that importers comply with Federal laws and regulations regarding alcohol and tobacco products or that TTB can authorize alternatives that are not contrary to law and are consistent with the intent of existing requirements.

Current Actions: There are no program changes or adjustments to this information collection, and TTB is submitting for extension purposes only.

Type of Review: Extension of a currently approved collection.

Affected Public: Businesses and other for-profits; State and local governments.

- *Number of Respondents:* 10,550.
- *Average Responses per Respondent:* 6 per year.
- *Number of Responses:* 63,300.
- *Average per-response Burden:* 0.33 hours (20 minutes).
- *Total Burden:* 21,100 hours.

OMB Control No. 1513–0083

Title: Excise Tax Return.

TTB Form Number: TTB F 5000.24.

Abstract: Under the IRC at 26 U.S.C. 5061(a) and 5703(b), the Federal alcohol and tobacco excise taxes imposed by the IRC are collected on the basis of a return, containing such information as the Secretary requires by regulation. Under those IRC authorities, the TTB regulations require such excise taxpayers, other than those in Puerto Rico, report their alcohol or tobacco excise tax liability using TTB F 5000.24, Excise Tax Return. Tobacco taxpayers and large alcohol producers file their returns and pay their excise taxes on a semi-monthly basis, while certain small alcohol producers file returns and pay taxes on a quarterly or annual basis, depending on certain circumstances. The collected information is necessary to establish a taxpayer's identity, the amount and type of taxes due, and the amount of the payment made.

Current Actions: There are no program changes to this information collection, and TTB is submitting for extension purposes only. As for adjustments, due to a change in agency estimates, TTB is increasing the estimated number of annual respondents, total responses, and burden hours associated with this information collection.

Type of Review: Extension of a currently approved collection.

Affected Public: Businesses and other for-profits.

- *Number of Respondents:* 20,382.
- *Average Responses per Respondent:* 6.2.
- *Number of Responses:* 126,370.
- *Average per-response Burden:* 0.75 hours (45 minutes).
- *Total Burden:* 94,775.5 hours.

OMB Control No. 1513–0092

Title: Marks on Wine Containers.

TTB REC Number: TTB REC 5120/3.

Abstract: The IRC at 26 U.S.C. 5041 imposes a per gallon Federal excise tax of varying rates on six classes of wine—three classes of still wines (based on alcohol content), two classes of effervescent wines, and one class of hard cider. Under the authority of the IRC at 26 U.S.C. 5368, 5388, and 5662, the TTB regulations in 27 CFR part 24, Wine, require wine premises proprietors to correctly identify wines kept on or removed from their premises by placing certain marks, labels, or other information on all production, storage, and consumer containers of wine. Because of the varying excise tax rates on wines, and because different tax classes of wine may be produced at the same premises, the required information is necessary to ensure that wines are correctly identified for excise tax purposes. However, the placement of identifying information on wine containers is a usual and customary business practice carried out by wine premises proprietors, regardless of any regulatory requirement to do so, in order to track their wine production and inventory and, ultimately, identify the products for the consumer.

Current Actions: There are no program changes to this information collection, and TTB is submitting for extension purposes only. As for adjustments, due to a change in agency estimates, TTB is increasing the estimated number of annual

respondents and total responses associated with this information collection.

Type of Review: Extension of a currently approved collection.

Affected Public: Businesses and other for-profits.

- *Number of Respondents:* 17,000.
- *Average Responses per Respondent:* 1 (once per year).
- *Number of Responses:* 17,000.
- *Average per-response and Total Burden:* None. This information collection consists of usual and customary marks and labels on wine containers placed by respondents during the normal course of business, regardless of any regulatory requirement to do so. As such, under the Office of Management and Budget (OMB) regulations at 5 CFR 1320.3(b)(2), this information collection imposes no additional burden on respondents.

OMB Control No. 1513–0113

Title: Special Tax ''Renewal'' Registration and Return/Special Tax Location Registration Listing.

TTB Form Number: TTB F 5630.5R.

Abstract: The IRC at 26 U.S.C. 5731 and 5732 requires manufacturers of tobacco products, manufacturers of cigarette papers and tubes, and export warehouse proprietors to pay an annual special (occupational) tax (SOT) for each such premises that they operate, on the basis of a return and under regulations issued by the Secretary. TTB annually sends a SOT return and premises registration form, TTB F 5630.5R, with pre-populated premises data to tobacco industry members that have previously paid special tax. TTB's use of TTB F 5630.5R facilitates the registration of premises subject to SOT and the timely payment of that tax by businesses subject to it.

Current Actions: There are no program changes or adjustments to this information collection, and TTB is submitting for extension purposes only.

Type of Review: Extension of a currently approved collection.

Affected Public: Businesses and other for-profits.

- *Number of Respondents:* 220.
- *Average Responses per Respondent:* 1 (one) per year.
- *Number of Responses:* 220.
- *Average per-response Burden:* 0.25 hours (15 minutes).
- *Total Burden:* 55 hours.

OMB Control No. 1513–0115

Title: Usual and Customary Business Records Relating to Wine.

TTB REC Number: TTB REC 5120/1.

Abstract: Under the authority of the IRC at 26 U.S.C. 5362, 5367, 5369, 5370, and 5555, the TTB regulations require wineries, taxpaid wine bottling houses, and vinegar plants to keep certain usual and customary business records. These records include purchase and sales invoices, and internal records related to their production and processing of wine, and their packaging, storage, and shipping operations. TTB routinely inspects these records to verify proper payment of Federal wine excise taxes, and to ensure that proprietors produce, package, store, ship, and transfer wine in compliance with the applicable Federal statutory and regulatory requirements.

Current Actions: There are no program changes to this information collection, and TTB is submitting for extension purposes only. As for adjustments, due to a change in agency estimates, TTB is increasing the estimated number of annual respondents, total responses, and burden hours associated with this information collection.

Type of Review: Extension of a currently approved collection.

Affected Public: Businesses and other for-profits.

- *Number of Respondents:* 17,000.
- *Average Responses per Respondent:* 1 (one) per year.
- *Number of Responses:* 17,000.
- *Average per-response and Total Burden:* None. This information collection consists of usual and customary business records kept by wine industry members during the normal course of business, regardless of any regulatory requirement to do so. As such, under the Office of Management and Budget (OMB) regulations at 5 CFR 1320.3(b)(2), this information collection imposes no additional burden on respondents.

OMB Control No. 1513–0123

Title: Application, Permit, and Report—Wine and Beer (Puerto Rico); and Application, Permit and Report—Distilled Spirits Products (Puerto Rico).

TTB Form Number: TTB F 5110.21, F 5110.51.

Abstract: In general, under the IRC at 26 U.S.C. 7652, merchandise manufactured in Puerto Rico and shipped to the United States for consumption or sale is subject to a tax equal to the internal revenue tax imposed in the United States upon like articles of merchandise of domestic manufacture. That section also authorizes the Secretary to issue regulations regarding the collection of such taxes, which, as provided in that section, are largely transferred to the treasury of Puerto Rico. Under that IRC authority, the TTB regulations in 27 CFR part 26 require persons who intend to ship alcohol products produced in Puerto Rico to the United States for consumption or sale to file an application and permit to compute the tax on, tax-pay, and withdraw those products for shipment. As such, the TTB regulations prescribe the use of TTB F 5100.21 for beer or wine products, and TTB F 5110.51 for distilled spirits products. In cases where the respondent makes the shipment taxpaid, TTB uses the required information to verify that the respondent has paid the correct amount of tax. In cases where the respondent is eligible to defer the tax payment, TTB uses the information to ensure that the respondent's bond coverage is adequate to cover the taxes due. If necessary, TTB also uses the collected information to enforce collection of any Federal excise tax owed on such shipments.

Current Actions: There are no program changes or adjustments to this information collection, and TTB is submitting for extension purposes only.

Type of Review: Extension of a currently approved collection.

Affected Public: Businesses and other for-profits.

- *Number of Respondents:* 35.
- *Average Responses per Respondent:* 1 (one) per year.
- *Number of Responses:* 35.
- *Average per-response Burden:* 1 hour.
- *Total Burden:* 35 hours.

OMB Control No. 1513–0125

Title: Distilled Spirits Bond.

TTB Form Number: TTB F 5110.56.

Abstract: The IRC at 26 U.S.C. 5173 and 5181 requires DSPs and AFPs, respectively, to furnish a bond, unless exempted from doing so under the IRC at 26 U.S.C. 5551(d) or 5181(c)(3). Under those IRC authorities, the TTB regulations in 27 CFR part 19 require proprietors of such plants that are required to submit a bond to use TTB F 5110.56 to file with TTB either a surety bond or a collateral bond using cash or U.S. securities. Using that same form, proprietors also may withdraw coverage for one or more plants, and DSP proprietors may provide operations coverage for adjacent wine cellars. The collected information is necessary to implement the statutory provisions and ensure payment of delinquent Federal alcohol excise tax liabilities.

Current Actions: There are no program changes to this information collection, and TTB is submitting for extension purposes only. As for adjustments, due to a change in agency estimates resulting from continued growth in the number of DSPs in the

United States, TTB is increasing the estimated number of annual respondents, total responses, and burden hours associated with this information collection.

Type of Review: Extension of a currently approved collection.

Affected Public: Businesses and other for-profits.

- *Number of Respondents:* 400.
- *Average Responses per Respondent:* 1 (one) per year.
- *Number of Responses:* 400.
- *Average per-response Burden:* 1 hour.
- *Total Burden:* 400 hours.

OMB Control No. 1513–0128

Title: Records to Support Tax Free and Tax Overpayment Sales of Firearms and Ammunition.

TTB Form Number: TTB F 5600.33, TTB F 5600.34, TTB F 5600.35, TTB F 5600.36, TTB F 5600.37.

Abstract: The Internal Revenue Code (IRC) at 26 U.S.C. 4181 imposes a tax on the sale of firearms and ammunition. However, under the IRC at 26 U.S.C. 4221(a), certain sales may be made tax-free, including sales made for further manufacture, export, or use as supplies on vessels or aircraft, and sales made to a State or local government or to a nonprofit education organization for their exclusive use. In addition, for such sales where the tax has been paid, the tax is considered an overpayment subject to credit or refund under the IRC at 26 U.S.C. 6416(b)(2) and (3). The TTB regulations in 27 CFR part 53 prescribe that those otherwise subject to this tax must maintain records, including statements or certificates containing specified information, documenting the tax-free or tax-overpaid nature of such sales. Respondents may use commercial records or self-generated supporting statement or certificates, or, for certain transactions, respondents may use TTB-provided forms, which, when completed, document the required supporting information. The required supporting information is maintained by respondents at their business premises, and TTB may examine these records during audits.

Current Actions: There are no program changes or adjustments to this information collection, and TTB is submitting for extension purposes only.

Type of Review: Extension of a currently approved collection.

Affected Public: Businesses and other for-profits.

- *Number of Respondents:* 3,500.
- *Average Responses per Respondent:* 12 (once per month).
- *Number of Responses:* 42,000.
- *Average per-response Burden:* 0.375 hours (22.5 minutes).
- *Total Burden:* 15,750 hours.

Dated: November 16, 2023.

Amy R. Greenberg,

Director, Regulations and Rulings Division.

[FR Doc. 2023–25767 Filed 11–21–23; 8:45 am]

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Part II

Department of Health and Human Services

Centers for Medicare & Medicaid Services

42 CFR Parts 405, 410, 416, et al.

45 CFR Part 180

Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems; Quality Reporting Programs; Payment for Intensive Outpatient Services in Hospital Outpatient Departments, Community Mental Health Centers, Rural Health Clinics, Federally Qualified Health Centers, and Opioid Treatment Programs; Hospital Price Transparency; Changes to Community Mental Health Centers Conditions of Participation, Changes to the Inpatient Prospective Payment System Medicare Code Editor; Rural Emergency Hospital Conditions of Participation Technical Correction; Final Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 405, 410, 416, 419, 424, 485, 488, and 489

Office of the Secretary

45 CFR Part 180

[CMS–1786–FC]

RIN 0938–AV09

Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems; Quality Reporting Programs; Payment for Intensive Outpatient Services in Hospital Outpatient Departments, Community Mental Health Centers, Rural Health Clinics, Federally Qualified Health Centers, and Opioid Treatment Programs; Hospital Price Transparency; Changes to Community Mental Health Centers Conditions of Participation, Changes to the Inpatient Prospective Payment System Medicare Code Editor; Rural Emergency Hospital Conditions of Participation Technical Correction

AGENCY: Centers for Medicare & Medicaid Services (CMS), Department of Health and Human Services (HHS).

ACTION: Final rule with comment period.

SUMMARY: This final rule with comment period revises the Medicare hospital outpatient prospective payment system (OPPS) and the Medicare ambulatory surgical center (ASC) payment system for calendar year 2024 based on our continuing experience with these systems. In this final rule, we describe the 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 final rule updates and refines the requirements for the Hospital Outpatient Quality Reporting (OQR) Program, the ASC Quality Reporting (ASCQR) Program, and the Rural Emergency Hospital Quality Reporting (REHQR) Program. In this final rule, we are also establishing a payment for certain intensive outpatient services under Medicare, beginning January 1, 2024. In addition, this final rule updates and refines requirements for hospitals to make public their standard charge information and enforcement of hospital price transparency. We are finalizing changes to the community mental health center (CMHC) Conditions of Participation (CoPs) to provide requirements for furnishing intensive outpatient (IOP) services, and we are finalizing the proposed personnel qualifications for mental health counselors (MHCs) and marriage and family therapists (MFTs). Additionally, we are finalizing the removal of discussion of the inpatient prospective payment system (IPPS) Medicare Code Editor (MCE) from the annual IPPS rulemakings, beginning with the fiscal year (FY) 2025 rulemaking. Finally, we are finalizing a technical correction to the Rural Emergency Hospital (REH) CoPs under the standard for the designation and certification of REHs.

DATES:

Effective date: The provisions of this rule are effective January 1, 2024.

Comment period: To be assured consideration, comments must be received at one of the addresses provided below, by January 1, 2024.

ADDRESSES: In commenting, please refer to file code CMS–1786–FC.

Comments, including mass comment submissions, must be submitted in one of the following three ways (please choose only one of the ways listed):

1. *Electronically.* You may submit electronic comments on this regulation to *https://www.regulations.gov.* Follow the ''Submit a comment'' instructions.

2. *By regular mail.* You may mail written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–1786–FC, P.O. Box 8010, Baltimore, MD 21244–8010.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By express or overnight mail.* You may send written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–1786–FC, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.

For information on viewing public comments, see the beginning of the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT:

Au'Sha Washington, *AushaWashington@cms.hhs.gov* or 410–786–3736.

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 at *Scott.Talaga@cms.hhs.gov* or Mitali Dayal via email at *Mitali.Dayal2@cms.hhs.gov.*

Ambulatory Surgical Center Quality Reporting (ASCQR) Program policies, contact Anita Bhatia via email at *Anita.Bhatia@cms.hhs.gov.*

Ambulatory Surgical Center Quality Reporting (ASCQR) Program measures, contact Marsha Hertzberg via email at *marsha.hertzberg@cms.hhs.gov.*

Biosimilars Packaging Exception, contact Gil Ngan via email at *gil.ngan@cms.hhs.gov*.

Blood and Blood Products, contact Josh McFeeters via email at *Joshua.McFeeters@cms.hhs.gov.*

Cancer Hospital Payments, contact Scott Talaga via email at *Scott.Talaga@cms.hhs.gov*.

Cardiac Rehabilitation, Intensive Cardiac Rehabilitation and Pulmonary Rehabilitation Services, contact Nate Vercauteren via email at *Nathan.Vercauteren@cms.hhs.gov.*

CMS Web Posting of the OPPS and ASC Payment Files, contact Chuck Braver via email at *Chuck.Braver@cms.hhs.gov.*

Community Mental Health Centers (CMHC) Conditions of Participation, contact Mary Rossi-Coajou via email at *Mary.RossiCoajou@cms.hhs.gov* or Cara Meyer via email at *Cara.Meyer@cms.hhs.gov*.

Composite APCs (Multiple Imaging and Mental Health), via email at Mitali Dayal via email at *Mitali.Dayal2@cms.hhs.gov*.

Comprehensive APCs (C–APCs), contact Mitali Dayal via email at *Mitali.Dayal2@cms.hhs.gov.*

COVID–19 Final Rules, contact Au'Sha Washington via email at *Ausha.Washington@cms.hhs.gov.*

Hospital Outpatient Quality Reporting (OQR) Program policies, contact Kimberly Go via email *Kimberly.Go@cms.hhs.gov.*

Hospital Outpatient Quality Reporting (OQR) Program measures, contact Janis Grady via email *Janis.Grady@cms.hhs.gov*.

Hospital Outpatient Visits (Emergency Department Visits and Critical Care Visits), contact Abby Cesnik via email at *Abigail.Cesnik@cms.hhs.gov.*

Hospital Price Transparency (HPT), contact Terri Postma via email at *PriceTransparencyHospitalCharges@cms.hhs.gov*.

Inpatient Only (IPO) Procedures List, contact Abigail Cesnik via email at *Abigail.Cesnik@cms.hhs.gov*.

Inpatient Prospective Payment System (IPPS) Medicare Code Editor, contact Mady Hue via email at *Marilu.Hue@cms.hhs.gov*.

Mental Health Services Furnished Remotely by Hospital Staff to Beneficiaries in Their Homes, contact Emily Yoder via email at *Emily.Yoder@cms.hhs.gov.*

Method to Control Unnecessary Increases in the Volume of Clinic Visit

Services Furnished in Excepted Off-Campus Provider-Based Departments (PBDs), contact Nate Vercauteren via email at *Nathan.Vercauteren@cms.hhs.gov.*

New Technology Intraocular Lenses (NTIOLs), contact Scott Talaga via email at *Scott.Talaga@cms.hhs.gov.*

No Cost/Full Credit and Partial Credit Devices, contact Scott Talaga via email at *Scott.Talaga@cms.hhs.gov.*

Opioid Treatment Program (OTP) Intensive Outpatient Services (IOP) contact Lindsey Baldwin via email at *Lindsey.Baldwin@cms.hhs.gov* and Ariana Pitcher at *Ariana.Pitcher@cms.hhs.gov.*

OPPS Brachytherapy, contact Cory Duke via email at *Cory.Duke@cms.hhs.gov* and Scott Talaga via email at *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 at *Erick.Chuang@cms.hhs.gov,* or Scott Talaga via email at *Scott.Talaga@cms.hhs.gov,* or Josh McFeeters via email at *Joshua.McFeeters@cms.hhs.gov.*

OPPS Dental Policy, contact Nicole Marcos via email at *Nicole.Marcos@cms.hhs.gov.*

OPPS Drugs, Radiopharmaceuticals, Biologicals, and Biosimilar Products, contact Josh McFeeters via email at *Joshua.McFeeters@cms.hhs.gov,* Gil Ngan via email at *Gil.Ngan@cms.hhs.gov,* Cory Duke via email at *Cory.Duke@cms.hhs.gov,* or Au'Sha Washington via email at *Ausha.Washington@cms.hhs.gov.*

OPPS New Technology Procedures/Services, contact the New Technology APC mailbox at *NewTechAPCapplications@cms.hhs.gov.*

OPPS Packaged Items/Services, contact Mitali Dayal via email at *Mitali.Dayal2@cms.hhs.gov* or Cory Duke via email at *Cory.Duke@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 at *Marina.Kushnirova@cms.hhs.gov.*

Partial Hospitalization Program (PHP), Intensive Outpatient (IOP), and Community Mental Health Center (CMHC) Issues, contact the PHP Payment Policy Mailbox at *PHPPaymentPolicy@cms.hhs.gov.*

Request for Public Comments on Potential Payment under the IPPS for Establishing and Maintaining Access to Essential Medicines, contact *DAC@cms.hhs.gov*.

Rural Emergency Hospital Conditions of Participation, contact Kianna Banks via email *Kianna.Banks@cms.hhs.gov.*

Rural Emergency Hospital Quality Reporting (REHQR) Program policies, contact Anita Bhatia via email at *Anita.Bhatia@cms.hhs.gov.*

Rural Emergency Hospital Quality Reporting (REHQR) Program measures, contact Melissa Hager via email *Melissa.Hager@cms.hhs.gov.*

Rural Health Clinic (RHC) and Federally Qualified Health Center (FQHC) Intensive Outpatient Services (IOP), contact the RHC Payment Policy Mailbox at *RHC@cms.hhs.gov* or the FQHC Payment Policy Mailbox at *FQHC-PPS@cms.hhs.gov.*

Separate Payment for High-Cost Drugs Provided by Indian Health Service and Tribally-Owned Facilities, contact Josh McFeeters via email at *Joshua.McFeeters@cms.hhs.gov.*

Skin Substitutes, contact Josh McFeeters via email at *Joshua.McFeeters@cms.hhs.gov.*

All Other Issues Related to Hospital Outpatient Payments Not Previously Identified, contact the OPPS mailbox at *OutpatientPPS@cms.hhs.gov.*

All Other Issues Related to the Ambulatory Surgical Center Payments Not Previously Identified, contact the ASC mailbox at *ASCPPS@cms.hhs.gov.*

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: *https://www.regulations.gov.* Follow the search instructions on that website to view public comments. CMS will not post on *Regulations.gov* public comments that make threats to individuals or institutions or suggest that the individual will take actions to harm the individual. CMS continues to encourage individuals not to submit duplicative comments. We will post acceptable comments from multiple unique commenters even if the content is identical or nearly identical to other 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 calendar year (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/payment/prospective-payment-systems/hospital-outpatient/regulations-notices.*

The Addenda relating to the ASC payment system are available at: *https://www.cms.gov/medicare/payment/prospective-payment-systems/ambulatory-surgical-center-asc/asc-regulations-and-notices.*

Current Procedural Terminology (CPT) Copyright Notice

Throughout this final rule with comment period, we use CPT codes and descriptions to refer to a variety of services. We note that CPT codes and descriptions are copyright 2021 American Medical Association (AMA). All Rights Reserved. CPT is a registered trademark of the AMA. Applicable Federal Acquisition Regulations and Defense Federal Acquisition Regulations apply.

Table of Contents

I. Summary and Background

A. Executive Summary of This Document

1. Purpose

In this final rule with comment period, we are updating 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, 2024. 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 of the Department of Health and Human Services (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 practice, changes in technology, and the addition of new services, new cost data, and other relevant information and factors. In addition, under section 1833(i)(D)(v) of the Act, we annually review and update the ASC payment rates. This final rule with comment period 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 final rule with comment period. In addition, this final rule with comment period updates and refines the requirements for the Hospital Outpatient Quality Reporting (OQR) Program, the ASC Quality Reporting (ASCQR) Program, and Rural Emergency Hospital Quality Reporting (REHQR) Program. In addition, this final rule with comment period establishes payment for intensive outpatient services under Medicare, beginning January 1, 2024. This final rule with comment period also updates and refines the requirements for hospitals to make public their standard charges and CMS enforcement of hospital price transparency regulations. In addition, we are finalizing changes to the CMHC CoPs to provide requirements for furnishing IOP services. In addition, we are finalizing changes to the CMHC CoPs to provide requirements for furnishing IOP services, as well as finalizing the proposed personnel qualifications for MHCs and MFTs. We are also finalizing the removal of discussion of the IPPS Medicare Code Editor (MCE) from the annual IPPS rulemakings, beginning with the FY 2025 rulemaking. Finally, we are finalizing a technical correction to the Rural Emergency Hospital (REH) CoPs under the standard for the designation and certification of REHs.

2. Summary of the Major Provisions

- *OPPS Update:* For 2024, we are increasing the payment rates under the OPPS by an Outpatient Department (OPD) fee schedule increase factor of 3.1 percent. This increase factor is based on the final inpatient hospital market basket percentage increase of 3.3 percent for inpatient services paid under the hospital inpatient prospective payment system (IPPS) reduced by a final productivity adjustment of 0.2 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) 2024 will be approximately $88.9 billion, an increase of approximately $6.0 billion compared to estimated CY 2023 OPPS payments.

We are continuing to implement the statutory 2.0 percentage point reduction in payments for hospitals that fail to meet the hospital outpatient quality reporting requirements by applying a reporting factor of 0.9806 to the OPPS payments and copayments for all applicable services.

- *Data used in CY 2024 OPPS/ASC Ratesetting:* To set OPPS and ASC payment rates, we normally use the most updated claims and cost report data available. The best available claims data is the most recent set of data which would be from 2 years prior to the calendar year that is the subject of rulemaking. Cost report data usually lags the claims data by a year and we believe that using the most updated cost report extract available from the Healthcare Cost Report Information System (HCRIS) is appropriate for CY 2024 OPPS ratesetting. Therefore, we are using our typical data process of using the most updated cost reports and claims data available for CY 2024 OPPS ratesetting.
- *Partial Hospitalization Update:* For CY 2024, we are finalizing changes to our methodology used to calculate the Community Mental Health Center (CMHC) and hospital-based PHP (HB PHP) geometric mean per diem costs. We also are finalizing changes to expand PHP payment from two APCs to four APCs.
- *Medicare Payment for Intensive Outpatient Programs:* Beginning in CY 2024, we are finalizing payment for intensive outpatient program (IOP) services under Medicare. We are finalizing the scope of benefits, physician certification requirements, coding and billing, and payment rates under the IOP benefit. IOP services may be furnished in hospital outpatient departments, community mental health centers (CMHCs), federally qualified health centers (FQHCs), and rural health clinics (RHCs). We also are finalizing payment for intensive outpatient services provided by opioid treatment programs (OTPs) under the existing OTP benefit.
- *Changes to the Inpatient Only (IPO) List:* For 2024, we are finalizing our proposal to not remove any services from the IPO list for CY 2024.
- 340B*Acquired Drugs:* For CY 2024, we are continuing to apply the default rate, generally average sales price (ASP) plus 6 percent, to 340B acquired drugs and biologicals in this final rule with comment period. Therefore, drugs and biologicals acquired under the 340B program will be paid at the same payment rate as those drugs and biologicals not acquired under the 340B program.
- *Biosimilar Packaging Exception:* For CY 2024, we are finalizing our proposal to except biosimilars from the OPPS threshold packaging policy when their reference products are separately paid. However, we are not finalizing that all the biosimilars related to the reference product would be similarly

packaged if a reference product's per-day cost falls below the threshold packaging policy.

• *Finalizing to Pay IHS and Tribal Hospitals that Convert to a Rural Emergency Hospital (REH) Under the IHS All-Inclusive Rate (AIR):* For CY 2024, we are finalizing that IHS and tribal hospitals that convert to an REH be paid for hospital outpatient services under the same all-inclusive rate that would otherwise apply if these services were performed by an IHS or tribal hospital that is not an REH. We also are finalizing that IHS and tribal hospitals that convert to an REH would receive the REH monthly facility payment consistent with how this payment is applied to REHs that are not tribally or IHS operated.

• *Device Pass-Through Payment Applications:* For CY 2024, we received six applications for device pass-through payments. We sought public comment on these applications and are approving four applicants for device pass-through payment status in this final rule with comment period.

• *Cancer Hospital Payment Adjustment:* For CY 2024, we are continuing 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. Section 16002(b) of the 21st Century Cures Act requires that this weighted average PCR be reduced by 1.0 percentage point. In light of the public health emergency (PHE) impact on claims and cost data used to calculate the target PCR, we have maintained the CY 2021 target PCR of 0.89 through CYs 2022 and 2023. In this final rule with comment period, we are finalizing to reduce the target PCR by 1.0 percentage point each calendar year until the target PCR equals the PCR of non-cancer hospitals using the most recently submitted or settled cost report data. For CY 2024, we are finalizing a target PCR of 0.88 to determine the CY 2024 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 0.88 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. In light of the impact of the COVID–19 PHE on healthcare utilization, we are finalizing to extend our policy to update the ASC payment system using the hospital market basket update an additional 2 years—through CYs 2024 and 2025. Using the hospital market basket methodology, for CY 2024, we are increasing payment rates under the ASC payment system by 3.1 percent for ASCs that meet the quality reporting requirements under the ASCQR Program. This increase is based on a hospital market basket percentage increase of 3.3 percent reduced by a productivity adjustment of 0.2 percentage point. Based on this final update, we estimate that total payments to ASCs (including beneficiary cost sharing and estimated changes in enrollment, utilization, and case-mix) for CY 2024 will be approximately $7.1 billion, an increase of approximately $207 million compared to estimated CY 2023 Medicare payments.

• *Changes to the List of ASC Covered Surgical Procedures:* For CY 2024, we are adding 37 surgical procedures, including total shoulder arthroplasty (TSA) (Healthcare Common Procedure Coding System (HCPCS) code 23472), to the ASC covered procedures list (CPL) based upon existing criteria at § 416.166.

• *Hospital Outpatient Quality Reporting (OQR) Program:* We are finalizing our proposals to: (1) modify the COVID–19 Vaccination Coverage Among Healthcare Personnel (HCP) measure beginning with the CY 2024 reporting period/CY 2026 payment determination; (2) modify the Cataracts: Improvement in Patient's Visual Function Within 90 Days Following Cataract Surgery measure beginning with the voluntary CY 2024 reporting period; (3) modify the Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients measure beginning with the CY 2024 reporting period/CY 2026 payment determination; and (4) amend multiple codified regulations to replace references to ''QualityNet'' with ''CMS-designated information system'' or ''CMS website,'' and to make other conforming technical edits, to accommodate recent and future systems requirements and mitigate confusion for program participants.

We are finalizing with modification the proposal to adopt the Risk-Standardized Patient-Reported Outcome-Based Performance Measure (PRO–PM) Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA) in the HOPD Setting (THA/TKA PRO–PM) with voluntary reporting beginning with the CY 2025 reporting period through the CY 2027 reporting period followed by mandatory reporting beginning one year later than proposed with the CY 2028 reporting period/CY 2031 payment determination.

We are finalizing with modification the proposal to adopt the Excessive Radiation Dose or Inadequate Image Quality for Diagnostic Computed Tomography (CT) in Adults (Hospital Level—Outpatient) measure with voluntary reporting beginning with the CY 2025 reporting period and mandatory reporting beginning 1 year later than proposed with the CY 2027 reporting period/CY 2029 payment determination.

We are not finalizing our proposal to remove the Left without Being Seen measure. We are also not finalizing our proposal to re-adopt with modification the Hospital Outpatient Volume Data on Selected Outpatient Procedures measure.

We also requested public comment on: (1) patient and workforce safety (including sepsis); (2) behavioral health (including suicide prevention); and (3) telehealth as potential future measurement topic areas in the Hospital OQR Program.

• *Ambulatory Surgical Center Quality Reporting (ASCQR) Program:* We are finalizing our proposals to: (1) modify the COVID–19 Vaccination Coverage Among Health Care Personnel (HCP) measure beginning with the CY 2024 Reporting Period/CY 2026 payment determination; (2) modify the Cataracts: Improvement in Patient's Visual Function Within 90 Days Following Cataract Surgery measure beginning with the voluntary CY 2024 reporting period; (3) modify the Endoscopy/Polyp Surveillance: Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients measure beginning with the CY 2024 reporting period/CY 2026 payment determination; and (4) amend multiple codified regulations to replace references to ''QualityNet'' with ''CMS-designated information system'' or ''CMS website,'' and to make other conforming technical edits, to accommodate recent and future systems requirements and mitigate confusion for program participants.

We are finalizing with modification the proposal to adopt the Risk-Standardized Patient-Reported Outcome-Based Performance Measure (PRO–PM) Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA) in the ASC Setting (THA/TKA PRO–PM) with voluntary reporting beginning with the CY 2025 reporting period through the CY 2027 reporting period followed by mandatory reporting beginning 1 year later than proposed with the CY 2028 reporting period/CY 2031 payment determination.

We are not finalizing our proposal to re-adopt with modification the ASC Facility Volume Data on Selected ASC Surgical Procedures measure.

• *Rural Emergency Hospital Quality Reporting (REHQR) Program:* We are finalizing our proposals to: (1) codify the statutory authority for the REHQR Program; (2) adopt and codify policies related to measure retention and measure modification; (3) adopt one chart-abstracted measure, Median Time from Emergency Department (ED) Arrival to ED Departure for Discharged ED Patients, beginning with the CY 2024 reporting period; (4) adopt three claims-based measures, Abdomen Computed Tomography (CT)—Use of Contrast Material, Facility 7-Day Risk-Standardized Hospital Visit Rate After Outpatient Colonoscopy, and Risk-Standardized Hospital Visits Within 7 Days After Hospital Outpatient Surgery, beginning with the CY 2024 reporting period; (5) establish related reporting requirements beginning with the CY 2024 reporting period; (6) adopt and codify policies related to public reporting of data; (7) codify foundational requirements related to REHQR Program participation; (8) adopt and codify policies related to the form, manner, and timing of data submission under the REHQR Program; (9) adopt and codify a review and corrections period for submitted data; and (10) adopt and codify an Extraordinary Circumstances Exception (ECE) process for data submission requirements.

We are finalizing with modification the proposal to adopt and codify a policy related to immediate measure removal such that it is referred to more appropriately as immediate measure suspension. In such a case, a quality measure considered by CMS to have potential patient safety concerns will be immediately suspended from the program and then addressed in the next appropriate rulemaking cycle.

We also requested comment on the following potential measures and approaches for implementing quality reporting under the REHQR Program: (1) electronic clinical quality measures (eCQMs); (2) care coordination measures; and (3) a tiered approach for quality measure reporting.

• *Mental Health Services Furnished Remotely by Hospital Staff to Beneficiaries in Their Homes:* For CY 2024, we are finalizing technical refinements to the existing coding for remote mental health services to allow for multiple units to be billed daily. We also are finalizing to create a new, untimed code to describe group psychotherapy. Finally, we are delaying the in-person visit requirements until January 1, 2025.

• *OPPS Payment for Dental Services:* For CY 2024, we are assigning over 240 HCPCS codes describing dental services to various clinical APCs to align with Medicare payment provisions regarding dental services adopted in the CY 2024 Physician Fee Schedule (PFS) final rule (87 FR 69404; November 18, 2023).

• *Comment Solicitation on Payment for High-Cost Drugs Provided by Indian Health Service and Tribal Facilities:* We sought comment on whether Medicare should pay separately for high-cost drugs provided by IHS and tribal facilities. Commenters supported establishing a payment methodology that would allow IHS and Tribal healthcare facilities to receive separate payment outside of the IHS outpatient hospital all-inclusive rate (AIR) for oncology drugs and services whose costs exceed the AIR. Their preferred approach was to treat the AIR payment amount as a payment threshold and to have a separate payment for a drug if the cost of the drug was more than the AIR. Commenters also wanted CMS to ensure the integrity of the AIR if separate payment is established for high-cost oncology drugs and other high-cost services. We will consider these comments for future rulemaking.

• *Supervision by Nurse Practitioners, Physician Assistants and Clinical Nurse Specialists of Cardiac, Intensive Cardiac and Pulmonary Rehabilitation Services Furnished to Outpatients:* For CY 2024, to comply with section 51008 of the Bipartisan Budget Act of 2018 and to ensure consistency with final revisions to §§ 410.47 and 410.49 in the CY 2024 PFS final rule, published in the **Federal Register** of November 16, 2023 (FR Doc. 2023–24184), we are revising § 410.27(a)(1)(iv)(B)(*1*) to expand the practitioners who may supervise cardiac rehabilitation (CR), intensive cardiac rehabilitation (ICR), and pulmonary rehabilitation (PR) services to include nurse practitioners (NPs), physician assistants (PAs), and clinical nurse specialists (CNSs). We also are allowing for the direct supervision requirement for CR, ICR, and PR to include virtual presence of the physician through audio-video real-time communications technology (excluding audio-only) through December 31, 2024, and extend this policy to the nonphysician practitioners, that is NPs, PAs, and CNSs, who are eligible to supervise these services in CY 2024.

• *Payment for Intensive Cardiac Rehabilitation Services (ICR) Provided by an Off-Campus, Non-Excepted Provider Based Department (PBD) of a Hospital:* For CY 2024, to address an unintended reimbursement disparity created by application of the off-campus, non-excepted payment rate to intensive cardiac rehabilitation services (ICR), we are paying for ICR services furnished by an off-campus, non-excepted PBD of a hospital at 100 percent of the OPPS rate, which is the amount paid for these services under the PFS.

• *Final Updates to Requirements for Hospitals to Make Public a List of Their Standard Charges:* We are finalizing our proposals to revise several of our HPT requirements in order to improve our monitoring and enforcement capabilities by improving access to, and the usability of, hospital standard charge information; reducing the compliance burden on hospitals by providing CMS templates and technical guidance for display of hospital standard charge information; aligning, where feasible, certain HPT requirements and processes with requirements and processes we have implemented in the Transparency in Coverage (TIC) initiative; and making other modifications to our monitoring and enforcement capabilities that will, among other things, increase its transparency to the public. Together, we believe these activities will enhance existing and future enforcement actions while also providing the public with more meaningful standard charge information that can be used to improve the accuracy of consumer-friendly price estimator tools. Specifically, we are finalizing: (1) definitions of several terms; (2) a requirement that hospitals make a good faith effort to ensure standard charge information is true, accurate, and complete, and to include a statement affirming this in the machine-readable file (MRF); (3) new data elements that hospitals must include in their MRFs, as well a requirement that hospitals encode standard charge information in a CMS template layout; (4) phased implementation timeline applicable to the new requirements we are finalizing in this final rule with comment period; (5) a requirement that hospitals to include a .txt file in the root folder that includes a direct link to the MRF and a link in the footer on its website that links directly to the publicly available web page that hosts the link to the MRF; and (6) improvements to our enforcement process by updating our methods to assess hospital compliance, requiring hospitals to acknowledge receipt of warning notices, working with health system officials to address noncompliance issues in one or more hospitals that are part of a health system, and publicizing more

information about CMS enforcement activities related to individual hospital compliance. Specifically, and as discussed in more detail in section XVIII of this final rule with comment, we are finalizing that the effective date of the changes to the hospital price transparency regulations at 45 CFR part 180 will be January 1, 2024. However, the regulation text will specify later dates by which hospitals must be in compliance with some of these new requirements, and we will begin enforcing those requirements on those specified dates. We believe this phased implementation approach is necessary to provide hospitals time to collect and encode the required standard charge information completely and accurately.

• *Community Mental Health Center (CMHC) Conditions of Participation (CoPs):* The Consolidated Appropriations Act (CAA), 2023 (Pub. L. 117–238) established in section 4124 coverage of intensive outpatient (IOP) services in CMHCs. The legislation extended Medicare coverage and payment of IOP services furnished by a CMHC beginning January 1, 2024, adding to the existing coverage and payment for partial hospitalization (PHP) services in CMHCs. Section 4121 of the CAA, 2023 also established a new Medicare benefit category for services furnished and directly billed by Mental Health Counselors (MHCs) and Marriage and Family Therapists (MFTs). To implement these provisions of section 4121 of the CAA, 2023, CMS is finalizing, as proposed, to modify the requirements for CMHCs to include IOP services throughout the CoPs. We are also finalizing our proposal to modify the CMHC CoPs for personnel qualifications to add a definition of marriage and family therapists and revise the current definition of mental health counselors. In addition, we are adding MFTs and MHCs to the list of practitioners who can lead interdisciplinary team meetings when deemed necessary.

• *Changes to the Inpatient Prospective Payment System Medicare Code Editor:* Consistent with the process that is used for updates to the Integrated Outpatient Code Editor (I/OCE) and other Medicare claims editing systems, we are finalizing our proposal to remove discussion of the IPPS Medicare Code Editor (MCE) from the annual IPPS rulemakings, beginning with the FY 2025 rulemaking, and to generally address future changes or updates to the MCE through instruction to the MACs.

• *Request for Public Comments on Potential Payment under the IPPS and OPPS for Establishing and Maintaining Access to Essential Medicines:* We sought comment on potential separate payment under the IPPS for establishing and maintaining access to a buffer stock of essential medicines.

• *Rural Emergency Hospital (REH) Conditions of Participation (CoPs):* On November 23, 2022, we published a final rule for the REH health and safety standards, which was included in the ''Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Organ Acquisition; Rural Emergency Hospitals: Payment Policies, Conditions of Participation, Provider Enrollment, Physician Self-Referral; New Service Category for Hospital Outpatient Department Prior Authorization Process; Overall Hospital Quality Star Rating; COVID–19'' final rule with comment period (87 FR 71748). We are finalizing as proposed a technical correction to the REH CoPs under the standard for the designation and certification of REHs.

3. Summary of Costs and Benefits

In section XXVI of this final rule with comment period, we set forth a detailed analysis of the regulatory and federalism impacts that the changes will have on affected entities and beneficiaries. Key estimated impacts are described below.

a. Impacts of All OPPS Changes

Table 168 in section XXVI.C of this final rule with comment period displays the distributional impact of all the OPPS changes on various groups of hospitals and CMHCs for CY 2024 compared to all estimated OPPS payments in CY 2023. We estimate that the final policies in this final rule would result in a 3.2 percent overall increase in OPPS payments to providers. We estimate that total OPPS payments for CY 2024, including beneficiary cost-sharing, to the approximately 3,600 facilities paid under the OPPS (including general acute care hospitals, children's hospitals, cancer hospitals, and CMHCs) will increase by approximately $2.2 billion compared to CY 2023 payments, excluding our estimated changes in enrollment, utilization, and case-mix.

We estimated the isolated impact of our OPPS policies on CMHCs because CMHCs have historically only been paid for partial hospitalization services under the OPPS. Beginning in CY 2024, they will also be paid for new intensive outpatient program (IOP) 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 9.2 percent increase in CY 2024 payments to CMHCs relative to their CY 2023 payments.

b. Impacts of the Updated Wage Indexes

We estimate that our update of the wage indexes based on the fiscal year (FY) 2024 IPPS final rule wage indexes will result in a 0.0 percent increase for urban hospitals under the OPPS and a 1.2 percent increase for rural hospitals. These wage indexes include the continued implementation of the Office of Management and Budget (OMB) labor market area delineations based on 2010 Decennial Census data, with updates, as discussed in section II.C of this final rule with comment period.

c. Impacts of the Rural Adjustment and the Cancer Hospital Payment Adjustment

We are implementing the reduction to the cancer hospital payment adjustment for CY 2024 required by section 1833(t)(18)(C) of the Act, as added by section 16002(b) of the 21st Century Cures Act, and the final target payment-to-cost ratio (PCR) for CY 2024 cancer hospital adjustment of 0.89. However, as section 16002 requires that we reduce the target PCR by 0.01, that brings the final target PCR to 0.88 instead. This is 0.01 less than the target PCR of 0.89 from CY 2021 through CY 2023, which was previously held at the pre-PHE target.

d. Impacts of the OPD Fee Schedule Increase Factor

For the CY 2024 OPPS/ASC, we are establishing an OPD fee schedule increase factor of 3.1 percent and applying that increase factor to the conversion factor for CY 2024. As a result of the OPD fee schedule increase factor and other budget neutrality adjustments, we estimate that urban hospitals will experience an increase in payments of approximately 3.2 percent and that rural hospitals will experience an increase in payments of 4.2 percent. Classifying hospitals by teaching status, we estimate non-teaching hospitals will experience an increase in payments of 3.9 percent, minor teaching hospitals will experience an increase in payments of 3.5 percent, and major teaching hospitals will experience an increase in payments of 2.4 percent. We also classified hospitals by the type of ownership. We estimate that hospitals with voluntary ownership will experience an increase of 3.2 percent in payments, while hospitals with government ownership will experience an increase of 2.8 percent in payments. We estimate that hospitals with proprietary ownership will experience an increase of 4.6 percent in payments.

e. Impacts of the Final ASC Payment Update

For impact purposes, the surgical procedures on the ASC covered surgical procedure list 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 2024 payment rates, compared to estimated CY 2023 payment rates, generally ranges between a decrease of 11 percent and an increase of 8 percent, depending on the service, with some exceptions. We estimate the impact of applying the final inpatient hospital market basket update to ASC payment rates will increase payments by $207 million under the ASC payment system in CY 2024. We note that an increase based on the Consumer Price Index for all urban consumers (CPI–U) update would be 2.5 percent and would increase payments by $174 million under the ASC payment system in CY 2024. This increase would have been based on a projected CPI–U update of 2.9 percent minus a multifactor productivity adjustment required by the Affordable Care Act of 0.4 percentage point.

f. Impacts of Hospital Price Transparency

The policies we are finalizing to enhance automated access to hospital MRFs and aggregation and use of MRF data are estimated to increase burden on hospitals, including a one-time mean of $2,787 per hospital, and a total national cost of $19,784,539 ($2,787 × 7,098 hospitals). The cost estimate reflects estimated costs ranging from $1,274 and $4,181 per hospital, and a total national cost ranging from $9,040,620 to $29,676,809. As discussed in detail in section XXVI of this final rule with comment period, we believe that the benefits to the public (and to hospitals themselves) outweigh the burden imposed on hospitals.

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; 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; the Further Consolidated Appropriations Act, 2020 (Pub. L. 116–94), enacted on December 20, 2019; the Coronavirus Aid, Relief, and Economic Security Act (Pub. L. 116–136), enacted on March 27, 2020; the Consolidated Appropriations Act, 2021 (Pub. L. 116–260), enacted on December 27, 2020; the Inflation Reduction Act, 2022 (Pub. L. 117–169), enacted on August 16, 2022; and Consolidated Appropriations Act (CAA), 2023 (Pub. L. 117–238), enacted December 29, 2022.

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 final rule with comment period. 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 are:

- 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, the relative payment weights, and the wage and other adjustments to take into account changes in medical practices, changes in technology, 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/payment/prospective-payment-systems/hospital-outpatient/regulations-notices.*

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 expert outside advisory panel composed of an appropriate selection of representatives of providers to annually review (and advise the Secretary concerning) 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 (the PHS 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). 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 ASC covered surgical 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 21, 2022, for a 2-year period.

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 21, 2023. Prior to each meeting, we publish a notice in the **Federal Register** to announce the meeting, 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). CMS is currently accepting nominations at: *https://mearis.cms.gov.*

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 21, 2023, meeting that the subcommittees continue. We accepted this recommendation.

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 *https://facadatabase.gov.*

F. Public Comments Received on the CY 2024 OPPS/ASC Proposed Rule

We received approximately 3,777 timely pieces of correspondence on the CY 2024 OPPS/ASC proposed rule that appeared in the **Federal Register** on July 31, 2023 (88 FR 49552 through 49921), from individuals, elected officials, providers and suppliers, practitioners, manufacturers and advocacy groups. We provide summaries of the public comments, and our responses are set forth in the various sections of this final rule with comment period under the appropriate headings. We note that we received some public comments that were outside the scope of the CY 2024 OPPS/ASC proposed rule. Out-of-scope-public comments are not addressed in this CY 2024 OPPS/ASC final rule with comment period.

G. Public Comments Received on the CY 2023 OPPS/ASC Final Rule With Comment Period

We received approximately 12 timely pieces of correspondence on the CY 2023 OPPS/ASC final rule with comment period that appeared in the **Federal Register** on November 23, 2022 (87 FR 71748).

II. Updates Affecting OPPS Payments

A. 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 Ambulatory Payment Classifications (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 2024 OPPS, we proposed to recalibrate the APC relative payment weights for services furnished on or after January 1, 2024, and before January 1, 2025 (CY 2024), using the same basic methodology that we described in the CY 2023 OPPS/ASC final rule with comment period (86 FR 63466), using CY 2022 claims data. That is, we proposed to recalibrate the relative payment weights for each APC based on claims and cost report data for hospital outpatient department (HOPD) services to construct a database for calculating APC group weights.

For the purpose of recalibrating the proposed APC relative payment weights for CY 2024, we began with approximately 180 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, 2022, and before January 1, 2023, before applying our exclusionary criteria and other methodological adjustments. After the application of those data processing changes, we used approximately 93 million final action claims to develop the proposed CY 2024 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 the CY 2024 OPPS/ASC proposed rule on the CMS website at: *https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient.*

Addendum N to the CY 2024 OPPS/ASC proposed rule (which is available via the internet on the CMS website at: *https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient/regulations-notices*) included the proposed list of bypass codes for CY 2024. The proposed list of bypass codes contains codes that are reported on claims for services in CY 2022 and, therefore, includes codes that were in effect in CY 2022 and used for billing. We retained these deleted bypass codes on the proposed CY 2024 bypass list because these codes existed in CY 2022 and were covered OPD services in that period, and CY 2022 claims data were used to calculate proposed CY 2024 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 are identified by asterisks (*) in the third column of Addendum N to the CY 2024 OPPS/ASC proposed rule. HCPCS codes that we proposed to add for CY 2024 are identified by asterisks (*) in the fourth column of Addendum N.

We did not receive any public comments on our general proposal to recalibrate the relative payment weights for each APC based on claims and cost report data for HOPD services or on our

proposed bypass code process. We are finalizing as proposed the ''pseudo'' single claims process and the final CY 2024 list of bypass codes, as displayed in Addendum N to this final rule with comment period (which is available via the internet on the CMS website). For this final rule with comment period, for the purpose of recalibrating the final APC relative payment weights for CY 2024, we used approximately 103 million final actions 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, 2022, and before January 1, 2023. 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 final rule with comment period on the CMS website at: *https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient.*

b. Calculation and Use of Cost-to-Charge Ratios (CCRs)

For CY 2024, we proposed 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 proposed CY 2024 APC payment rates are based, we calculated hospital-specific departmental CCRs for each hospital for which we had CY 2022 claims data by comparing these claims data to the most recently available hospital cost reports, which, in most cases, are from CY 2021. For the proposed CY 2024 OPPS payment rates, we used the set of claims processed during CY 2022. 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 2022 (the year of claims data we used to calculate the proposed CY 2024 OPPS payment rates) and updates to the National Uniform Billing Committee (NUBC) 2022 Data specifications Manual. That crosswalk is available for review and continuous comment on the CMS website at *https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient.*

In the CY 2023 OPPS/ASC final rule with comment period, a few commenters recommended that we revise our revenue code-to-cost center crosswalk to provide consistency with the NUBC definitions and to improve the accuracy of cost data for OPPS ratesetting with respect to chimeric antigen receptor therapy (CAR–T) administration services (87 FR 71758). In that final rule with comment period, we stated that we intend to explore the implications of this recommendation further and may consider such changes in future rulemaking. In the CY 2024 OPPS/ASC proposed rule, we explored the impacts of the commenters' recommendation from the CY 2023 OPPS/ASC final rule with comment period that we assign primary cost centers to certain CAR–T-related revenue codes that were not previously assigned cost centers. Specifically, in the CY 2024 OPPS/ASC proposed rule, we explored the commenter's recommendations regarding changes to the revenue code-to-cost center crosswalk, which included:

- Revising revenue codes 0870 (Cell/Gene Therapy General Classification) and 0871 (Cell Collection) to be mapped to a primary cost center of 9000 (Clinic);
- Revising revenue codes 0872 (Specialized Biologic Processing and Storage—Prior to Transport) and 0873 (Storage and Processing After Receipt of Cells from Manufacturer) to be mapped to a primary cost center of 3350 (Hematology);
- Revising revenue codes 0874 (Infusion of Modified Cells) and 0875 (Injection of Modified Cells) to be mapped to a primary cost center of 6400 (Intravenous Therapy); and
- Revising revenue codes 0891 (Special Processed Drugs—FDA Approved Cell Therapy) and 0892 (Special Processed Drugs—FDA Approved Gene Therapy) to be mapped to a primary cost center of 7300 (Drugs Charged to Patients).

After reviewing the impact of these crosswalk revisions on our proposed CY 2024 OPPS APC geometric mean costs, we only observed an increase in the geometric mean cost of CPT code 0540T (Chimeric antigen receptor t-cell (car-t) therapy; car-t cell administration, autologous)—from $148.31 to $294.17 for the CY 2024 OPPS/ASC proposed rule—as a result of the revenue code for CPT code 0540T being assigned to a new cost center and the new corresponding cost-to-charge ratio. We did not observe any significant impact on APC geometric mean costs or payment as a result of these revisions. We stated that we believe these revisions would provide greater consistency with the NUBC definitions (which already adopted these revenue code revisions) and more accurately account for the costs of CAR–T administration services under the OPPS. Therefore, for CY 2024 and subsequent years, we proposed to adopt the aforementioned revisions to revenue codes 0870, 0871 0872, 0873, 0874, 0875, 0891, and 0892 in our revenue code-to-cost center crosswalk.

We solicited comment on our proposed changes to the revenue code-to-cost center crosswalk for CY 2024.

In accordance with our longstanding policy, similar to our finalized policy for CY 2023 OPPS ratesetting, we proposed to calculate CCRs for the standard cost centers—cost centers with a predefined label—and nonstandard cost centers—cost centers defined by a hospital—accepted by the electronic cost report database. In general, the most detailed level at which we calculate CCRs is the hospital-specific departmental level.

While we generally view the use of additional cost data as improving our OPPS ratesetting process, we have historically not included cost report lines for certain nonstandard cost centers in the OPPS ratesetting database construction when hospitals have reported these nonstandard cost centers on cost report lines that do not correspond to the cost center number. We believe it is important to further investigate the accuracy of these cost report data before including such data in the ratesetting process. Further, we believe it is appropriate to gather additional information from the public as well before including them in OPPS ratesetting. For CY 2024, we proposed not to include the nonstandard cost centers reported in this way in the OPPS ratesetting database construction.

Comment: Two commenters supported our proposed revenue code-to-cost center crosswalk changes associated with CAR–T.

Response: We appreciate the commenters' support for our proposal.

Comment: A few commenters listed a number of concerns regarding the revenue code-to-cost center crosswalk mappings associated with revenue codes 0815 and 0819. They noted that the 2552–96 revenue code-to-cost center crosswalk does not show the cost center used for ratesetting. They also noted that the current 2552–10 revenue code-to-cost center crosswalk includes a primary cost center mapping to 112.50 and no secondary or tertiary cost centers listed.

A commenter requested more detail around the cost reporting and billing patterns related to revenue codes 0815 and cost centers 112.50 and 7700. A commenter believed that the mapping

for revenue code 0819 to cost center 8600 was incongruent with CMS instructions for cost reporting periods after 2017 to no longer include donor costs in cost center 8600. They believed that this mapping should not apply.

Commenters stated that cost center 7700 represented a logical alternative mapping for revenue code 0815 but noted that it did not represent all donor search and cell acquisition costs because those costs were only recently calculated through Worksheet D–6 of the Medicare cost report and that data would not be available for ratesetting for several years. They also suggested that CMS review the use of the hospital overall ancillary CCR until more accurate information could be obtained in both cost center 7700 and Worksheet D–6. A commenter also requested that CMS ensure that the Worksheet D–6 is available for all cost reporting periods beginning on or after October 1, 2020.

Response: As discussed in this section and briefly in the claims accounting narrative available online, the revenue code-to-cost center crosswalk is a hierarchy that attempts to apply departmental cost center CCRs to estimate costs from charges. Where no specific CCR is available, the provider's overall ancillary CCR will be applied. There may be significant differences in the cost reports used in our ratesetting process, based on providers' charging structures as well as cost reporting periods. As a result, the revenue code-to-cost center crosswalk is designed to accommodate that flexibility by selecting what we believe to be the most accurate CCRs available.

The Medicare cost report form 2552–10 was implemented for cost reporting periods on or after May 1, 2010. Providers have familiarity with cost reporting using this form. While there may be a range in the cost reporting periods available, all cost report data used in ratesetting for the CY 2024 OPPS final rule with comment period are based on the Medicare cost report form 2552–10. The 2552–96 crosswalk is largely provided for historical reference purposes and not because it is actively used in our ratesetting process. However, we can consider removing those worksheets from the form if they no longer serve a purpose for hospitals.

With regard to the primary mapping of revenue code 0815 to cost center 112.50 (Stem Cell Acquisition) indicated in the display version of the revenue code-to-cost center crosswalk, the cost center was inadvertently listed as a primary mapping. The primary and sole mapping for revenue code 0815 in our current ratesetting process is to cost center 7700 (Allogeneic Stem Cell Acquisition). In cases where that cost center CCR is not available in a provider's cost report but services are billed using revenue code 0815, the overall ancillary CCR would instead be applied to reduce charges to estimated cost. We note that there are no cost reports we are including in the CY 2024 OPPS ratesetting process that report cost and charges under 112.50, and there are no revenue code-to-cost center crosswalk mappings to that cost center.

As discussed earlier, the cost reports used in OPPS ratesetting can have varying cost reporting periods and varying cost reporting structures. Therefore, the cost center CCR mappings included in the revenue code-to-cost center crosswalk are designed to accommodate this variability. For revenue code 0815 (Allogeneic Stem Cell Acquisition Services), most of the providers billing using this revenue code are also cost reporting with cost center 7700. Within our ratesetting process, the CCRs for cost center 7700 are significantly higher than those for the overall ancillary CCR; and we continue to believe that the preference should be to use the cost center 7700 CCR unless it is not otherwise available. We note that billing using revenue code 0819 (Organ Acquisition: Other donor) is extremely limited, with only a single line observed within our data. We believe that having the flexibility to use its cost center 8600 mapping where this revenue code is billed is more reflective than the overall ancillary CCR. However, we will monitor the data to determine if this cost center CCR mapping continues to remain appropriate in the future.

While we do not have any specific changes at this time associated with the data from Worksheet D–6 of the Medicare cost report form, we will review the data as they become available. Based on that review, we will consider inclusion of that data and integration into the cost estimation process, if appropriate. We appreciate commenter input as we consider possible changes in the OPPS ratesetting process we use to estimate service costs. We also note that the cost reporting software has already been updated to allow for submission of data regarding these acquisition costs for cost reporting periods on or after October 1, 2020.

After consideration of the public comments we received, we are finalizing the proposed crosswalk, including the proposed changes associated with CAR–T. In addition, we are making the change to our display copy of the revenue code-to-cost center crosswalk to assign cost center 77 as the primary cost center CCR mapping for revenue code 0815.

2. Final Data Development and Calculation of Costs Used for Ratesetting

In this section of this final rule with comment period, we discuss the use of claims to calculate the OPPS payment rates for CY 2024. The Hospital OPPS page on the CMS website on which this final rule with comment period is posted (*https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient*) provides an accounting of claims used in the development of the final 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, *https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient,* 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 International Classification of Diseases, Tenth Revision, Clinical Modification (ICD–10–CM) diagnosis codes and revenue code payment amounts. This file is derived from the CY 2022 claims that are used to calculate the final payment rates for this final rule with comment period.

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.

We used the methodology described in sections II.A.2.a through II.A.2.c of this final rule with comment period to calculate the costs we used to establish the final relative payment weights used in calculating the OPPS payment rates for CY 2024 shown in Addenda A and B to this final rule with comment period (which are available via the internet on

the CMS website at: *https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient/regulations-notices*). We refer readers to section II.A.4 of this final rule with comment period 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 items and 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 2024 OPPS, we proposed to continue to remove claim lines with modifier ''PN'' from the ratesetting process.

For details of the claims accounting process used in final rule with comment period, we refer readers to the claims accounting narrative under supporting documentation for this final rule with comment period on the CMS website at: *https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient.*

We did not receive any public comments on our proposal and are finalizing our proposal to continue to remove claim lines reported with modifier ''PN'' from the ratesetting process.

a. Calculation of Single Procedure APC Criteria-Based Costs

(1) Blood and Blood Products

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.

In the CY 2024 OPPS/ASC proposed rule, we proposed to continue to establish payment rates for blood and blood products using our blood-specific CCR methodology (88 FR 49562), 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. To address the differences in CCRs and to better reflect hospitals' costs, our methodology simulates 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 and applies this mean ratio to the overall CCRs of hospitals not reporting costs and charges for blood cost centers on their cost reports. We proposed to calculate the costs upon which the proposed 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 takes into account the unique charging and cost accounting structure of each hospital, it 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. This methodology also yields more accurate estimated costs for these products and results in payment rates for blood and blood products that appropriately reflect the relative estimated costs of these products for hospitals without blood cost centers and for these blood products in general.

We refer readers to Addendum B to this final rule with comment period (which is available via the internet on the CMS website at *https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient/regulations-notices*) for the final CY 2024 payment rates for blood and blood products (which are generally identified with status indicator ''R'').

For a more detailed discussion of payments for blood and blood products through APCs, we refer readers to:

- the CY 2005 OPPS proposed rule (69 FR 50524 and 50525) for a more comprehensive discussion of the blood-specific CCR methodology;
- the CY 2008 OPPS/ASC final rule with comment period (72 FR 66807 through 66810) for a detailed history of the OPPS payment for blood and blood products; and
- the CY 2015 OPPS/ASC final rule with comment period (79 FR 66795 and 66796) for additional discussion of our policy not to make separate payments for blood and blood products when they appear on the same claims as services assigned to a C–APC.

Comment: Two commenters discussed our payment policies for blood and blood products. One commenter expressed concerns about lower payment rates for some blood products in CY 2024 as compared to CY 2023 and encouraged CMS to work with interested parties in the blood products and blood services community to address this issue. The other commenter expressed their support for separate payment for blood and blood products in the OPPS for most services.

Response: We appreciate the input from the commenters, and we will keep these issues in mind in future rulemaking.

After consideration of the public comments we received, we are adopting as final our proposals for blood and blood products using our blood-specific CCR methodology without modification. Refer to Addendum B to this final rule with comment period (which is available via the internet on the CMS website) for the final CY 2024 payment rates for blood and blood products.

(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—cancer treatment through solid source radioactive implants—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 and 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 2024, except where otherwise indicated, we proposed to use the costs derived from CY 2022 claims data to set the proposed CY 2024 payment rates for brachytherapy sources because CY 2022 is the year of data we proposed to use to set the proposed payment rates for most other items and services that would be paid under the CY 2024 OPPS. We proposed this methodology for CY 2024 and subsequent years. With the exception of the proposed payment rate for brachytherapy source C2645 (Brachytherapy planar source, palladium-103, per square millimeter) and the proposed payment rates for low-volume brachytherapy APCs discussed in section III.D of the CY 2024 OPPS/ASC proposed rule (88 FR 49563), we proposed to base the payment rates for brachytherapy sources on the geometric mean unit costs for each source, consistent with the methodology that we proposed for other items and services paid under the OPPS, as discussed in section II.A.2 of the CY 2024 OPPS/ASC proposed rule (88 FR 49563). We also proposed for CY 2024 and subsequent years 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). For CY 2024 and subsequent years, we proposed 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, per mCi), which is based on the policy we established in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66785). For CY 2024 and subsequent years, we also proposed 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 2024 payment rates for brachytherapy sources are included on Addendum B to the CY 2024 OPPS/ASC 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 the brachytherapy source's APC—APC 2648 (Brachytx planar, p-103). 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 for APC 2648 (Brachytx planar, p-103). Our CY 2018 claims data available for the CY 2020 OPPS/ASC final rule with comment period (84 FR 61142) included two claims with a geometric mean cost for HCPCS code C2645 of $1.02 per mm^2. In response to comments from interested parties, we agreed 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. Similarly, in the absence of sufficient claims data to establish an APC payment rate, in the CY 2021, CY 2022, and CY 2023 OPPS/ASC final rules with comment period (85 FR 85879 and 85880 and 86 FR 63469 and 87 FR 71760 and 71761), we finalized our policy to use our equitable adjustment authority under section 1833(t)(2)(E) of the Act to maintain the CY 2019 payment rate of $4.69 per mm^2 for HCPCS code C2645 for CY 2021, for CY 2022, and for CY 2023.

We reviewed CY 2022 claims data available for the CY 2024 OPPS/ASC proposed rule, and we observed three claims that reported HCPCS code C2645. Each claim reported one unit of HCPCS code C2645 and the geometric mean unit cost from these three claims was $168.67. We stated we were unable to use these claims for ratesetting purposes given the reporting of only one unit per claim and the high geometric mean cost. Therefore, we proposed to use our equitable adjustment authority under section 1833(t)(2)(E) of the Act to maintain the CY 2023 payment rate of $4.69 per mm^2 for HCPCS code C2645, which we proposed to assign to APC 2648 (Brachytx planar, p-103), for CY 2024.

For this final rule with comment period, we once again reviewed CY 2022 claims data available; and we observed the same three claims that reported HCPCS code C2645.

Additionally, for CY 2022 and subsequent calendar years, we adopted a Universal Low Volume APC policy for clinical and brachytherapy APCs. As discussed in further detail in section X.C of the CY 2022 OPPS/ASC final rule with comment period (86 FR 63743 through 63747), we adopted this policy to mitigate wide variation in payment rates that occur from year to year for APCs with low utilization. Such volatility in payment rates from year to year can result in even lower utilization and potential barriers to access. Brachytherapy APCs that have fewer than 100 single claims used for ratesetting purposes are designated as Low Volume APCs unless an alternative payment rate is applied, such as the use of our equitable adjustment authority under section 1833(t)(2)(E) of the Act in the case of APC 2648 (Brachytx planar, p-103), for which HCPCS code C2645 (Brachytherapy planar source, palladium-103, per square millimeter) is the only code assigned as discussed previously in this section.

For CY 2024, we proposed to designate five brachytherapy APCs as Low Volume APCs as these APCs meet

our criteria to be designated as a Low Volume APC. For more information on the brachytherapy APCs we proposed to designate as Low Volume APCs, see section III.D of the CY 2024 OPPS/ASC proposed rule (88 FR 49628) and section III.D of this final rule with comment period.

We invited interested parties to submit recommendations for new codes to describe new brachytherapy sources. We will continue to add new brachytherapy source codes and descriptors to our systems for payment on a quarterly basis.

We did not receive any public comments on either proposal described. We are finalizing, without modification, to use our equitable adjustment authority under section 1833(t)(2)(E) of the Act to maintain the CY 2023 payment rate of $4.69 per mm^2 for HCPCS code C2645, which is assigned to APC 2648 (Brachytx planar, p-103), for CY 2024.

Similarly, for CY 2024 and subsequent years we are finalizing, without modification, our proposal to continue to set the payment rates for other brachytherapy sources that are not otherwise assigned to designated Low Volume APCs for CY 2024 using our established prospective payment methodology. The final CY 2024 payment rates for brachytherapy sources are included in Addendum B to this final rule with comment period (which is available via the internet on the CMS website) and are identified with status indicator ''U.'' We continue to invite interested parties to submit recommendations for new codes to describe new brachytherapy sources. Such recommendations should be directed via email to *outpatientpps@cms.hhs.gov* or by mail to the Division of Outpatient Care, Mail Stop C4–01–26, Centers for Medicare and 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 2024

(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 and 66810). We have gradually added new C–APCs since the policy was implemented beginning in CY 2015, with the number of C–APCs now totaling 72 (80 FR 70332; 81 FR 79584 and 79585; 83 FR 58844 through 58846; 84 FR 61158 through 61166; 85 FR 85885; 86 FR 63474; and 87 FR 71769).

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. One example of a primary service would be a partial mastectomy and an example of a secondary service packaged into that primary service would be a radiation therapy procedure.

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 and 66801). A list of services excluded from the C–APC policy is included in Addendum J to this final rule with comment period (which is available via the internet on the CMS website at *https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient/regulations-notices*). If a service does not appear on this list of excluded services, payment for it will be packaged into the payment for the primary C–APC service when it appears on an outpatient claim with a primary C–APC service.

The C–APC policy payment methodology set forth in the CY 2014 OPPS/ASC final rule with comment period 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,'' [1] 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.'' [2] Specifically, we make a payment through C–APC 8011 for a claim that:

[1] Status indicator ''J1'' denotes Hospital Part B Services Paid Through a Comprehensive APC. Further information can be found in CY 2024 Addendum D1.

[2] Status indicator ''J2'' denotes Hospital Part B Services That May Be Paid Through a Comprehensive APC. Further information can be found in CY 2024 Addendum D1.

• 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 one 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 set 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, such as speech language pathology, 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, 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.[3]

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 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

[3] *https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/bp102c15.pdf.*

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 final rule with comment period, 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 2024, we 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 2024, along with all the other final complexity adjustments, in Addendum J to this final rule with comment period (which is available via the internet on the CMS website at *https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient/regulations-notices*).

Addendum J to this final rule with comment period 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 final rule with comment period 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 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 four digits of the designated primary service followed by a letter. For example, the final 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 will be reassigned to C–APC 5224 when CPT code 33208 is the primary code. Providing the information contained in Addendum J to this final rule with comment period allows interested parties the opportunity to better assess the impact associated with the assignment of claims with each of the paired code combinations eligible for a complexity adjustment.

Comment: We received support from commenters for a variety of existing and proposed complexity adjustments.

Response: We thank the commenters for their support.

Comment: Multiple commenters requested that CMS apply a complexity adjustment to additional code combinations. The specific C–APC complexity adjustment code combinations requested by the commenters for CY 2024 are listed in Table 1 below.

BILLING CODE 4150–28–P

TABLE 1: C-APC COMPLEXITY ADJUSTMENTS REQUESTED BY COMMENTERS FOR CY 2024

Primary "J1" HCPCS/CPT Code	Secondary "J1" HCPCS/CPT code	Primary C-APC Assignment	Requested complexity adjusted C-APC assignment
28297 (Correction, hallux valgus (bunionectomy), with sesamoidectomy, when performed; with first metatarsal and medial cuneiform joint arthrodesis, any method)	**27687** (Gastrocnemius recession (e.g., strayer procedure))	5114	5115
28740 (Arthrodesis, midtarsal or tarsometatarsal, single joint)	**27687** (Gastrocnemius recession (e.g., strayer procedure))	5114	5115
	27691 (Transfer or transplant of single tendon (with muscle redirection or rerouting); deep (e.g., anterior tibial or posterior tibial through interosseous space, flexor digitorum longus, flexor hallucis longus, or peroneal tendon to midfoot or hindfoot))	5114	5115
	28740 (Arthrodesis, midtarsal or tarsometatarsal, single joint)	5114	5115
43270 (Esophagogastroduodenoscopy, flexible, transoral; with ablation of tumor(s), polyp(s), or other lesion(s) (includes pre- and post-dilation and guide wire passage, when performed)	**43252** (Esophagogastroduodenoscopy, flexible, transoral; with optical endomicroscopy)	5302	5303
43252 (Esophagogastroduodenoscopy, flexible, transoral; with optical endomicroscopy)	**43239** (Esophagogastroduodenoscopy, flexible, transoral; with biopsy, single or multiple)	5302	5303
	43270 ((Esophagogastroduodenoscopy, flexible, transoral; with ablation of tumor(s), polyp(s), or other lesion(s) (includes pre- and post-dilation and guide wire passage, when performed))	5302	5303

C9600 (Percutaneous transcatheter placement of drug eluting intracoronary stent(s), with coronary angioplasty when performed; single major coronary artery or branch)	**C1761** (Catheter, transluminal intravascular lithotripsy, coronary)	5193	5194
92928 (Percutaneous transcatheter placement of intracoronary stent(s), with coronary angioplasty when performed; single major coronary artery or branch)		5193	5194
92943 (Percutaneous transluminal revascularization of chronic total occlusion, coronary artery, coronary artery branch, or coronary artery bypass graft, any combination of intracoronary stent, atherectomy and angioplasty; single vessel)		5193	5194
92920 (Percutaneous transluminal coronary angioplasty; single major coronary artery or branch)		5192	5193
31629 (Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with transbronchial needle aspiration biopsy(s), trachea, main stem and/or lobar bronchus(i))	**31652** (Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with endobronchial ultrasound (ebus) guided transtracheal and/or transbronchial sampling (e.g., aspiration[s]/biopsy[ies]), one or two mediastinal and/or hilar lymph node stations or structure)	5154	5155
43260 (Endoscopic retrograde cholangiopancreatography (ercp); diagnostic, including collection of specimen(s) by brushing or washing, when performed (separate procedure))	**43273** (Endoscopic cannulation of papilla with direct visualization of pancreatic/common bile duct(s) (list separately in addition to code(s) for primary procedure))	5303	5304
43261 (Endoscopic retrograde cholangiopancreatography (ercp); with biopsy, single or multiple)		5303	5304
43262 (Endoscopic retrograde cholangiopancreatography (ercp); with sphincterotomy/papillotomy)		5303	5304
43264 (Endoscopic retrograde cholangiopancreatography (ercp); with removal of calculi/debris from biliary/pancreatic duct(s))		5303	5304
47534 (Placement of biliary drainage catheter, percutaneous,	**47542** (Balloon dilation of biliary duct(s) or of ampulla	5341	5342

including diagnostic cholangiography when performed, imaging guidance (eg, ultrasound and/or fluoroscopy), and all associated radiological supervision and interpretation; internal-external)	(sphincteroplasty), percutaneous, including imaging guidance (e.g., fluoroscopy), and all associated radiological supervision and interpretation, each duct (list separately in addition to code for primary procedure))		
20982 (Ablation therapy for reduction or eradication of 1 or more bone tumors (e.g., metastasis) including adjacent soft tissue when involved by tumor extension, percutaneous, including imaging guidance when performed; radiofrequency)	**22510** (Percutaneous vertebroplasty (bone biopsy included when performed), 1 vertebral body, unilateral or bilateral injection, inclusive of all imaging guidance; cervicothoracic)	5114	5115
20982 ((Ablation therapy for reduction or eradication of 1 or more bone tumors (e.g., metastasis) including adjacent soft tissue when involved by tumor extension, percutaneous, including imaging guidance when performed; radiofrequency))	**22511** (Percutaneous vertebroplasty (bone biopsy included when performed), 1 vertebral body, unilateral or bilateral injection, inclusive of all imaging guidance; lumbosacral)	5114	5115
29827 (Arthroscopy, shoulder, surgical; with rotator cuff repair)	**C1763** (Connective tissue, non-human (includes synthetic))	5114	5115
52214 (Cystourethroscopy, with fulguration (including cryosurgery or laser surgery) of trigone, bladder neck, prostatic fossa, urethra, or periurethral glands)	**C9738** (Adjunctive blue light cystoscopy with fluorescent imaging agent (list separately in addition to code for primary procedure))	5374	5375
52224 (Cystourethroscopy, with fulguration (including cryosurgery or laser surgery) or treatment of minor (less than 0.5 cm) lesion(s) with or without biopsy)		5374	5375
52234 (Cystourethroscopy, with fulguration (including cryosurgery or laser surgery) and/or resection of; small bladder tumor(s) (0.5 up to 2.0 cm))		5374	5375
52235 (Cystourethroscopy, with fulguration (including cryosurgery or laser surgery) and/or resection		5374	5375

of; medium bladder tumor(s) (2.0 to 5.0 cm))			
52240 (Cystourethroscopy, with fulguration (including cryosurgery or laser surgery) and/or resection of; large bladder tumor(s))		5375	5376

BILLING CODE 4150–28–C

Response: We reviewed each of the requested code combinations suggested by commenters, listed in Table 1, against our complexity adjustment criteria. The code combination for primary HCPCS code 43270 with secondary HCPCS code 43252 meets our cost and frequency criteria, qualifying for a complexity adjustment for CY 2024. All the remaining code combinations listed failed to meet our cost or frequency criteria and do not qualify for complexity adjustments for CY 2024. Additionally, the code combinations for primary HCPCS codes, C9600, 92928, 92943, and 92920 with secondary HCPCS code C1761 would not qualify for complexity adjustments for CY 2024 as the Coronary IVL device, described by C1761, is still on transitional pass-through status through June 2024. Addendum J to this final rule with comment period includes the cost statistics for each code combination that was evaluated for a complexity adjustment.

Comment: Commenters requested that CMS modify, waive, or eliminate the established C–APC complexity adjustment eligibility criteria of 25 or more claims reporting the code combination (frequency) and a violation of the 2 times rule in the originating C–APC (cost) to allow additional code combinations to qualify for complexity adjustments. These commenters were concerned that C–APC packaging and a lack of complexity adjustment would limit access to procedures. Specifically, some commenters expressed concern that CMS's methodology for determining complexity adjustments is unnecessarily restrictive, particularly the 25-claim threshold, and suggested that CMS eliminate the 25-claim threshold and implement a complexity adjustment whenever a code pair exceeds the cost threshold. Other commenter suggestions included considering an amount halfway between the standard APC and the complexity-adjusted APC as a cost threshold, as well as a implementing a sliding scale approach for procedures with high frequency that do not meet the cost criteria.

Commenters were concerned that when multiple ''J1'' primary services are reported on a claim, along with an add-on service, the add-on service is not evaluated for a complexity adjustment. Commenters cited examples where significant claims volume from add-on services may not be incorporated into the complexity adjustment evaluation. Commenters also reiterated requests to broaden the complexity adjustment policy and allow clusters of procedures, consisting of a ''J1'' code pair and multiple other associated add-on codes used in combination with that ''J1'' code pair, to qualify for complexity adjustments. Commenters stated that there are certain complex procedures that include numerous add-on codes and this approach would allow more accurate reflection of medical practice when multiple procedures are performed together. They noted that lack of additional payment for these code combinations can present a financial challenge for the providers who perform these more resource intensive services.

In addition, commenters requested that CMS expand its review of procedure combinations to include ''J1'' and expiring transitional pass-through codes to allow facilities to continue to provide these services after pass-through expiration.

Response: We appreciate these comments. At this time, we do not believe changes to the C–APC complexity adjustment criteria are necessary or that we should make exceptions to the criteria to allow claims with the code combinations suggested by the commenters to receive complexity adjustments. As we stated in the CY 2017 OPPS/ASC final rule (81 FR 79582), we believe that the complexity adjustment criteria, which require a frequency of 25 or more claims reporting a code combination and a violation of the 2 times rule in the originating C–APC, are appropriate to determine if a combination of procedures represents a complex, costly subset of the primary service that should qualify for the adjustment and be paid at the next higher paying C–APC in the clinical family. As we previously stated in the CY 2020 OPPS/ASC final rule with comment period (84 FR 61161), a minimum of 25 claims is already a very low threshold for a national payment system. Lowering the minimum of 25 claims further could lead to unnecessary complexity adjustments for service combinations that are rarely performed.

As we explained in the CY 2019 OPPS/ASC final rule with comment period (83 FR 58843), we do not believe that it is necessary to adjust the complexity adjustment criteria to allow claims that include more than two ''J1'' procedures, add-on codes, or procedures that are not assigned to C–APCs to qualify for a complexity adjustment. As previously mentioned, we believe the current criteria are adequate to determine if a combination of procedures represents a complex, costly subset of the primary service. We will continue to monitor the application of the complexity adjustment criteria for future rulemaking.

After consideration of the public comments we received, we are finalizing the C–APC complexity adjustment policy for CY 2024 as proposed. We are also finalizing the proposed complexity adjustments, with the addition of one new code combination suggested by commenters, that meet our complexity adjustment criteria.

(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 them. 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 are 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 beginning in CY 2020, payment for services assigned to a New Technology APC 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 (84 FR 61167).

(3) Exclusion of Drugs and Biologicals Described by HCPCS Code C9399 (Unclassified Drugs or Biologicals) From the C–APC Policy

Section 1833(t)(15) of the Act, as added by section 621(a)(1) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Pub. L. 108–173), provides for payment under the OPPS for new drugs and biologicals until HCPCS codes are assigned. Under this provision, we are required to make payment for a covered outpatient drug or biological that is furnished as part of covered outpatient department services but for which a HCPCS code has not yet been assigned in an amount equal to 95 percent of average wholesale price (AWP) for the drug or biological.

In the CY 2005 OPPS/ASC final rule with comment period (69 FR 65805), we implemented section 1833(t)(15) of the Act by instructing hospitals to bill for a drug or biological that is newly approved by the Food and Drug Administration (FDA) and that does not yet have a HCPCS code by reporting the National Drug Code (NDC) for the product along with the newly created HCPCS code C9399 (Unclassified drugs or biologicals). We explained that when HCPCS code C9399 appears on a claim, the Outpatient Code Editor (OCE) suspends the claim for manual pricing by the Medicare Administrative Contractor (MAC). The MAC prices the claim at 95 percent of the drug or biological's AWP, using Red Book or an equivalent recognized compendium, and processes the claim for payment. We emphasized that this approach enables hospitals to bill and receive payment for a new drug or biological concurrent with its approval by the FDA. The hospital does not have to wait for the next quarterly release or for approval of a product specific HCPCS code to receive payment for a newly approved drug or biological or to resubmit claims for adjustment. We instructed that hospitals would discontinue billing HCPCS code C9399 and the NDC upon implementation of a product specific HCPCS code, status indicator, and appropriate payment amount with the next quarterly update. We also note that HCPCS code C9399 is paid in a similar manner in the ASC setting, as 42 CFR 416.171(b) outlines that certain drugs and biologicals for which separate payment is allowed under the OPPS are considered covered ancillary services for which the OPPS payment rate, which is 95 percent of AWP for HCPCS code C9399, applies. Since the implementation of the C–APC policy in 2015, payment for drugs and biologicals described by HCPCS code C9399 had been included in the C–APC payment when these products appear on a claim with a primary C–APC service. Packaging payment for these drugs and biologicals that appear on a hospital outpatient claim with a primary C–APC service is consistent with our C–APC packaging policy under which we make payment for all items and services, including all non-pass-through drugs, reported on the hospital outpatient claim as being integral, ancillary, supportive, dependent, and adjunctive to the primary service and representing components of a complete comprehensive service, with certain limited exceptions (78 FR 74869). It was our position that the total payment for the C–APC with which payment for a drug or biological described by HCPCS code C9399 is packaged includes payment for the drug or biological at 95 percent of its AWP.

However, we determined that in certain instances, drugs and biologicals described by HCPCS code C9399 are not being paid at 95 percent of their AWPs when payment for them is packaged with payment for a primary C–APC service. In order to ensure payment for new drugs, biologicals, and radiopharmaceuticals described by HCPCS code C9399 at 95 percent of their AWP, for CY 2023 and subsequent years, we finalized our proposal to exclude any drug, biological, or radiopharmaceutical described by HCPCS code C9399 from packaging when the drug, biological, or radiopharmaceutical is included on a claim with a ''J1'' service, which is the status indicator assigned to a C–APC, and a claim with a ''J2'' service, which is the status indicator assigned to comprehensive observation services. See Addendum J for the CY 2024 C–APC payment policy exclusions.

In the CY 2023 OPPS/ASC final rule with comment period, we finalized the proposal in section XI. ''CY 2023 OPPS Payment Status and Comment Indicators'' of the CY 2024 OPPS/ASC proposed rule to add a new definition to status indicator ''A'' to include unclassified drugs and biologicals that are reportable with HCPCS code C9399 (87 FR 72051). The definition, found in Addendum D1, would ensure the MAC prices claims for drugs, biologicals, or radiopharmaceuticals billed with HCPCS code C9399 at 95 percent of the drug or biological's AWP and pays separately for the drug, biological, or radiopharmaceutical under the OPPS when it appears on the same claim as a primary C–APC service.

(4) Additional C–APCs for CY 2024

For CY 2024 and subsequent years, we proposed 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 did not propose to convert any standard APCs to C–APCs in CY 2024, but we did propose to create two new APCs that will both be C–APCs. Thus, we

proposed that the number of C–APCs for CY 2024 would be 72 C–APCs.

We proposed to split the Level 2 Intraocular APC (APC 5492) into two and assign the higher cost procedures previously within this APC to a new Level 3 Intraocular APC (APC 5493). The previous Level 3, Level 4, and Level 5 Intraocular APCs (APCs 5493, 5494, and 5495) would be renamed the Level 4, Level 5, and Level 6 Intraocular APC (APCs 5494, 5495, and 5496), respectively. We refer readers to section III.E of the CY 2024 OPPS/ASC proposed rule (88 FR 49552) for more information regarding the proposal.

We also proposed to add a new Level 2 Abdominal/Peritoneal/Biliary and Related Procedures APC (APC 5342) to improve clinical and resource homogeneity in the Level 1 Abdominal/Peritoneal/Biliary and Related Procedures APC (APC 5341).

Comment: Commenters supported the creation of the two new proposed C–APCs, C–APCs 5342 (Level 2 Abdominal/Peritoneal/Biliary and Related Procedures APC) and 5496 (Level 6 Intraocular APC) for CY 2024, based on resource cost and clinical characteristics.

Response: We appreciate commenters' support.

Comment: Several commenters expressed concerns with the C–APC methodology for surgical insertion codes for brachytherapy treatment, noting that these concerns impact beneficiary access to brachytherapy in the HOPD setting. These commenters stated that the C–APC methodology lacks the appropriate charge capture mechanisms to accurately reflect the services associated with the C–APC, that there are significant variations in the clinical practice and billing patterns in the hospital claims data used for ratesetting, and that the C–APC rates do not accurately or fully reflect the services and costs associated with the primary procedure. Commenters urged the agency to explore alternatives, including that CMS discontinue the C–APC policy for all brachytherapy insertion codes, implementing a modified C–APC methodology to allow separate payment for specified preparation and planning codes, or moving brachytherapy for cervical cancer treatment to C–APC 5416 (Level 6 Gynecologic Procedures).

Response: We appreciate the comments on the C–APC methodology. However, we believe that the current C–APC methodology is appropriately applied to these surgical procedures and is accurately capturing costs, particularly as the brachytherapy sources used for these procedures are excluded from C–APC packaging and are separately payable. This methodology also enables hospitals to manage their resources with maximum flexibility by monitoring and adjusting the volume and efficiency of services themselves.

We reviewed the request by commenters to move brachytherapy procedures, CPT code 57155 and CPT code 58346, to a higher paying C–APC. For CPT code 57155, the claims data in the two times rule evaluation show that this code is being paid at the appropriate level in C–APC 5415 (Level 5 Gynecologic Procedures). For CPT code 53846, given that this code has fewer than 100 claims, it does not meet the significance threshold for the two times rule evaluation, and we do not believe the few claims available provide an accurate reflection of the service's cost sufficient to move this procedure to a higher C–APC. We will continue to examine these concerns and will determine if any modifications to this policy are warranted in future rulemaking.

Comment: Several commenters requested that CMS unpackage and pay separately for all status indicator ''K'' drugs from C–APCs due to certain instances of high-cost drugs and biologics, such as CAR–T, being paid through C–APC 8011 and potentially impacting beneficiary access to high-cost therapies.

Response: We thank the commenters for their comments. We will take the issue of C–APCs and payments for high-cost drugs into consideration for future rulemaking.

After consideration of the public comments we received, we are finalizing as proposed C–APCs 5342 (Level 2 Abdominal/Peritoneal/Biliary and Related Procedures APC) and 5496 (Level 6 Intraocular APC) for CY 2024. Table 2 lists the final C–APCs for CY 2024. All C–APCs are displayed in Addendum J to this CY 2024 OPPS/ASC final rule with comment period (which is available via the internet on the CMS website). Addendum J to this final rule with comment period also contains all the data related to the C–APC payment policy methodology, including the list of complexity adjustments and other information for CY 2024.

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TABLE 2: FINAL CY 2024 C-APCs

C-APC	CY 2024 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	

C-APC	CY 2024 APC Group Title	Clinical Family	New C-APC
5313	Level 3 Lower GI Procedures	GIXXX	
5331	Complex GI Procedures	GIXXX	
5341	Level 1 Abdominal/Peritoneal/Biliary and Related Procedures	GIXXX	
5342	Level 2 Abdominal/Peritoneal/Biliary and Related Procedures	GIXXX	*
5361	Level 1 Laparoscopy and Related Services	LAPXX	
5362	Level 2 Laparoscopy and Related Services	LAPXX	
5372	Level 2 Urology and Related Services	UROXX	
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	
5496	Level 6 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. 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 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, 59242, and 59246 through 52950) for more recent background.

(1) Mental Health Services Composite APC

For CY 2024, we proposed 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 (88 FR 49572). 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 2018 OPPS/ASC proposed rule and final rule with comment period (82 FR 33580, 33581, 59246, and 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 Integrated OCE (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 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.

We proposed 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 per diem payment rate for 3 partial hospitalization services provided in a

day by a hospital, those specified mental health services would be paid through composite APC 8010 for CY 2024. In addition, we proposed to set the payment rate for composite APC 8010 at the same payment rate that we proposed for APC 5863, which is a partial hospitalization per diem payment rate for 3 partial hospitalization services furnished in a day by a hospital, and that the hospital continue to be paid the proposed payment rate for composite APC 8010. We explained that while APC 5863 is no longer the maximum partial hospitalization per diem payment rate for a hospital, due to proposed APC 5864, which is 4 or more hospital-based PHP services per day, discussed in section VIII.B of this CY 2024 OPPS/ASC proposed rule, we believed it was still appropriate to apply the APC 5863 per diem payment amount as the upper limit on payment per day for individual OPPS mental health services. This is because the daily mental health cap would not be expected to reach a level of intensity beyond 3 services per day, as described by APC 5863. The PHP is meant to be the most intensive mental health services program, requiring inpatient care if PHP is not received. We would not anticipate more than three services per patient on a given day, as patients needing additional services in 1 day would potentially require an inpatient admission, as described by APC 5863. Thus, setting the mental health cap at APC 5863, rather than the 4 service per day APC 5864, is more consistent with our longstanding policy, which has been for the 3 service per day APC. We note that the proposed CY 2024 payment amount for APC 5863 would be comparable to the CY 2023 payment amount for APC 5863, which is the PHP APC used to set the daily mental health cap for CY 2023.

However, as we have historically set the daily mental health cap for composite APC 8010 at the maximum partial hospitalization per diem payment rate for a hospital, we also solicited comment on whether the next higher-level APC, proposed APC 5864, which is for four hospital-based PHP services per day, would be appropriate to use as the daily mental health cap.

Comment: One commenter supported CMS's alternative proposal to use APC 5864 as the basis for setting the daily mental health cap for APC 8010. They stated that as CMS is introducing APC 5864 to capture four or more hospital-based PHP services per day, as opposed to three services in APC 5863, the mental health cap should be increased to match this new code.

Response: We thank the commenter for their comment. Although setting the daily mental health cap at APC 5863 would be comparable to the CY 2023 payment for APC 5863, we recognize that raising the cap allows hospitals increased flexibility to determine the level of care necessary for their patient. Additionally, setting the mental health cap at APC 5864 aligns with 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. Based upon the comment we received as well as the fact that we have historically set the daily mental health cap for composite APC 8010 at the maximum partial hospitalization per diem payment rate for a hospital, we are finalizing APC 5864, which is for four hospital-based PHP services per day, as the daily mental health cap.

Comment: Several commenters recommended that CMS change the status indicator for two neuropsychological testing codes (HCPCS codes 96133 and 96137) from SI = N to SI = Q3 to allow separate payment for additional hours of testing on the same date or increase the payment rate for the primary testing procedure code. The commenters noted that the payment rate for Composite APC 8010, which is capped at the maximum per diem partial hospitalization rate, is lower than the individual HCPCS code APC payment rates and does not provide sufficient payment for these procedures.

Response: After reviewing this issue, we believe the Composite APC methodology is being appropriately applied in this case, as packaging multiple testing services performed on a single date of service creates incentives for hospitals to provide these services in the most cost-efficient manner. We will continue to examine these concerns and will determine if any modifications to this policy are warranted in future rulemaking.

After consideration of the public comments we received, we are finalizing our proposal, without modification, 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 2024. In addition, we are finalizing setting the payment rate for composite APC 8010 for CY 2024 at the same payment rate that we set for APC 5864, which is the maximum partial hospitalization per diem payment rate for a hospital.

(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 3 below.

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 2024, we proposed 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.

For CY 2024, except where otherwise indicated, we proposed to use the costs derived from CY 2022 claims data to set the proposed CY 2024 payment rates. Therefore, for CY 2024, the 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 2022 claims available for the CY 2024 OPPS/ASC proposed rule that qualify 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 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), were identified by asterisks in Addendum N to the CY 2024 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 the CY 2024 OPPS/ASC proposed rule (88 FR 49561).

For this CY 2024 OPPS/ASC final rule, we were able to identify approximately 0.99 million ''single session'' claims out of an estimated 2.2 million potential claims for payment through composite APCs from our ratesetting claims data, which represents approximately 45.0 percent of all eligible claims, to calculate the final CY 2024 geometric mean costs for the multiple imaging composite APCs. Table 2 of this CY 2024 OPPS/ASC final rule lists the final HCPCS codes that would be subject to the multiple imaging composite APC policy and their respective families and approximate composite APC final geometric mean costs for CY 2024.

We did not receive any public comments on this policy. We are finalizing our proposal to continue the use of multiple imaging composite APCs to pay for services providing more than one imaging procedure from the same family on the same date without modification. Table 3 below lists the HCPCS codes that will be subject to the multiple imaging composite APC policy and their respective families and approximate composite APC final geometric mean costs for CY 2024.

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TABLE 3: OPPS IMAGING FAMILIES AND MULTIPLE IMAGING PROCEDURE COMPOSITE APCS

Family 1 – Ultrasound	
CY 2024 APC 8004 (Ultrasound Composite)	**CY 2024 Approximate APC Geometric Mean Cost = $314.27**
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 2024 APC 8005 (CT and CTA without Contrast Composite) *	**CY 2024 Approximate APC Geometric Mean Cost = $231.39**
0633T	Ct breast w/3d uni c-
0636T	Ct breast w/3d bi c-
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 2024 APC 8006 (CT and CTA with Contrast Composite)	CY 2024 Approximate APC Geometric Mean Cost = $439.51
0634T	Ct breast w/3d uni c+
0635T	Ct breast w/3d uni c-/c+
0637T	Ct breast w/3d bi c+
0638T	Ct breast w/3d bi c-/c+
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 2024 APC 8007 (MRI and MRA without Contrast Composite) *	**CY 2024 Approximate APC Geometric Mean Cost = $537.26**
0609T	Mrs disc pain acquisj data
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 2024 APC 8008 (MRI and MRA with Contrast Composite)	**CY 2024 Approximate APC Geometric Mean Cost = $854.60**
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. 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. 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.

b. Policy and Comment Solicitation on Packaged Items and Services

For CY 2024, 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 hospital outpatient department 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.

For CY 2024, we did not propose any changes to the overall packaging policy discussed above. We proposed to 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.

While we did not propose any changes to the overall packaging policy, we solicited comments on potential modifications to our packaging policy as described in the following sections.

Comment: Several commenters expressed concerns that packaging policies may create access barriers and incentives for stinting on care. They urged CMS to do a comprehensive evaluation and study all OPPS packaging policies to determine whether they reduce patients' access to appropriate therapies and quality of care. They also requested CMS provide continued opportunity for interested parties to weigh in to help advance patient access to new innovations.

One commenter suggested that packaging can only create the types of efficiency incentives CMS intends when there are certain principles in place, recommending CMS only package items/services that truly have substitutes, take cost and volume into consideration when determining whether to package an item/service, and package the charges for packaged items and/or services in a more logical and deliberate manner. Another commenter clarified that potential access issues cannot always be identified by a decline in volume of packaged services; access issues also occur when patients do not receive the most clinically appropriate drug, biological, or service because of how packaging policies prioritize minimizing costs. Commenters felt that these issues are increasingly important as health care moves toward more personalized medicine and new innovations.

Commenters stated that, when CMS defines a packaging threshold, manufacturers may select a price to ensure that the costs exceed the packaging threshold to market the fact that separate CMS payment is available. Commenter felt this conflicted with CMS' goal to provide hospitals with incentives to choose the most clinically viable and cost-effective option for their patients.

Response: We appreciate the comments on this issue, and we will take these suggestions into consideration for future rulemaking.

After consideration of the public comments we received, we are finalizing our overall OPPS packing policy, as proposed, for CY 2024.

c. Comment Solicitation on Access to Non-Opioid Treatments for Pain Relief

The Consolidated Appropriations Act (CAA), 2023 (Pub. L. 117–328), was signed into law on December 29, 2022. Section 4135(a) and (b) of the CAA, 2023, titled ''Access to Non-Opioid Treatments for Pain Relief,'' amended sections 1833(t)(16) and 1833(i) of the Act, respectively, to provide for temporary additional payments for non-opioid treatments for pain relief (as that term is defined in section 1833(t)(16)(G)(i) of the Act). In particular, section 1833(t)(16)(G) of the Act provides that with respect to a non-opioid treatment for pain relief furnished on or after January 1, 2025, and before January 1, 2028, the Secretary shall not package payment for the non-opioid treatment for pain relief into payment for a covered OPD service (or group of services) and shall make an additional payment for the non-opioid treatment for pain relief as specified in clause (ii) of that section. Clauses (ii) and (iii) of section 1833(t)(16)(G) of the Act provide for the amount of additional payment and set a limitation on that amount, respectively. Because the additional payments are required to begin on January 1, 2025, we previously stated that we will include our proposals to implement the CAA, 2023, section 4135 amendments in the CY 2025 OPPS/ASC proposed rule. We discussed section 4135 of CAA, 2023, at length in section XIII.F of the CY 2024 OPPS/ASC proposed rule (88 FR 49767), and we solicited comment on numerous aspects of this future policy. While we expect this policy to operate similarly in the ASC and HOPD settings, we welcomed comment on whether there are any HOPD-specific payment issues we should take into consideration as we plan to implement section 1833(t)(16)(G) of the Act for CY 2025.

We thank commenters for their detailed comments regarding the implementation of section 4135 of the CAA, 2023. We received a range of comments regarding potential qualifying drugs, biologicals, devices, and services, as well as evidence requirements for medical devices, payment amounts, and payment limitations. See section XIII.F of this final rule with comment period for a brief summary of the comments received. We intend to take these comments into consideration as we develop our proposals for the CY 2025 OPPS/ASC proposed rule.

d. Comment Solicitation on OPPS Packaging Policy for Diagnostic Radiopharmaceuticals

(i) Background on OPPS Packaging Policy for Diagnostic Radiopharmaceuticals

Under the OPPS, we package several categories of nonpass-through drugs, biologicals, and radiopharmaceuticals, regardless of the cost of the products. As the products are packaged according to

the policies in § 419.2(b), we refer to these packaged drugs, biologicals, and radiopharmaceuticals as ''policy-packaged'' drugs, biologicals, and radiopharmaceuticals. In particular, under § 419.2(b)(15), payment for drugs, biologicals, and radiopharmaceuticals that function as supplies when used in a diagnostic test or procedure is packaged with the payment for the related procedure or service. Packaging costs into a single aggregate payment for a service, encounter, or episode of care is a fundamental principle that distinguishes a prospective payment system from a fee schedule. In general, packaging the costs of supportive items and services into the payment for the primary procedure or service with which they are associated encourages hospital efficiencies and enables hospitals to manage their resources with maximum flexibility.

Diagnostic radiopharmaceuticals, which include contrast agents, stress agents, and other products, are one specific type of product that is policy packaged under the category described by § 419.2(b)(15). Since we implemented this policy in CY 2008, interested parties have raised concerns regarding policy packaging of diagnostic radiopharmaceuticals. In previous rulemaking (87 FR 71962 and 71963), commenters recommended that CMS always pay separately for diagnostic radiopharmaceuticals paid under the OPPS, not just when the products have pass-through payment status. Many of these commenters mentioned that pass-through payment status helps the diffusion of new diagnostic radiopharmaceuticals into the market. However, commenters believe the packaged payment rate is often inadequate after pass-through status expires, especially in cases where the diagnostic radiopharmaceutical is high-cost and has low utilization.

CMS has previously heard from interested parties regarding alternative payment methodologies, such as subjecting diagnostic radiopharmaceuticals to the drug packaging threshold and creating separate APC payments for diagnostic radiopharmaceuticals with a per-day cost greater than $500. Interested parties have also recommended that we analyze our nuclear medicine APC structure and consider establishing additional nuclear medicine APCs to more accurately reflect the costs of diagnostic radiopharmaceuticals. Historically, commenters opposed incorporating the cost of diagnostic radiopharmaceuticals into the associated nuclear medicine APC as the nuclear medicine APCs are sometimes paid at a lower rate than the payment rate for the diagnostic radiopharmaceutical itself when it has pass-through payment status (87 FR 71962 and 71963).

Importantly, commenters historically have also been concerned that packaging payment for precision diagnostic radiopharmaceuticals in the outpatient setting creates barriers to beneficiary access for safety net hospitals serving a high proportion of Medicare beneficiaries and hospitals serving underserved communities (87 FR 71962 and 71963). Commenters specified that certain populations, such as those with Alzheimer's disease, depend on the use of certain high-cost diagnostic radiopharmaceuticals. Commenters discussed difficulties enrolling hospitals in clinical studies due to OPPS packaging policies. Commenters also suggested that CMS pay separately under the OPPS specifically for radiopharmaceuticals that are used for Alzheimer's disease. Additionally, commenters have recommended that CMS continue to apply radiolabeled product edits to the nuclear medicine procedures to ensure that all packaged costs are included on nuclear medicine claims in order to establish appropriate payment rates in the future. Many of these comments and our responses have been discussed in rulemaking since the policy to package diagnostic radiopharmaceuticals was adopted. We refer readers to the CY 2023 OPPS/ASC final rule with comment period (87 FR 71962 and 71963) for the most recent discussion of this subject.

As stated in the CY 2024 OPPS/ASC proposed rule (88 FR 49577), we continue to believe that diagnostic radiopharmaceuticals are an integral component of many nuclear medicine and imaging procedures and charges associated with them should be reported on hospital claims to the extent they are used. Accordingly, the payment for the radiopharmaceuticals should be reflected within the payment for the primary procedure. We note that ratesetting uses the geometric mean of reported procedure costs based on data submitted to CMS from all hospitals paid under the OPPS to set the payment rate for the service. The costs that are calculated by Medicare reflect the average costs of items and services that are packaged into a primary procedure and will not necessarily equal the sum of the cost of the primary procedure and the average sales price of the specific items and services used in the procedure in each case. Furthermore, the costs are based on the reported costs submitted to Medicare by the hospitals and not the list price established by the manufacturer. Claims data that include the radiopharmaceutical packaged with the associated procedure reflect the combined cost of the procedure and the radiopharmaceutical used in the procedure.

As CMS has reiterated over the years, we believe these packaging policies are inherent principles of the OPPS and are essential to a prospective payment system. We are also committed to ensuring beneficiary access to diagnostic radiopharmaceuticals while also ensuring the availability of new and innovative diagnostic tools for Medicare beneficiaries. Therefore, we sought public comments on potential modifications to our packaging policy for diagnostic radiopharmaceuticals in order to ensure equitable payment and continued beneficiary access.

Below we include the comment solicitation described in the CY 2024 OPPS/ASC proposed rule (88 FR 49578) followed by a brief summary of the public comments we received.

(ii) Comment Solicitation on Potential Issues Caused by Current Payment of Diagnostic Radiopharmaceuticals Under the OPPS

As described in the CY 2024 OPPS/ASC proposed rule (88 FR 49578), we solicited comment on how the OPPS packaging policy for diagnostic radiopharmaceuticals has impacted beneficiary access, including whether there are specific patient populations or clinical disease states for whom this issue is especially critical. We sought information on specific cost-prohibitive diagnostic radiopharmaceuticals that commenters believe are superior to alternative diagnostic modalities. We were interested to learn the specific clinical scenarios that exist for which it is only clinically appropriate to use the more expensive diagnostic radiopharmaceutical, rather than a lower cost alternative, as well as what clinical scenarios exist in which the only diagnostic modality is a high-cost radiopharmaceutical. We sought information or evidence that these high-cost diagnostic radiopharmaceuticals have unique clinical value, and access has been negatively impacted by our packaging policy. We also sought information about whether commenters believe these high-cost and low-utilization diagnostic radiopharmaceuticals are being appropriately utilized according to their clinical treatment algorithm, meaning the stepwise procedures generally accepted by the medical community for diagnosis, or clinical practice guidelines.

We were also interested in learning more about whether there is a difference in outcomes for patients, or patient quality of care, based on the radiopharmaceutical used as well as whether there is a difference for hospitals, such as in terms of financial outcomes, based on the radiopharmaceutical that used.

(iii) Comment Solicitation on New Approaches To Payment of Diagnostic Radiopharmaceuticals Under the OPPS

In addition, we solicited comment on the following potential approaches that would enhance beneficiary access, while also maintaining the principles of the outpatient prospective payment system. These approaches included: (1) paying separately for diagnostic radiopharmaceuticals with per-day costs above the OPPS drug packaging threshold of $140; (2) establishing a specific per-day cost threshold that may be greater or less than the OPPS drug packaging threshold; (3) restructuring APCs, including by adding nuclear medicine APCs for services that utilize high-cost diagnostic radiopharmaceuticals; (4) creating specific payment policies for diagnostic radiopharmaceuticals used in clinical trials; and (5) adopting codes that incorporate the disease state being diagnosed or a diagnostic indication of a particular class of diagnostic radiopharmaceuticals.

To expand upon the first listed option on which we solicited comments, we specifically sought comments about whether we should use our statutory authority for separately payable drugs, biologicals, and radiopharmaceuticals under 1833(t)(14)(A)(iii)(II) of the Act in order to pay separately for diagnostic radiopharmaceuticals and subject those diagnostic radiopharmaceuticals to the longstanding OPPS drug packaging threshold policy, proposed to be $140 for CY 2023. Or said another way, payment for diagnostic radiopharmaceuticals with per-day costs greater than $140 would not be packaged and would be paid separately based on available average sales price (ASP), wholesale acquisition cost (WAC), or average wholesale price (AWP) data with the applicable add-on. This would be similar to payment for therapeutic radiopharmaceuticals and other drugs and biologicals as discussed in section V.B. of the CY 2024 OPPS/ASC proposed rule. We believe this could be a reasonable first step as this threshold is well understood and known to commenters as therapeutic drugs, biologicals, and radiopharmaceuticals are currently paid separately if they have a calculated per-day cost above this threshold and are not policy-packaged. However, it is also our longstanding belief that diagnostic radiopharmaceuticals should have their payment packaged as they function as supplies during a diagnostic test or procedure and enable the provision of an independent service and are not themselves the primary therapeutic modality. We sought additional information from interested parties on this approach. We note, for CY 2024, the OPPS drug packaging threshold was proposed to be $140. However, based on updated data, we are finalizing a threshold of $135 for CY 2024. For more information on the drug packaging threshold, see section V.B.1.a of this final rule with comment period.

Regarding the second listed option, we sought comment on whether to pay separately for a diagnostic radiopharmaceutical with a specific per-day cost threshold that may be greater or less than the OPPS drug packaging threshold. Specifically, we were interested to learn why interested parties believe a threshold-based policy is important as well as interested parties' rationale for creating a threshold that would be different from the OPPS drug packaging threshold.

Regarding the third listed option, we have heard from some interested parties that they believe APC restructuring, including adding additional nuclear medicine APCs for services utilizing high-cost diagnostic radiopharmaceuticals, would be appropriate. We sought comment as to how these interested parties specifically envision operationalizing this approach and what advantage this approach would have for beneficiaries, hospitals, and CMS over other options.

For the fourth listed option, we recently became aware that some interested parties believe that CMS packaging policies could influence participation of beneficiaries and testing sites in clinical trials, particularly those studying Alzheimer's disease, and were interested to learn more about these concerns. While we believe there could be a multitude of reasons for difficulty in recruiting study sites and beneficiaries for clinical trials, including the COVID–19 PHE, we requested comment as to whether CMS should consider creating payment policies for diagnostic radiopharmaceuticals used in clinical trials. Specifically, we were interested to learn what commenters believe an appropriate payment mechanism would be for these diagnostic radiopharmaceuticals, whether there are certain disease states or categories of trials for which we should target our payment policies, ways in which this policy could help promote equitable recruitment and diverse participation, and the method by which CMS should determine which clinical trial diagnostic radiopharmaceuticals should be subject to this policy.

Finally, for approach five, we sought comment on new codes that CMS could adopt that may incorporate the disease state being diagnosed or a diagnostic indication of a particular class of diagnostic radiopharmaceuticals. CMS could create indication-specific coding to reflect the imaging procedure and the target of the imaging procedure. For example, CMS could create a code to represent a positron emission tomography (PET) scan that detects a specific protein. If multiple diagnostic radiopharmaceuticals are available to use during this PET scan to detect this specific protein, then their payment would be packaged into the payment for this newly created code and reflected in the payment for this code. Therefore, if there is a specific clinical indication for which only very costly diagnostic radiopharmaceuticals are available, our data would appropriately reflect their utilization. Alternatively, if there is a specific clinical indication in which a wide variety of diagnostic radiopharmaceuticals can be used, all with varying costs, then our data would reflect this and our payment rates would not incentivize a higher-cost diagnostic radiopharmaceutical when there is a lower-cost, but clinically similar, diagnostic radiopharmaceutical alternative. This coding approach could be coupled with the restructuring of the nuclear medicine APC family. We believe this approach of more granular coding could allow for more specific data to be reported and thus more targeted and appropriate payment rates to be developed. This approach would also help to maintain the principles of a prospective payment system by maintaining current packaging policies as payment for the diagnostic radiopharmaceutical would continue to be packaged into the payment for the procedure in which the diagnostic radiopharmaceutical is used.

We also sought additional explanation from interested parties as to why they believe their suggested approach is the best policy approach to ensure beneficiary access to diagnostic radiopharmaceuticals and equitable payment for innovative and effective technologies. We welcomed comment regarding ideas discussed in this section, discussed in prior rulemaking, or new ideas for payment for diagnostic radiopharmaceuticals in the OPPS.

Finally, we were interested in hearing from stakeholders how the discussed policy modifications might impact our overarching goal of utilizing packaging policies to better align OPPS policies with those of a prospective payment system rather than a fee schedule. We stated we would also like to know if making any of the policy changes discussed previously could have negative consequences for beneficiaries, such as unintentionally influencing clinical practice decisions, increasing beneficiary cost-sharing obligations, or inadvertently encouraging the use of higher-cost diagnostic radiopharmaceuticals over lower cost, but equally effective, diagnostic options.

In the CY 2024 OPPS/ASC proposed rule (88 FR 49578), we noted that depending on the comments received, we may adopt as final one or more alternative payment mechanisms for radiopharmaceuticals for CY 2024.

Comment: We received a significant number of comments in response to the comment solicitation on potential issues caused by our current payment policy for diagnostic radiopharmaceuticals under the OPPS and on new approaches to payment for these products. Overall, commenters described clinical scenarios in which they believed CMS' payment policies created the most significant access issues, and accordingly, commenters urged CMS to reform payment policy for diagnostic radiopharmaceuticals to address these concerns. However, there was not a general consensus among commenters as to the most effective way for CMS to reform its OPPS diagnostic radiopharmaceutical payment policy.

Commenters expressed concerns regarding the CMS policy to package diagnostic radiopharmaceuticals and the financial burden it has on facilities. These commenters believed radiopharmaceuticals are not supplies but instead are essential elements in driving the procedures themselves. Commenters believe that, for newer, more innovative radiopharmaceuticals, the current OPPS packaging policy has led to a lack of patient access to the technologies after their pass-through status expires, especially if there is no clinical alternative. Commenters also suggested that many of these diagnostic radiopharmaceuticals offer additional precision and improved clinical outcomes compared to predecessor products for a variety of disease states. Commenters also discussed that, in their view, some groups were more disadvantaged than others, such as rural communities and minority groups, from the lack of access. Similarly, some commenters discussed that the impact was more profound on certain disease states, such as neuroendocrine tumors, Alzheimer's disease, Parkinson's disease, Lewy body dementia, epilepsy, brain disorders, thyroid disorders, neuroendocrine tumors, heart disease, and a variety of cancers.

Many commenters suggested potential ways to develop a payment policy to address some of these issues. Predominately, most commenters requested that CMS provide separate payment for diagnostic radiopharmaceuticals. However, we received many different suggestions as to the best way to pay separately. Some commenters believed paying separately for all diagnostic radiopharmaceuticals regardless of their per-day cost was the best methodology to avoid encouraging upward price inflation to above a certain threshold. Other commenters thought that applying the existing OPPS per-day cost threshold (finalized to be $135 for CY 2024) to the payment of diagnostic radiopharmaceuticals would be an adequate solution. Others supported a $500 threshold, and many cited the Facilitating Innovative Nuclear Diagnostics Act (FIND Act) of 2023 as their rationale for that number. Some of commenters recommended the OPPS drug packaging threshold but recognized the $500 threshold number may be a more targeted approach relative to the OPPS drug packaging threshold as the higher cost diagnostic radiopharmaceuticals were the most disadvantaged by the OPPS packaging policy in their view. Still others contended the opposite that $500 would be too high a threshold. Many deferred to CMS to pick an appropriate packaging threshold for diagnostic radiopharmaceuticals. Others requested more information to allow them to make a more well-informed comment on this issue. Many commenters requested CMS use the ASP methodology in order to pay for diagnostic radiopharmaceuticals. Similarly, some suggested we pay for diagnostic radiopharmaceuticals similarly to the Physician Fee Schedule methodology and others recommended CMS reassess the pass-through payment methodology.

The majority of commenters discussed their views on providing separate payment for diagnostic radiopharmaceuticals, but some commenters also discussed the other aspects of the policy we solicited comment on. Commenters' views were mixed on these aspects. For example, some commenters supported CMS restructuring the nuclear medicine APCs and more specifically, one commenter supported packaging diagnostic radiopharmaceuticals in a new APC. However, other commenters did not believe this was sufficiently targeted enough or that it did not provide the needed granularity, and some thought new APCs would not accurately account for the variable costs of diagnostic radiopharmaceuticals and those yet to be approved. Similarly, many acknowledged that diagnostic radiopharmaceuticals should be paid separately in clinical trials, but that a clinical trial-specific policy would not address the broader issue at hand. Several commenters did recognize the difficulties that some clinical trials that utilize diagnostic radiopharmaceuticals have had in recruiting patients, such as the NEW IDEAS trial. Many commenters did not recommend CMS pursue issuing new HCPCS codes for disease-specific diagnostic radiopharmaceuticals as the process would be too complex, burdensome, lack the required specificity, and require continual updating. Alternatively, at least one commenter indicated that this methodology could have some merit in addressing this issue. This commenter stated that a specific code that incorporates the disease state would provide clinical and scientific specificity, which would enable CMS to collect data to improve care.

Many requested CMS create a new policy to be implemented for CY 2024, while others requested that CMS release more information on the per-day threshold and any proposed changes to the payment methodology before finalizing a new payment policy. These commenters acknowledged that reimbursement policy changes are complex and require careful consideration and an evaluation of all relevant factors. Some commenters were concerned with how any changes for CY 2024 could impact the Nuclear Medicine APC rates and requested an opportunity to evaluate and comment on those changes before they become the new policy.

Response: We sincerely thank commenters for their interest and engagement on this important issue. We agree this is a complex and important issue and, given the wide array of information presented through the public comment process, we intend to further consider these points and take them into consideration for future notice and comment rulemaking. We welcome ongoing dialogue and engagement from stakeholders regarding suggestions for potential future payment changes, including on any of the five potential approaches included in the original comment solicitation as well as any other potential solutions.

Please also see section V of this final rule with comment period, OPPS Payment for Drugs, Biologicals, and Radiopharmaceuticals, for additional details on payment for diagnostic radiopharmaceuticals in the OPPS.

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 2023 OPPS/ASC final rule with comment period (87 FR 71778 through 71780), we applied this policy and calculated the relative payment weights for each APC for CY 2023 that were shown in Addenda A and B of the CY 2023 OPPS/ASC 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 the CY 2023 OPPS/ASC final rule with comment period (87 FR 71757 through 71777). For CY 2024, as we did for CY 2023, we proposed to continue to apply the policy established in CY 2013 and calculate relative payment weights for each APC for CY 2024 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 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 Evaluation or Assessment and Management (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 2024, as we did for CY 2023, 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 2024, as we did for CY 2023, we proposed 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.

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 2024 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 proposed to compare the estimated aggregate weight using the CY 2023 scaled relative payment weights to the estimated aggregate weight using the proposed CY 2024 unscaled relative payment weights.

For CY 2023, we multiplied the CY 2023 scaled APC relative payment weight applicable to a service paid under the OPPS by the volume of that service from CY 2022 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 2024, we proposed to apply the same process using the estimated CY 2024 unscaled relative payment weights rather than scaled relative payment weights. We proposed to calculate the weight scalar by dividing the CY 2023 estimated aggregate weight by the unscaled CY 2024 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/payment/prospective-payment-systems/hospital-outpatient.* Click on the link labeled ''Hospital Outpatient Prospective Paymen—Notice of Final Rulemaking with Comment Period (NFRM)'' for 2024, which can be found under the heading ''Hospital Outpatient Regulations and Notices'' and open the claims accounting document link, which is labeled ''2024 NPRM OPPS Claims Accounting (PDF).''

We proposed to compare the estimated unscaled relative payment weights in CY 2024 to the estimated total relative payment weights in CY 2023 using CY 2022 claims data, holding all other components of the payment system constant to isolate changes in total weight. Based on this comparison, we proposed to adjust the calculated CY 2024 unscaled relative payment weights for purposes of budget neutrality. We proposed to adjust the estimated CY 2024 unscaled relative payment weights by multiplying them by a proposed weight scalar of 1.4529 to ensure that the proposed CY 2024 relative payment weights are scaled to be budget neutral. The proposed CY 2024 relative payment weights listed in Addenda A and B to the CY 2024 OPPS/ASC 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 the CY 2024 OPPS/ASC proposed rule.

Section 1833(t)(14) of the Act provides the payment rates for certain specified covered outpatient drugs (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 the CY 2024 OPPS/ASC proposed rule) is included in the budget neutrality calculations for the CY 2024 OPPS.

We did not receive any public comments on the proposed weight scalar calculation, and we are finalizing our proposal to use the calculation process described in the proposed rule, without modification, for CY 2024. For CY 2024, as we did for CY 2023, we will continue to apply the policy established in CY 2013 and calculate relative payment weights for each APC for CY 2024 using geometric mean-based APC costs. For CY 2024, as we did for CY 2023, we will assign APC 5012 a relative payment weight of 1.00; and we will 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. To comply with this requirement concerning the APC changes, we will compare the estimated aggregate weight using the CY 2023 scaled relative payment weights to the estimated

aggregate weight using the CY 2024 unscaled relative payment weights.

Using updated final rule claims data, we are updating the estimated CY 2024 unscaled relative payment weights by multiplying them by a weight scalar of 1.4429 to ensure that the final CY 2024 relative payment weights are scaled to be budget neutral. The final CY 2024 relative payments weights listed in Addenda A and B of this final rule with comment period (available via the internet on the CMS website) were scaled and incorporate the recalibration adjustments discussed in sections II.A.1 and II.A.2 of this final rule with comment period.

B. Conversion Factor Update

1. OPD Fee Schedule Increase Factor

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 2024 IPPS/Long Term Care Hospital (LTCH) PPS proposed rule (88 FR 27004 and 27005), consistent with current law, based on IHS Global, Inc.'s fourth quarter 2022 forecast, the proposed FY 2024 IPPS market basket percentage increase was 3.0 percent. We noted that under our regular process for the CY 2024 OPPS/ASC final rule with comment period, we would use the market basket update for the FY 2024 IPPS/LTCH PPS final rule (88 FR 58640) which would be based on IHS Global, Inc.'s second quarter 2023 forecast of the FY 2024 IPPS market basket percentage increase. We stated that if that forecast is different than the IPPS market basket percentage increase used for the CY 2024 OPPS/ASC proposed rule, the CY 2024 OPPS/ASC final rule with comment period OPD fee schedule increase factor would reflect that updated forecast of the market basket percentage increase. We proposed for CY 2024 an OPD fee schedule increase factor of 2.8 percent for the CY 2024 OPPS (which is the proposed estimate of the hospital inpatient market basket percentage increase of 3.0 percent, less the proposed 0.2 percentage point productivity adjustment).

Comment: Many commenters indicated that the proposed CY 2024 OPPS fee schedule increase factor was inadequate because it failed to take into account the fiscal reality currently faced by hospitals due to inflation, operating margins, increased labor costs, and other economic factors. Some of these commenters reiterated concerns included in public comments submitted in response to the FY 2024 IPPS/LTCH PPS proposed rule about what they believed was the inadequacy of the IPPS market basket percentage increase. Commenters explained that because section 1833(t)(3)(C)(iv) requires the OPD fee schedule increase factor for a year to equal the IPPS market basket percentage increase factor applicable under section 1886(b)(3)(B)(iii) to hospital discharges in the fiscal year ending in such year, the same concerns that they articulated about the IPPS market basket apply with respect to the OPPS fee schedule increase factor.

Several commenters, in support of their argument that the proposed market basket percentage increase is inadequate, stated that hospitals continue to face significant inflationary pressures. Commenters specifically expressed concern that the proposed OPPS payment update for CY 2024 does not adequately consider the cost growth that hospitals have faced over the last few years, noting cost increases related to workforce (including contract labor), drugs, medical supplies, personal protective equipment (PPE), and capital investment. The commenters stated that the significant inflation over the past several years due to the COVID–19 PHE has not been fully captured by the OPPS payment update. Multiple commenters were concerned that CMS use of time-lagged data did not reflect current inflationary trends and encouraged CMS to use more recent economic data to calculate the market basket increase.

Many commenters, in support of their argument that the CY 2024 proposed market basket percentage increase is inadequate, pointed to a February 2022 analysis from the American Hospital Association stating that Medicare only pays 84 percent of hospital costs; and they cited MedPAC's March 2023 report to Congress, which stated that overall Medicare hospital margins were minus 8.2 percent without COVID–19 relief funds in 2021 and were projected to be minus 10 percent in 2023.

Several commenters appreciated the proposed payment increase but also agreed with other commenters that the proposed update is inadequate given inflation and labor and supply pressures that hospitals, particularly rural hospitals, have been facing and continue to face.

Many commenters had significant concerns that the proposed OPPS payment update does not adequately reflect labor costs. Commenters stated the significant increases in labor expenses over the last couple of years have been largely driven by increased utilization of contract staff (due to workforce shortages) and growth in employee salaries. Two commenters cited their own independent analysis of payroll data done by one of the commenters to calculate the increased cost of labor, which they stated was significantly higher than the annual increases for compensation prices that CMS finalized over the last several years. Given the significant difference between the increased cost of labor versus what CMS estimates using the Bureau of Labor Statistics' Employment Cost Index (ECI), many commenters stated they had significant concerns that CMS's data source for estimating the cost of labor does not capture current market dynamics and underestimates the actual cost of healthcare labor. They cited analysis predicting that nursing staff shortages will continue for the next several years. Specifically, commenters raised concerns about CMS's use of the ECI in the market basket. Commenters stated they believe the Bureau of Labor Statistics' (BLS) ECI does not accurately reflect the shift from salaried employees to contract labor since the ECI does not collect data for contract staff, and thus does not capture extraordinary labor cost growth associated with hospitals' increased reliance on clinicians contracted through staffing agencies in response to supply shortages. Multiple commenters highlighted their belief that a closely related measure—the Employer Costs for Employee Compensation (ECEC)—may be a better and more timely data source for growth in hospital compensation costs compared to the ECI. One commenter claimed that all else being equal, if the hospital ECI growth had matched the hospital ECEC growth, this would have meant an additional three percentage point increase in the IPPS market basket percentage increase over the 2019 to 2022 time period. The commenter noted that, in the FY 2024 IPPS/LTCH PPS final rule (88 FR 59032), CMS rejected the use of the ECEC as an alternative to the ECI as a measure of change in hospital wage costs because it includes both changes in compensation as well as changes in employment. However, the commenter felt there were flaws in both the ECI and the ECEC; and, according to the commenter, the ECEC has, based on a retrospective analysis, better predicted labor costs during this period of high inflation and price instability. Several commenters recommended that CMS

use its exceptions and adjustments authority under section 1886(d)(5)(I) of the Act to adopt new or supplemental data sources such as commercial databases on hospital payrolls, to ensure labor costs are adequately reflected in the payment update in the OPPS final rule.

One commenter also requested CMS identify more accurate data inputs and use its existing authority to calculate the final rule ''base'' (before additional adjustments) market basket update with data that better reflect the rapidly increasing input prices facing hospitals. The commenter suggested that CMS should consider using the average growth rate in allowable Medicare costs per risk adjusted discharge for IPPS hospitals between FY 2019 and FY 2021 to calculate the CY 2024 final rule market basket update rather than using the growth in the ECI as the price proxy for compensation in the IPPS and OPPS market basket. The commenter requested using Medicare cost report data from Worksheets D–1, Part II, Lines 48 and 49 and S–3, Part 1, Column 13 to determine the Medicare costs per discharge. The commenter stated that this growth rate will capture the increased cost of contract labor, unlike the ECI. Based on their analysis of Medicare cost report data, they found that this methodology would yield an unadjusted market basket update of 4.39 percent for FY 2024 and CY 2024 rather than the 2.8 percent net market basket update proposed by CMS.

The commenter also responded to CMS's analysis of using Medicare cost report data to Calculate the market basket increase in the FY 2024 IPPS/LTCH PPS final rule (88 FR 59032). The commenter believes that using the Medicare case mix index to risk adjust the costs per discharge will eliminate any case-mix changes and provide an accurate comparison of the resources used to treat patients. The commenter also believes that because they are measuring changes in costs from FY 2019 to FY 2021 there should be only a minimal impact on service inputs based on changes in technology. Finally, they assert the increase in case mix CMS observes is a direct result of hospitals caring for sicker, more resource-intensive patients as procedures that previously performed in the inpatient setting have become outpatient procedures.

The commenter also stated that Medicare margins have declined over the last 20 years and believes this is due to persistently inadequate Medicare market basket updates. They further stated that hospitals' financial situations are so precarious that MedPAC recommended to Congress that it increase IPPS and OPPS payments over what is currently in the law to preserve access.

Finally, several commenters also requested that CMS use its exceptions and adjustments authority under section 1886(d)(5)(I) to increase the CY 2024 OPPS hospital market basket update higher than the proposed percentage increase. One commenter urged CMS to review the hospital cost data and the margin on Medicare reimbursement and readjust payment rates based on the new baseline cost of care that includes the results of supply shocks and labor shortages. Two other commenters requested that CMS use its authority to increase the FY 2024 IPPS market basket percentage increase to at least 5 percent, which would result in a CY 2024 OPPS/ASC fee schedule increase factor of the same amount.

Response: We acknowledge commenters' concerns, however, as we stated in the CY 2024 OPPS/ASC proposed rule, section 1833(t)(3)(C)(iv) of the Act requires the OPD fee schedule increase factor for a year to equal the IPPS market basket percentage increase factor applicable under section 1886(b)(3)(B)(iii) to hospital discharges in the fiscal year ending in such year. Accordingly, we are unable to adopt a final OPD fee schedule increase factor different than the IPPS market basket percentage increase factor finalized in the FY 2024 IPPS/LTCH PPS final rule. We refer commenters to that final rule for responses regarding the issues commenters raised (88 FR 59032 and 59033).

2. Productivity Adjustment

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 ''productivity adjustment''). In the FY 2012 IPPS/LTCH PPS final rule (76 FR 51689 through 51692), we finalized our methodology for calculating and applying the productivity adjustment. The U.S. Department of Labor's Bureau of Labor Statistics (BLS) publishes the official measures of private nonfarm business productivity for the U.S. economy. We note that previously the productivity measure referenced in section 1886(b)(3)(B)(xi)(II) of the Act was published by BLS as private nonfarm business multifactor productivity. Beginning with the November 18, 2021, release of productivity data, BLS replaced the term multifactor productivity (MFP) with total factor productivity (TFP). BLS noted that this is a change in terminology only and will not affect the data or methodology. As a result of the BLS name change, the productivity measure referenced in section 1886(b)(3)(B)(xi)(II) of the Act is now published by BLS as private nonfarm business total factor productivity. However, as mentioned, the data and methods are unchanged. Please see *www.bls.gov* for the BLS historical published TFP data. A complete description of IHS Global, Inc.'s (IGI) TFP projection methodology is available on the CMS website at *https://www.cms.gov/data-research/statistics-trends-and-reports/medicare-program-rates-statistics/market-basket-research-and-information.* In addition, we note that beginning with the FY 2022 IPPS/LTCH PPS final rule, we refer to this adjustment as the productivity adjustment rather than the MFP adjustment to more closely track the statutory language in section 1886(b)(3)(B)(xi)(II) of the Act. We note that the adjustment continues to rely on the same underlying data and methodology. In the FY 2024 IPPS/LTCH PPS proposed rule (88 FR 27005), the proposed productivity adjustment for FY 2024 was 0.2 percentage point.

Therefore, we proposed that the productivity adjustment for the CY 2024 OPPS/ASC would be 0.2 percentage point. We also proposed that if more recent data subsequently became available after the publication of the CY 2024 OPPS/ASC proposed rule (for example, a more recent estimate of the market basket percentage increase and/or the productivity adjustment), we would use such updated data, if appropriate, to determine the CY 2024 market basket update and the productivity 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.

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

proposed for CY 2024 an OPD fee schedule increase factor of 2.8 percent for the CY 2024 OPPS/ASC (which is the proposed estimate of the hospital inpatient market basket percentage increase of 3.0 percent, less the proposed 0.2 percentage point productivity adjustment).

Comment: Several commenters expressed concern about the application of the productivity adjustment, stating that the PHE has had unimaginable impacts on hospital productivity. They stated that even before the PHE, the CMS Office of the Actuary (OACT) indicated that hospital productivity will be less than the general economy-wide productivity, which is the measure that is required by law to be used to derive the productivity adjustment. Commenters noted that hospitals are highly labor intensive and the large amounts of staff turnover during the PHE substantially reduced hospital productivity. Given that CMS is required by statute to implement a productivity adjustment to the market basket update, commenters asked the agency to work with Congress to permanently eliminate what they stated is an unjustified reduction to hospital payments. Further, they asked CMS to use its ''exceptions and adjustments'' authority under section 1886(d)(5)(I) of the Act to remove the productivity adjustment for any fiscal year that was covered under PHE determination (*i.e.,* 2020 (0.4 percent), 2021 (0.0 percent), 2022 (0.7 percent), and 2023 (0.3 percent)) from the calculation of the market basket update for FY 2024 and any year thereafter. A few commenters expressed concerns about the proposed productivity adjustment given the extreme and uncertain circumstances under which hospitals and health systems are currently operating and urged CMS to eliminate the productivity cut for FY 2024.

Response: While we appreciate the commenters' concerns, section 1833(t)(3)(F)(i) requires that after determining the OPD fee schedule increase factor under subparagraph (C)(iv), the Secretary shall reduce such increase factor by the productivity adjustment described in section 1886(b)(3)(B)(xi) of the Act. As required by statute, the FY 2024 productivity adjustment is derived based on the 10-year moving average growth in economy-wide productivity for the period ending FY 2024.

We thank the commenters for their comments. After consideration of the comments received and consistent with our proposal, we are finalizing an OPD fee schedule increase factor of 3.1 percent for CY 2024, which consists of the IPPS market basket increase factor of 3.3 percent less a 0.2 percentage point productivity adjustment.

3. Other Conversion Factor Adjustments

To set the OPPS conversion factor for 2024, we proposed to increase the CY 2023 conversion factor of $85.585 by 2.8 percent. In accordance with section 1833(t)(9)(B) of the Act, we proposed further to adjust the conversion factor for CY 2024 to ensure that any revisions made to the wage index and rural adjustment are made on a budget neutral basis. We proposed to calculate an overall budget neutrality factor of 0.9974 for wage index changes by comparing proposed total estimated payments from our simulation model using the proposed FY 2024 IPPS wage indexes to those payments using the FY 2023 IPPS wage indexes, as adopted on a calendar year basis for the OPPS. We further proposed to calculate an additional budget neutrality factor of 0.9975 to account for our proposed policy to cap wage index reductions for hospitals at 5 percent on an annual basis.

For CY 2024, we proposed to maintain the current rural adjustment policy, as discussed in section II.E of the CY 2024 OPPS/ASC proposed rule. Therefore, the proposed budget neutrality factor for the rural adjustment was 1.0000.

We proposed to calculate a CY 2024 budget neutrality adjustment factor for the cancer hospital payment adjustment by transitioning from the target PCR of 0.89 we finalized for CYs 2020 through 2023 (which included the 1.0 percentage point reduction as required by section 16002(b) of the 21st Century Cures Act) and incrementally reducing the target PCR by an additional 1.0 percentage point for each calendar year, beginning with CY 2024, until the target PCR equals the PCR of non-cancer hospitals calculated using the most recent data minus 1.0 percentage point as required by section 16002(b) of the 21st Century Cures Act. Therefore, we proposed to apply a budget neutrality adjustment factor of 1.0005 to the conversion factor for the cancer hospital payment adjustment. In accordance with section 1833(t)(18)(C) of the Act, as added by section 16002(b) of the 21st Century Cures Act (Pub. L. 114–255), we reduce the target PCR by 0.01, which brings the proposed target PCR to 0.88. This is 0.01 less than the target PCR of 0.89 from CY 2021 through CY 2023, which was held at the pre-PHE target.

For the CY 2024 OPPS/ASC proposed rule, we estimated that proposed pass-through spending for drugs, biologicals, and devices for CY 2024 would equal approximately $234.1 million, which represents 0.26 percent of total projected CY 2024 OPPS spending. Therefore, we stated that the proposed conversion factor would be adjusted by the difference between the 0.16 percent estimate of pass-through spending for CY 2023 and the 0.26 percent estimate of proposed pass-through spending for CY 2024, resulting in a proposed decrease to the conversion factor for CY 2024 of 0.1 percent.

We proposed that estimated payments for outliers would remain at 1.0 percent of total OPPS payments for CY 2024. We estimated for the CY 2024 OPPS/ASC proposed rule that outlier payments would be approximately 0.78 percent of total OPPS payments in CY 2023; the 1.00 percent for proposed outlier payments in CY 2024 would constitute a 0.22 percent increase in payment in CY 2024 relative to CY 2023.

For 2024, we proposed to use a conversion factor of $87.488 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 2.8 percent for CY 2024, the required proposed wage index budget neutrality adjustment of approximately 0.9974, the proposed 5 percent annual cap for individual hospital wage index reductions adjustment of approximately 0.9975, the proposed cancer hospital payment adjustment of 1.0005, and the proposed adjustment of an decrease of 0.1 percentage point of projected OPPS spending for the difference in pass-through spending, which resulted in a proposed conversion factor for CY 2024 of $87.488.

For CY 2024, we also proposed 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 proposed to make all other adjustments discussed above, but use a reduced OPD fee schedule update factor of 0.8 percent (that is, the proposed OPD fee schedule increase factor of 2.8 percent further reduced by 2.0 percentage points). This resulted in a proposed reduced conversion factor for CY 2024 of $85.782 for hospitals that fail to meet the Hospital OQR Program requirements (a difference of −1.706 in the conversion factor relative to hospitals that met the requirements). For further discussion of the Hospital OQR Program, we refer readers to section XIV of the CY 2024 OPPS/ASC

proposed rule. For 2024, we proposed to use a reduced conversion factor of $85.782 in the calculation of payments for hospitals that fail to meet the Hospital OQR Program requirements (a difference of –1.706 in the conversion factor relative to hospitals that met the requirements).

We received no comments on our proposed adjustments to the conversion factor for CY 2024. For this CY 2024 OPPS/ASC final rule with comment period, based on more recent data available, the OPD fee schedule increase factor for the CY 2024 OPPS is 3.1 percent (which reflects the 3.3 percent final estimate of the hospital inpatient market basket percentage increase with a −0.2 percentage point productivity adjustment). For CY 2024, we are using a conversion factor of $87.382 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 OPD fee schedule increase factor of 3.1 percent for CY 2024, the required wage index budget neutrality adjustment of 0.9912, the 5 percent annual cap for individual hospital wage index reductions of 0.9997, the cancer hospital payment adjustment of 1.0005, and the adjustment of 0.11 (or 0.27 less 0.16) percentage point of projected OPPS spending for the difference in pass-through spending that results in a conversion factor for CY 2024 of $87.382. We are also finalizing a reduced conversion factor of $85.687 in the calculation of payments for hospitals that fail to meet the Hospital OQR Program requirements (a difference of −1.695 in the conversion factor relative to hospitals that met the requirements).

The calculations we performed to determine the CY 2024 final conversion factor are shown in Table 4.

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TABLE 4: CALCULATION OF CY 2024 FINAL OPPS CONVERSION FACTOR

Start: CY 2023 Final OPPS Conversion Factor = **$85.585**
Step 1a: Adjust the conversion factor to temporarily account for additional drug and device pass-through spending and outlier spending in CY 2023. This action causes an increase in the conversion factor. So, the amount of both drug and device pass-through spending (0.0016) and the percentage of outlier spending (0.01). as a share of total OPPS outpatient hospital spending is subtracted from 1.0000, which represents total OPPS outpatient hospital spending for CY 2023. ➢ 1.0000– (0.0016+0.01) = 0.9884 *Step 1b:* Divide $85.585 by 0.9884 ➢ $85.585/0.9884 = **$86.589**
Step 2: Adjust the conversion factor by the required wage index budget neutrality adjustment of approximately 0.9912. This adjustment reduces the amount of OPPS outpatient hospital spending and is multiplied with $86.589. ➢ $86.589* 0.9912 = $**85.827**
Step 3: Adjust the conversion factor by the 5 percent annual cap for individual hospital wage index reductions adjustment of approximately 0.9997. This adjustment reduces the amount of OPPS outpatient hospital spending and is multiplied with $85.827. ➢ $85.827* 0.9997 = **$85.802**
Step 4: Adjust the conversion factor by the cancer hospital payment adjustment of 1.0005. Because the PCR for cancer hospitals is declining between CY 2023 and CY 2024, it increases the amount of OPPS outpatient hospital spending for providers that are not cancer hospitals and is multiplied with $85.802. ➢ $85.802*1.0005 = **$85.845**
Step 5: Adjust the conversion factor by rural SCH adjustment policy of 1.0000. Since we are maintaining our current policy, there is no impact on the conversion by this policy. ➢ $85.845*1.0000 = **$85.845**
Step 6a: Adjust the conversion factor by the OPD fee schedule increase factor of 0.031 for CY 2024. The OPD fee schedule increase factor increases outpatient hospital spending in CY 2024 over CY 2023 and is added to 1.0000 which represents total outpatient hospital OPPS spending in CY 2023.

➢ 1.0000+0.031 = 1.0310
Step 6b: Multiply $85.845 by 1.0310. ➢ $85.845*1.0310 = **$88.506**
Step 7a: Adjust the conversion factor to remove additional drug and device pass-through spending and outlier spending for CY 2024. This action causes a decrease in the conversion factor. So, the amount of both drug and device pass-through spending (0.0027) and the percentage of outlier spending (0.01) as a share of total OPPS outpatient hospital spending is subtracted from 1.0000, which represents total OPPS outpatient hospital spending for CY 2024. ➢ 1.0000– (0.0027+0.01) = 0.9873
Step 7b: Multiply $88.506 by 0.9873 to get the CY 2024 final OPPS conversion factor. ➢ $88.506/0.9873 = **$87.382**
Finish: **CY 2024 OPPS Conversion Factor = $87.382**

C. 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 CY 2024 OPPS/ASC final rule with comment period.

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 proposed to continue this policy for the CY 2024 OPPS/ASC (88 FR 49584). We refer readers to section II.H of the CY 2024 OPPS/ASC 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.

We did not receive any public comments on our proposal, and we are finalizing our proposal without modification.

As discussed in the claims accounting narrative included with the supporting documentation for this final rule with comment period (which is available via the internet on the CMS website (*https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient/regulations-notices*)), for estimating APC costs, we would standardize 60 percent of estimated claims costs for geographic area wage variation using the same FY 2024 pre-reclassified wage index that we 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/ASC 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. In the CY 2024 OPPS/ASC proposed rule (88 FR 49584 and 49585), we proposed 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, 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 2023 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 and 53370; for FY 2014, 78 FR 50590 and 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; for FY 2020, 84 FR 42312; for FY 2021, 85 FR 58765; for FY 2022, 86 FR 45178; and for FY 2023, 87 FR 49006.

We did not receive any public comments on our proposal, and we are finalizing our proposal without modification.

In addition to the changes required by the Affordable Care Act, we noted in the CY 2024 OPPS/ASC proposed rule (88 FR 49585) that the proposed FY 2024 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, the imputed floor wage index adjustment in all-urban states, an adjustment for occupational mix, an adjustment to the wage index based on commuting patterns of employees (the out-migration adjustment), and the permanent 5-percent cap on any decrease to a hospital's wage index from its wage index in a prior FY. Beginning with FY 2024, we proposed to include hospitals with § 412.103 reclassification along with geographically rural hospitals in all rural wage index calculations, and to exclude ''dual reclass'' hospitals (hospitals with simultaneous § 412.103 and Medicare Geographic Classification Review Board (MGCRB) reclassifications) implicated by the hold harmless provision at section 1886(d)(8)(C)(ii) of the Act (88 FR 26973 and 26974). We also proposed to continue the low wage index hospital policy, under which we increase the wage index for hospitals with a wage index value below the 25th percentile wage index value for a fiscal year by half the difference between the otherwise applicable final wage index value for a year for that hospital and the 25th percentile wage index value for that year across all hospitals. We refer readers to the FY 2024 IPPS/LTCH PPS proposed rule (88 FR 26963 through 26986) for a detailed discussion of all proposed changes to the FY 2024 IPPS wage indexes.

We noted that in the FY 2023 IPPS/LTCH PPS final rule (87 FR 49018 through 49021), we finalized a permanent approach to smooth year-to-year decreases in hospitals' wage indexes. Specifically, for FY 2023 and subsequent years, we apply a 5-percent cap on any decrease to a hospital's wage index from its wage index in the prior FY, regardless of the circumstances causing the decline. That is, a hospital's wage index for FY 2024 would not be less than 95 percent of its final wage index for FY 2023, and for subsequent years, a hospital's wage index would not be less than 95 percent of its final wage index for the prior FY. We stated that we believe this policy would increase the predictability of IPPS payments for hospitals and mitigate instability and significant negative impacts to hospitals resulting from changes to the wage index. It would also eliminate the need for temporary and potentially uncertain transition adjustments to the wage index in the future due to specific policy changes or circumstances outside hospitals' control. Except for newly opened hospitals, we will apply the cap for a fiscal year using the final wage index applicable to the hospital on the last day of the prior fiscal year. A newly opened hospital would be paid the wage index for the area in which it is geographically located for its first full or partial fiscal year, and it would not receive a cap for that first year, because it would not have been assigned a wage index in the prior year (in accordance with 42 CFR 419.41(c)(1) and 419.43(c), as noted above).

Core Based Statistical Areas (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 2024, under the OPPS, we are continuing to use only the FIPS county codes for purposes of crosswalking counties to CBSAs.

In the CY 2024 OPPS/ASC proposed rule, we proposed to use the FY 2024 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 rate for CY 2024 (88 FR 49585). Therefore, any policies and adjustments for the FY 2024 IPPS post-reclassified wage index would be reflected in the final CY 2024 OPPS wage index beginning on January 1, 2024. We refer readers to the FY 2024 IPPS/LTCH PPS proposed rule (88 FR 26963 through 26986) and the proposed FY 2024 hospital wage index files posted on the CMS website at *https://www.cms.gov/medicare/payment/prospective-payment-systems/acute-inpatient-pps/fy-2024-ipps-proposed-rule-home-page.* Regarding budget neutrality for the CY 2024 OPPS wage index, we refer readers to section II.B of this CY 2024 OPPS/ASC final rule with comment period. 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 policies and adjustments. We proposed to continue this policy for CY 2024 (88 FR 49585 and 49586). We refer readers to the FY 2024 IPPS/LTCH PPS proposed rule (88 FR 26963 through 26986) for a detailed

discussion of the proposed changes to the FY 2024 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)) (Pub. L. 108–173). 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 would apply if the hospital were paid under the IPPS. For CY 2024, we proposed 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) (88 FR 49585 and 49586). Furthermore, we proposed that the wage index that would apply for CY 2024 to non-IPPS hospitals paid under the OPPS would continue to include the rural floor adjustment and any policies and adjustments applied to the IPPS wage index to address wage index disparities. In addition, we proposed that the wage index that would apply to non-IPPS hospitals paid under the OPPS would include the 5-percent cap on wage index decreases.

Comment: Multiple commenters supported our policy to apply a 5-percent cap on any decrease to a hospital's wage index from its wage index in the prior FY. Commenters also requested that the proposed 5-percent cap policy be excluded from budget neutrality, which would allow the cap to be applied while avoiding decreases to the wage index in areas with high wage indexes.

Response: We appreciate the commenters' support of our policy to apply a 5-percent cap on any decrease to a hospital's wage index from its wage index in the prior FY. We finalized the proposal and the associated proposed budget neutrality adjustment in the FY 2023 IPPS/LTCH PPS final rule (87 FR 49018 through 49021) and agree that the policy will promote payment stability for HOPDs as well.

We stated in the FY 2023 IPPS/LTCH PPS final rule (87 FR 49021) that we will apply the cap in a budget neutral manner through a national adjustment to the standardized amount each fiscal year. Specifically, we will apply a budget neutrality adjustment to ensure that estimated aggregate payments under our wage index cap policy for hospitals that would have a decrease in their wage indexes for the upcoming fiscal year of more than 5 percent would equal what estimated aggregate payments would have been without the wage index cap policy. We proposed to apply a similar budget neutrality adjustment in the OPPS for each calendar year (87 FR 44530). For the OPPS, 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, which is inconsistent with the commenters' request to exclude the wage index cap policy from budget neutrality.

Comment: Multiple commenters supported our policy to treat urban hospitals reclassified as rural hospitals under § 412.103 as rural hospitals for purposes of the rural wage indexes and the rural floor.

Response: We appreciate the commenters' support of our policy.

Comment: Multiple commenters supported our low-wage index policy, which, for hospitals with a wage index value below the 25th percentile, increases the hospital's wage index by half the difference between the otherwise applicable wage index value for that hospital and the 25th percentile wage index value for all hospitals.

Response: We appreciate the support of the commenters.

After consideration of the public comments we received, we are finalizing our proposal without modification to use the FY 2024 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 rate for CY 2024. Any policies and adjustments for the FY 2024 IPPS post-reclassified wage index will be reflected in the final CY 2024 OPPS wage index beginning on January 1, 2024, including, but not limited to, reclassification of hospitals to different geographic areas, the rural floor provisions, the imputed floor wage index adjustment in all-urban states, an adjustment for occupational mix, an adjustment to the wage index based on commuting patterns of employees (the out-migration adjustment), 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, and a 5-percent cap on any decrease to a hospital's wage index from its wage index in the prior FY. We refer readers to the FY 2024 IPPS/LTCH PPS final rule (88 FR 58958 through 58988) and the FY 2024 hospital wage index files posted on the CMS website at *https://www.cms.gov/medicare/payment/prospective-payment-systems/acute-inpatient-pps/fy-2024-ipps-final-rule-home-page.* Regarding budget neutrality for the CY 2024 OPPS wage index, we refer readers to section II.B. of this final rule with comment period.

For CMHCs, for CY 2024, we proposed to continue to calculate the wage index by using the post-reclassification IPPS wage index based on the CBSA where the CMHC is located (88 FR 48586). Furthermore, we proposed that the wage index that would apply to a CMHC for CY 2024 would continue to include the rural floor adjustment and any policies and adjustments applied to the IPPS wage index to address wage index disparities. In addition, the wage index that would apply to CMHCs would include the 5-percent cap on wage index decreases. Also, we proposed that the wage index that would apply to CMHCs would not include the outmigration adjustment because that adjustment only applies to hospitals.

We did not receive any public comments on our proposals, and we are finalizing our proposals regarding CMHC wage index calculations without modification.

Table 4A associated with the FY 2024 IPPS/LTCH PPS final rule (available via the internet on the CMS website at: *https://www.cms.gov/medicare/payment/prospective-payment-systems/acute-inpatient-pps/fy-2024-ipps-final-rule-home-page*) identifies counties that would be eligible for the out-migration adjustment. Table 2 associated with the FY 2024 IPPS/LTCH PPS final rule (available for download via the website above) identifies IPPS hospitals that would receive the out-migration adjustment for FY 2024. We are including the outmigration adjustment information from Table 2 associated with the FY 2024 IPPS/LTCH PPS final rule as Addendum L to this final rule with comment period, with the addition of non-IPPS hospitals that would receive the section 505 outmigration adjustment under this final rule with comment period. 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/payment/prospective-payment-systems/hospital-outpatient/regulations-notices.* At this link, readers will find a link to the final FY 2024 IPPS wage index tables and Addendum L.

D. 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 (OMB NO: 0938–0050 for Form CMS–2552–10) 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 Claims Accounting Narrative for this CY 2024 OPPS/ASC final rule with comment period, which is posted on our website. We proposed to calculate the default ratios for CY 2024 using the most recent cost report data.

We did not receive any public comments on our proposal, and we are finalizing our proposal without modification to calculate the default ratios for CY 2024 using the June 2021 HCRIS cost reports, consistent with the broader proposal regarding CY 2024 OPPS ratesetting.

We no longer publish 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. Adjustment for Rural Sole Community Hospitals (SCHs) and Essential Access Community Hospitals (EACHs) Under Section 1833(t)(13)(B) of the Act for CY 2024

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 provides 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 the Balanced Budget Act of 1997 (BBA) (Pub. L. 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 2023.

For CY 2024, we proposed to continue the current policy of a 7.1 percent payment adjustment 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, applied in a budget neutral manner.

Comment: Two commenters requested that the 7.1 percent payment adjustment be allowed for providers other than rural SCHs and EACHs. The commenters suggested that Medicare dependent hospitals and urban sole community hospitals either receive the adjustment or be studied to see if they are eligible to receive the adjustment.

Response: Our study of the difference in costs by APC between hospitals in rural areas and hospitals in urban areas only showed a significant difference in costs for rural SCHs. We did not identify significant cost differences between hospitals in urban areas and Medicare dependent hospitals. In addition, our authority under section 1833(t)(13) of the Act only extends to rural hospitals. Therefore, we are not expanding the types of hospitals eligible for the 7.1 percent payment adjustment at this time.

Comment: Multiple commenters are in favor of our policy to apply a 7.1 percent payment adjustment for rural SCHs, including EACHs.

Response: We appreciate the commenters' support of our policy.

After consideration of the public comments we received, we are finalizing our proposal, without modification, to continue in CY 2024 our current policy of utilizing a budget neutral 7.1 percent payment adjustment for rural SCHs, including EACHs, for all services and procedures paid under the OPPS, excluding separately payable drugs and biologicals, devices paid under the pass-through payment policy, and items paid at charges reduced to costs.

F. Payment Adjustment for Certain Cancer Hospitals for CY 2024

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 department 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 added section 1833(t)(7), ''Transitional Adjustment to Limit Decline in Payment,'' to the Act, which requires the Secretary to determine OPPS payments to cancer and children's hospitals based on their pre-BBA payment amount (these hospitals are often referred to under this policy as ''held harmless'' and their payments are often referred to as ''hold harmless'' payments).

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 department 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 department 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 § 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 (OMB NO: 0938–0050), 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 (Pub. L. 111–148) 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 and 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. Table 5 displays the target PCR for purposes of the cancer hospital adjustment for CY 2012 through CY 2023.

TABLE 5: CANCER HOSPITAL ADJUSTMENT TARGET PAYMENT-TO-COST RATIOS (PCRS), CY 2012 THROUGH CY 2023

Calendar Year	Target PCR
2012	0.91
2013	0.91
2014	0.90
2015	0.90
2016	0.92
2017	0.91
2018	0.88
2019	0.88
2020	0.89
2021	0.89
2022	0.89
2023	0.89

2. Policy for CY 2024

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.

In the CY 2024 OPPS/ASC proposed rule (88 FR 49587 through 49589), we proposed to provide additional payments to the 11 specified cancer hospitals so that each cancer hospital's proposed PCR is equal to the weighted average PCR (or ''target PCR'') for the other OPPS hospitals, generally using the most recent submitted or settled cost report data that are available, reduced by 1.0 percentage point, to comply with section 16002(b) of the 21st Century Cures Act, and adjusted by the proposed post-Public Health Emergency transition as described later in this section. We did not propose an additional reduction beyond the 1.0 percentage point reduction required by section 16002(b) of the 21st Century Cures Act for CY 2024.

Under our established policy, to calculate the proposed CY 2024 target PCR, we used the same extract of cost report data from HCRIS used to estimate costs for the CY 2024 OPPS which, in most cases, would be the most recently available hospital cost reports. 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 2022 claims data that we used to model the impact of the proposed CY 2024 APC relative payment weights (3,406 hospitals) because it is appropriate to use the same set of hospitals that are being used to calibrate the modeled CY 2024 OPPS. The cost report data for the hospitals in this dataset were from cost report periods with fiscal year ends ranging from 2017 to 2022; however, the cost reporting periods were predominantly from fiscal years ending in 2021 and 2022. We then removed the cost report data of the 47 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 3,345 hospitals with cost report data.

Using this smaller dataset of cost report data, we estimated that, on average, the OPPS payments to other hospitals furnishing services under the OPPS were approximately 86 percent of reasonable cost (weighted average PCR of 0.86). Therefore, after applying the 1.0 percentage point reduction, as required by section 16002(b) of the 21st Century Cures Act, using our standard process 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 target PCR equal to 0.85 for each cancer hospital.

However, we noted that a proposed cancer hospital target PCR of 0.85 for CY 2024 is dramatically lower than the target PCR from previous years. Historically, as shown in Table 5 of the final rule, the target PCR for cancer hospitals has been between 0.88 and 0.92. In light of our concerns about the impact of the COVID–19 PHE on CY 2020 claims and cost data, we finalized a policy to continue the target PCR of 0.89 from CY 2021 for CY 2022 and for CY 2023 as an appropriate cancer hospital adjustment under our authority described in section 1833(t)(2)(E) of the Act. We explained that we believe the impact of the COVID–19 PHE claims and cost data used to calculate the target PCR of 0.85 may continue to have some limited influence on our target PCR calculations. However, we also explained that we believe we should begin to take into consideration the PCR of non-cancer hospitals based on the most recently available data for calculating the target PCR. We noted that we do not know if the changes in the data that have yielded a significantly lower PCR for non-cancer hospitals using the most recently available data are likely to continue in future years or if, when data from after the PHE is available, we will see the target PCR increase toward its historical norm. We stated that we are concerned that using the 0.85 target PCR calculated from the most recent data could lead to instability in cancer hospital adjustment payments and volatility in the PCR as we transition to utilizing post-PHE data. Therefore, in the CY 2024 OPPS/ASC proposed rule, we proposed to transition from the target PCR of 0.89 we finalized for CYs 2020 through 2023 (which included the 1.0 percentage point reduction as required by section 16002(b) of the 21st Century Cures Act) and incrementally reduce the target PCR by an additional 1.0 percentage point for each calendar year, beginning with CY 2024, until the target PCR equals the PCR of non-cancer hospitals calculated using the most recent data minus 1.0 percentage point as required by section 16002(b) of the 21st Century Cures Act. Therefore, utilizing this methodology for the CY 2024 OPPS/ASC proposed rule, we proposed to reduce the CY 2023 target PCR of 0.89 by 1 percentage point and proposed a cancer hospital target PCR of 0.88 for CY 2024.

Comment: Several commenters supported the proposed methodology of incrementally reducing the target PCR until it equals the target PCR based on cost report data. A few of those commenters also requested that the repayments made to 340B hospitals associated with the prior 340B-acquired drug policy be included in the final CY 2024 target PCR.

Response: We appreciate commenters' support for our proposal.

We also appreciate the commenters' suggestion to include repayments made to 340B hospitals in calculating the CY 2024 target PCR. The cancer hospital adjustment target PCR calculation relies on historical cost report data, and we believe that the proposed methodology continues to remain appropriate for the CY 2024 target PCR without the addition of anticipated future payments. However, the request raises a valid concern regarding if and how best to accommodate changes made as part of the final 340B Remedy policy. We believe that having public input on how to appropriately account for those changes once the 340B Remedy policy is finalized and implemented will be important, including because the cancer hospital adjustment is budget neutral within the OPPS and thus any changes to it will affect not only cancer

hospitals, but all hospitals paid under the system.

After consideration of the public comments we received, we are finalizing without modification our proposed policy to reduce the target PCR by 1 percentage point until such time that it equals the target PCR calculated based on cost report data. Therefore, a CY 2024 target PCR of 0.88 will apply to the 11 specified cancer hospitals for CY 2024.

Table 6 shows the estimated percentage increase in OPPS payments to each cancer hospital for CY 2024, due to the cancer hospital payment adjustment policy. The actual, final amount of the CY 2024 cancer hospital payment adjustment for each cancer hospital will be determined at cost report settlement and will depend on each hospital's CY 2024 payments and costs from the settled CY 2024 cost report. 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 6: ESTIMATED CY 2024 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 2024 due to Payment Adjustment
050146	City of Hope Comprehensive Cancer Center	58.0%
050660	USC Norris Cancer Hospital	34.2%
100079	Sylvester Comprehensive Cancer Center	41.9%
100271	H. Lee Moffitt Cancer Center & Research Institute	25.0%
220162	Dana-Farber Cancer Institute	43.1%
330154	Memorial Sloan-Kettering Cancer Center	58.1%
330354	Roswell Park Cancer Institute	19.1%
360242	James Cancer Hospital & Solove Research Institute	14.5%
390196	Fox Chase Cancer Center	20.8%
450076	M.D. Anderson Cancer Center	44.8%
500138	Seattle Cancer Care Alliance	39.4%

G. 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 dollar amount). In CY 2023, the outlier threshold was met when the hospital's cost of furnishing a service exceeded 1.75 times the APC payment amount (the multiplier threshold) and exceeded the APC payment amount plus $8,625 (the fixed-dollar amount threshold) (87 FR 71788 through 71790). If the hospital's cost of furnishing 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 hospital's 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 2022 OPPS payments, using CY 2022 claims available for this CY 2024 OPPS final rule, is approximately 0.95 percent. Therefore, for CY 2022, we estimate that

we did not meet the outlier target by 0.05 percent of total aggregated OPPS payments.

For this final rule with comment period, using CY 2022 claims data and CY 2023 payment rates, we estimate that the aggregate outlier payments for CY 2023 would be approximately 0.83 percent of the total CY 2023 OPPS payments. We provide estimated CY 2024 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/payment/prospective-payment-systems/hospital-outpatient.*

2. Outlier Calculation for CY 2024

For CY 2024, we proposed to continue our policy of estimating outlier payments to be 1.0 percent of the estimated aggregate total payments under the OPPS. We proposed 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 and IOP 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. We proposed to modify our outlier policy and which APCs are eligible for an outlier payment if a CMHC's cost for services exceeds 3.40 times the APC payment rate. The outlier payment would be calculated as 50 percent of the amount by which the cost exceeds 3.40 times the proposed APC payment rate.

For further discussion of CMHC outlier payments, we refer readers to section VIII.C of this final rule with comment period.

To ensure that the estimated CY 2024 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 the fixed-dollar threshold.

We calculated the proposed fixed-dollar threshold using the standard methodology most recently used for CY 2023 (87 FR 71788 through 71790). For purposes of estimating outlier payments for CY 2024, we use the hospital-specific overall ancillary CCRs available in the April 2023 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 generally use to model each OPPS update lag by two years.

In order to estimate the CY 2024 hospital outlier payments, we inflate the charges on the CY 2022 claims using the same proposed charge inflation factor of 1.118412 that we used to estimate the IPPS fixed-loss cost threshold for the FY 2024 IPPS/LTCH PPS proposed rule (88 FR 27220). We used an inflation factor of 1.05755 to estimate CY 2023 charges from the CY 2022 charges reported on CY 2022 claims before applying CY 2023 CCRs to estimate the percent of outliers paid in CY 2023. The proposed methodology for determining these charge inflation factors is discussed in the FY 2024 IPPS/LTCH PPS proposed rule (88 FR 27219 and 27220). As we stated in the CY 2005 OPPS final rule with comment period (69 FR 65844 through 65846), we believe that the use of the same 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 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 proposed to apply the same CCR adjustment factor that we proposed to apply for the FY 2024 IPPS outlier calculation to the CCRs used to simulate the proposed CY 2024 OPPS outlier payments to determine the fixed-dollar threshold. Specifically, for CY 2024, we proposed to apply an adjustment factor of 0.977799 to the CCRs that were in the April 2023 OPSF to trend them forward from CY 2023 to CY 2024. The methodology for calculating the proposed CCR adjustment factor, as well as the solicitation of comments on an alternative approach, is discussed in the FY 2024 IPPS/LTCH PPS proposed rule (88 FR 27221).

To model hospital outlier payments for the CY 2024 proposed rule, we applied the overall CCRs from the April 2023 OPSF after adjustment (using the proposed CCR inflation adjustment factor of 0.977799 to approximate CY 2024 CCRs) to charges on CY 2022 claims that were adjusted (using the proposed charge inflation factor of 1.118412 to approximate CY 2024 charges). We simulated aggregated CY 2022 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 2024 OPPS payments. We estimated that a proposed fixed-dollar threshold of $8,350, 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 or intensive outpatient services exceeds 3.40 times the APC payment rate, the outlier payment would be calculated as 50 percent of the amount by which the cost exceeds 3.40 times the APC 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 would 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 Outpatient Quality Reporting (OQR) Program requirements. For hospitals that fail to meet the Hospital OQR Program requirements, we proposed to continue the policy that we implemented in CY 2010 that the hospitals' costs would 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 the CY 2024 OPPS/ASC proposed rule.

We note that in section II.G. of the CY 2024 OPPS/ASC proposed rule and our references here to that proposal, discussion of the proposed fixed-dollar threshold referenced the prior year's proposal of $8,350 rather than the correct proposed threshold, which was $6,875. However, the correct proposed fixed-dollar outlier threshold of $6,875 was used in developing the hospital impacts and was noted in the discussion of the effect of the CY 2024 proposed

rule policies on payments to hospitals (88 FR 49895).

Comment: A commenter expressed concern about the increases in the fixed-dollar outlier threshold, noting that fewer cases would qualify for OPPS outlier payments.

Response: We appreciate the commenter's concern; however, we note that both the incorrect proposed fixed-dollar outlier threshold of $8,350 and the correct proposed threshold of $6,875 are a decrease from the CY 2023 fixed-dollar outlier threshold of $8,625. We have reviewed and analyzed our methodology as well as the most up to date CCRs available in the July 2023 OPSF for determining estimated outlier payments. We continue to believe that they are appropriate for estimating hospital costs for establishing the fixed-dollar outlier threshold.

The fixed-dollar threshold better targets outlier payments to those high-cost and complex procedures where a very costly service could present a hospital with significant financial loss. We maintain the target outlier percentage of 1.0 percent of estimated aggregate total payment under the OPPS and have a fixed-dollar threshold so that OPPS outlier payments are made only when the hospital would experience a significant loss for furnishing a particular service. The methodology we use to calculate the fixed-dollar threshold for the prospective payment year is based on several data inputs that may change from prior payment years. For instance, updated hospital CCR data and changes to the OPPS payment methodology influence projected outlier payments in the prospective year. As a result of those and other factors, the fixed-dollar threshold can also fluctuate from year to year.

In the past several years, we have seen significant increases in the fixed-dollar outlier threshold; however, the proposed CY 2024 fixed-dollar outlier threshold would have decreased relative to CY 2023. Further, we continue to observe a decrease under our final fixed-dollar outlier threshold when compared to the CY 2023. We believe that the changes that we observe in the fixed-dollar outlier threshold accurately reflect changes that hospitals are experiencing in providing healthcare. However, we will continue to monitor changes as more updated data are available.

After consideration of the public comment we received, we are finalizing our proposal, without modification, to continue our policy of estimating outlier payments to be 1.0 percent of the estimated aggregate total payments under the OPPS and to use our established methodology to set the OPPS outlier fixed-dollar loss threshold for CY 2024.

3. Final Outlier Calculation

Consistent with historical practice, we used updated data for this final rule with comment period for outlier calculations. For CY 2024, we are applying the overall CCRs from the July 2023 OPSF file after adjustment (using the CCR adjustment factor of 0.990843 to approximate CY 2024 CCRs) to charges on CY 2022 claims that were adjusted using a charge inflation factor of 1.11904 to approximate CY 2024 charges. These are the same CCR adjustment and charge inflation factors that were used to set the IPPS fixed-dollar thresholds for the FY 2024 IPPS/LTCH PPS final rule (88 FR 59353). We simulated aggregated CY 2024 hospital outlier payments using these costs for several different fixed-dollar thresholds, holding the 1.75 multiple-threshold constant and assuming that outlier payments will 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 payment equaled 1.0 percent of aggregated estimated total CY 2024 OPPS payments. We estimate that a fixed-dollar threshold of $7,750 combined with the multiple threshold of 1.75 times the APC payment rate, will allocate the 1.0 percent of aggregated total OPPS payments to outlier payments.

For CMHCs, if a CMHC's cost for partial hospitalization or intensive outpatient services exceeds 3.40 times the APC payment rate, the outlier payment will be calculated as 50 percent of the amount by which the cost exceeds 3.40 times the APC payment rate.

H. Calculation of an Adjusted Medicare Payment From the National Unadjusted Medicare Payment

The national unadjusted payment rate is the payment rate for most APCs before accounting for the wage index adjustment or any applicable adjustments. 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 2024 OPPS/ASC final rule with comment period, 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 final rule with comment period and the relative payment weight described in section II.A of this final rule with comment period. The national unadjusted payment rate for most APCs contained in Addendum A to this final rule with comment period (which is available via the CMS website ''Hospital Outpatient Regulations and Notices'') and for most HCPCS codes to which separate payment under the OPPS has been assigned in Addendum B to this final rule with comment period (which is available on the CMS website link above) is calculated by multiplying the final CY 2024 scaled weight for the APC by the CY 2024 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 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 final rule with comment period.

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 this final rule with comment period, 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 note 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 would receive for a specific service

from the national unadjusted payment rates presented in Addenda A and B to this final rule with comment period (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 2024 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/ASC final rule with comment period (65 FR 18496 and 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. 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 2024 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 are continuing to apply for the CY 2024 OPPS wage index any adjustments for the FY 2024 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 are applying for the CY 2024 OPPS, we refer readers to section II.C of this final rule with comment period.

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 the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Pub. L. 108–173). Addendum L to this final rule with comment period (which is available via the internet on the CMS website) contains the qualifying counties and the associated wage index increase developed for the final FY 2024 IPPS wage index (which are listed in Table 3 associated with the FY 2024 IPPS/LTCH PPS final rule and available via the internet on the CMS website at: *https://www.cms.gov/medicare/payment/prospective-payment-systems/acute-inpatient-pps*). (Click on the link on the left side of the screen titled ''FY 2024 IPPS Final Rule Home Page'' and select ''FY 2024 Final 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 = labor-portion of the 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 = 0.40 * (national unadjusted payment rate).

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.

Step 7. The adjusted payment rate is the sum of the wage adjusted labor-related portion of the national unadjusted payment rate and the nonlabor-related portion of the national unadjusted payment rate.

X_a is the labor-related portion of the national unadjusted payment rate (wage adjusted).

Y is the nonlabor-related portion of the national unadjusted payment rate.

Adjusted Medicare Payment = $X_a + Y$

We are providing examples below of the calculation of both the full and reduced national unadjusted payment rates that would 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 final CY 2024 full national unadjusted payment rate for APC 5071 is $671.05. The final reduced national adjusted payment rate for APC 5071 for a hospital that fails to meet the Hospital OQR Program requirements is $658.03. This reduced rate is calculated by multiplying the reporting ratio of 0.9806 by the full unadjusted payment rate for APC 5071.

Step 1. The labor-related portion of the final full national unadjusted payment is approximately $402.63 (0.60 * $671.05). The labor-related portion of the final reduced national adjusted payment is approximately $394.82 (0.60 * $658.03).

Step 2 & 3. The FY 2024 wage index for a provider located in CBSA 35614 in New York, which includes the adoption of the final IPPS 2024 wage index policies, is 1.3562.

Step 4. The wage adjusted labor-related portion of the final full national unadjusted payment is approximately $546.05 ($402.63 *1.3562). The wage adjusted labor-related portion of the final reduced national adjusted payment is approximately $535.45 ($394.82 * 1.3562).

Step 5. The nonlabor-related portion of the final full national unadjusted payment is approximately $268.42 (0.40 * $671.05). The nonlabor-related portion of the final reduced national adjusted payment is approximately $263.21 (0.40 * $658.03).

Step 6. For this example of a provider located in Brooklyn, New York, the rural adjustment for rural SCHs does not apply.

Step 7. The sum of the labor-related and nonlabor-related portions of the final full national unadjusted payment is approximately $814.47 ($546.05 + $268.42). The sum of the portions of the final reduced national adjusted payment is approximately $798.66 ($535.45 + $263.21) as shown in Table 7.

TABLE 7: FINAL FULL NATIONAL UNADJUSTED PAYMENT RATE AND FINAL REDUCED NATIONAL ADJUSTED PAYMENT RATE

Final Full national unadjusted payment rate	Final Reduced national adjusted payment rate
$814.47	$798.66

We did not receive any public comments on these steps under the methodology that we included in the CY 2024 OPPS/ASC proposed rule to determine the APC payments for CY 2024. Therefore, we are using the steps in the methodology specified above, to demonstrate the calculation of the final CY 2024 OPPS payments using the same parameters.

I. 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. For a discussion of the changes made by the Affordable Care Act with regard to copayments for preventive services furnished on and after January 1, 2011, we refer readers to section XII.B of the CY 2011 OPPS/ASC final rule with comment period (75 FR 72013).

Section 122 of the Consolidated Appropriations Act (CAA) of 2021 (Pub. L. 116–260), Waiving Medicare Coinsurance for Certain Colorectal Cancer Screening Tests, amends section 1833(a) of the Act to offer a special coinsurance rule for screening flexible sigmoidoscopies and screening colonoscopies, regardless of the code that is billed for the establishment of a diagnosis as a result of the test, or for the removal of tissue or other matter or other procedure, that is furnished in connection with, as a result of, and in the same clinical encounter as the colorectal cancer screening test. We refer readers to section X.B of the CY 2022 OPPS/ASC final rule with comment period for the full discussion of this policy (86 FR 63740 through 63743). Under the regulation at 42 CFR 410.152(l)(5)(i)(B), the Medicare Part B payment percentage for colorectal cancer screening tests described in the regulation at § 410.37(j) that are furnished in CY 2023 through 2026 is 85 percent, with beneficiary coinsurance equal to 15 percent.

On August 16, 2022, the Inflation Reduction Act of 2022 (IRA) (Pub. L. 117–169) was signed into law. Section 11101(a) of the IRA amended section 1847A of the Act by adding a new subsection (i), which requires the payment of rebates into the Supplementary Medical Insurance Trust Fund for Part B rebatable drugs if the payment limit amount exceeds the inflation-adjusted payment amount, which is calculated as set forth in section 1847A(i)(3)(C) of the Act. The provisions of section 11101 of the IRA are currently being implemented through program instruction, as permitted under section 1847A(c)(5)(C) of the Act. As such, we issued guidance for the computation of inflation-adjusted beneficiary coinsurance under section 1847A(i)(5) of the Act and amounts paid under section 1833(a)(1)(EE) of the Act on February 9, 2023.[4] [5] For additional information regarding implementation of section 11101 of the IRA, please see the inflation rebates resources page at *https://www.cms.gov/inflation-reduction-act-and-medicare/inflation-rebates-medicare.* We also refer readers

[4] *https://www.cms.gov/files/document/medicare-part-b-inflation-rebate-program-initial-guidance.pdf.*

[5] In addition, beginning with the April 2023 ASP Drug Pricing file, the file includes the coinsurance percentage for each drug and specifies ''inflation-adjusted coinsurance'' in the ''Notes'' column if the coinsurance for a drug is less than 20 percent of the Medicare Part B payment amount. Drug pricing files are available at *https://www.cms.gov/medicare/medicare-fee-for-service-part-b-drugs/mcrpartbdrugavgsalesprice.*

to the CY 2024 PFS proposed rule (88 FR 52262) for a detailed discussion of proposals related to inflation-adjusted beneficiary coinsurance and Medicare payment for Medicare Part B rebatable drugs.

Section 11101(b) of the IRA amended sections 1833(i) and 1833(t)(8) of the Act by adding a new paragraph (9) and subparagraph (F), respectively. Section 1833(i)(9) requires under the ASC payment system that in the case of a Part B rebatable drug, in lieu of calculation of coinsurance that would otherwise apply under the ASC payment system, the provisions of section 1847A(i)(5) of the Act shall, as determined appropriate by the Secretary, apply for calculation of beneficiary coinsurance in the same manner as the provisions of section 1847A(i)(5) of the Act apply under that section. Similarly, section 1833(t)(8)(F) of the Act requires under the OPPS that in the case of a Part B rebatable drug (except for a drug that has no copayment applied under subparagraph (E) of such section or for which payment is packaged into the payment for a covered OPD service or group of services), in lieu of the calculation of the copayment amount that would otherwise apply under the OPPS, the provisions of section 1847A(i)(5) of the Act shall, as determined appropriate by the Secretary, apply in the same manner as the provisions of section 1847A(i)(5) of the Act apply under that section. Section 1847A(i)(5) of the Act requires that for Part B rebatable drugs, as defined in section 1847A(i)(2)(A) of the Act, furnished on or after April 1, 2023, in calendar quarters in which the amount specified in section 1847A(i)(3)(A)(ii)(I) of the Act (or, in the case of selected drugs described under section 1192(c) of the Act, the amount specified in section 1847A(b)(1)(B) of the Act), exceeds the inflation-adjusted payment amount determined in accordance with section 1847A(i)(3)(C) of the Act, the coinsurance will be 20 percent of the inflation-adjusted payment amount for such quarter (hereafter, the inflation-adjusted coinsurance amount). This inflation-adjusted coinsurance amount is applied as a percent, as determined by the Secretary, to the payment amount that would otherwise apply for such calendar quarter in accordance with section 1847A(b)(1)(B) or (C) of the Act, as applicable, including in the case of a selected drug.

Paragraph (9) of section 1833(i) of the Act and subparagraph (F) of section 1833(t)(8) of the Act, as added by section 11101(b) of the IRA, also provide that in lieu of the amounts of payment otherwise applicable under the ASC payment system and the OPPS, the provisions of paragraph (1)(EE) of subsection (a) of section 1833 of the Act shall apply, as determined appropriate by the Secretary. Section 11101(b) of the IRA amended section 1833(a)(1) of the Act by adding a new subparagraph (EE), which requires that if the specific payment amount described in section 1847A(i)(3)(A)(ii)(I) of the Act (or, in the case of a selected drug, the payment amount described in section 1847A(b)(1)(B) of the Act) exceeds the inflation-adjusted payment amount of a Part B rebatable drug, the Part B payment will, subject to the deductible and sequestration, equal the difference between such payment amount and the inflation-adjusted coinsurance amount.

In the CY 2024 OPPS/ASC proposed rule, we proposed to codify the OPPS program payment and cost sharing amounts for Part B rebatable drugs as required by section 1833(t)(8)(F) by adding a new paragraph (e) to § 419.41, which cross-references the regulations proposed in the CY 2024 PFS proposed rule (§§ 410.152(m) and 489.30(b)(6)). We also proposed to amend the regulation text to reflect our longstanding policies for calculating the Medicare program payment and cost sharing amounts for separately payable drugs and biologicals by adding a new paragraph (d) to § 419.41. Similarly, we proposed to codify the ASC cost sharing amounts for Part B rebatable drugs as required by section 1833(i)(9) of the Act by revising § 416.172(d) to include a cross-reference to 42 CFR 489.30(b)(6), as proposed in the CY 2024 PFS proposed rule to codify the cost sharing amounts for Part B rebatable drugs with prices increasing at a rate faster than inflation. We did not propose any changes to the ASC regulations at 42 CFR part 416 to reflect the Medicare payment amount for Part B rebatable drugs with prices increasing at a rate faster than inflation, because 42 CFR 416.171(b) already incorporates, for the ASC payment system, the payment amounts that apply for the OPPS under 42 CFR part 419. Part 419 would include our proposed new § 419.41(e), which addresses Medicare payment for Part B rebatable drugs under the OPPS.

We did not receive any public comments on our proposal to codify amendments to §§ 419.41 and 416.172. Therefore, we are finalizing our proposal to codify the OPPS program payment and cost sharing amounts for Part B rebatable drugs as required by section 1833(t)(8)(F) of the Act by adding a new paragraph (e) to § 419.41. We are also finalizing our proposal to amend the regulation text to reflect our longstanding policies for calculating the Medicare program payment and cost sharing amounts for separately payable drugs and biologicals by adding a new paragraph (d) to § 419.41. We are finalizing our proposal to codify the ASC cost sharing amounts for Part B rebatable drugs as required by section 1833(i)(9) of the Act by revising § 416.172(d) to include a cross-reference to 42 CFR 489.30(b)(6), as finalized in the CY 2024 PFS final rule to codify the cost sharing amounts for Part B rebatable drugs with prices increasing at a rate faster than inflation.

Comment: A commenter pointed out an error in the preamble of the CY 2024 OPPS/ASC proposed rule related to the rebatable drugs under the IRA. Specifically, the commenter noted that the preamble language incorrectly suggested that a provider is paid the amount specified in section 1833(a)(1)(EE) with respect to a Part B rebatable drug when the inflation-adjusted amount exceeds the specified payment amount, which is the inverse of what the statute provides and therefore, is incorrect.

Response: We thank the commenter for pointing out the error where the references to the specified payment amount and the inflation-adjusted amount were inadvertently transposed in the preamble. We have corrected the preamble for this final rule with comment period.

2. OPPS Copayment Policy

For CY 2024, we proposed 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 for a discussion of that methodology (68 FR 63458).) In addition, we proposed 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 final national unadjusted copayment amounts for services payable under the OPPS that would be effective January 1, 2024, are included in Addenda A and B to this final rule with comment period (which are available via the internet on the CMS website).

As discussed in section XIV.E of the CY 2024 OPPS/ASC proposed rule (88

FR 49594) and this final rule with comment period, for CY 2024, 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 and 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).

We did not receive any public comments on our proposal, and we are finalizing our proposal to determine copayment amounts for new and revised APCs using the same methodology that we implemented beginning in CY 2004. In addition, we are finalizing the use of 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 finalized national unadjusted copayment amounts for services payable under the OPPS that would be effective January 1, 2024, are included in Addenda A and B to this final rule with comment period (which are available via the internet on the CMS website).

3. 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, $134.21 is approximately 20 percent of the full national unadjusted payment rate of $671.05. For APCs with only a minimum unadjusted copayment in Addenda A and B to this final rule with comment period (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 this with comment period. Calculate the rural adjustment for eligible providers, as indicated in Step 6 under section II.H of this final rule with comment period.

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 this final rule with comment period, 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 0.9806.

The finalized unadjusted copayments for services payable under the OPPS that would be effective January 1, 2024, are shown in Addenda A and B to this final rule with comment period (which are available via the CMS website). We note that the final national unadjusted payment rates and copayment rates shown in Addenda A and B to this final rule with comment period reflect the CY 2024 OPD fee schedule increase factor discussed in section II.B of this final rule with comment period.

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. 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. HCPCS codes are used to report surgical procedures, medical services, items, and supplies under the hospital OPPS. 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 that is established and maintained by the American Medical Association (AMA), and consists of Category I, II, III, multianalyte assays with algorithmic analyses (MAAA), and proprietary laboratory analyses (PLAA) CPT codes. Level II, which is established and 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 OPPS payment system. Specifically, we recognize 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;
- MAAA CPT codes, which describe laboratory multianalyte assays with algorithmic analyses (MAA);
- PLA CPT codes, which describe proprietary laboratory analyses (PLA) services; 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.

The 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 (via their website) 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 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 the 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, status indicators, and APC assignments through our annual rulemaking process.

We note that, under the OPPS, the APC assignment determines the payment rate for an item, procedure, or service. The items, procedures, or services not exclusively 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. (CY 2024 Payment Status and Comment Indicators) of this final rule with comment period, 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 final rule with comment period.

1. April 2023 HCPCS Codes Proposed Rule Comment Solicitation

For the April 2023 update, 67 new HCPCS codes were established and made effective on April 1, 2023. Through the April 2023 OPPS quarterly update CR (Transmittal 11937, Change Request 13136, dated March 31, 2023), we recognized several new HCPCS codes for separate payment under the OPPS. We solicited public comments on the proposed APC and status indicator assignments for the codes listed in Table 6 (New HCPCS Codes Effective April 1, 2023) of the CY 2024 OPPS/ASC proposed rule (88 FR 49595 through 49599), which are also displayed in Table 8.

We received some public comments on the proposed OPPS APC and SI assignments for the new Level II HCPCS codes implemented in April 2023. The comments and our responses are addressed in their respective sections of this final rule with comment period, which include, but are not limited to: sections III.C. (New Technology APCs), III.E. (OPPS APC-Specific Policies), and IV. (OPPS Payment for Devices). For those April 2023 codes for which we received no comments, we are finalizing the proposed APC and status indicator assignments. We note that several of the HCPCS C-codes have been replaced with HCPCS J-codes, effective January 1, 2024. Their replacement codes are listed in Table 8. In addition, in prior years we included the final OPPS status indicators and APC assignments in the coding preamble tables, however, because the same information can be found in Addendum B, we are no longer including them in Table 8. Therefore, readers are advised to refer to the OPPS Addendum B for the final OPPS status indicators, APC assignments, and payment rates for all codes reportable under the hospital OPPS. These new codes that were effective April 1, 2023, were assigned to comment indicator ''NP'' in Addendum B to the CY 2024 OPPS/ASC proposed rule to indicate that the codes are assigned to an interim APC assignment and comments would be accepted on their interim APC assignments. The complete list of status indicators and definitions used under the OPPS can be found in Addendum D1 to this final rule with comment period, while the complete list of comment indicators and definitions can be found in Addendum D2 to this final rule with comment period. We note that OPPS Addendum B (OPPS payment file by HCPCS code), Addendum D1 (OPPS Status Indicators), and Addendum D2 (OPPS Comment Indicators) are available via the internet on the CMS website.

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TABLE 8: NEW HCPCS CODES EFFECTIVE APRIL 1, 2023

April 2023 HCPCS Code	CY 2024 HCPCS Code	CY 2024 Long Descriptor
A2019	A2019	Kerecis omega3 marigen shield, per square centimeter
A2020	A2020	Ac5 advanced wound system (ac5)
A2021	A2021	Neomatrix, per square centimeter
A4341	A4341	Indwelling intraurethral drainage device with valve, patient inserted, replacement only, each
A4342	A4342	Accessories for patient inserted indwelling intraurethral drainage device with valve, replacement only, each
A4560	A4560	Neuromuscular electrical stimulator (nmes), disposable, replacement only
A6590	A6590	External urinary catheters; disposable, with wicking material, for use with suction pump, per month
A6591	A6591	External urinary catheter; non-disposable, for use with suction pump, per month
A7049	A7049	Expiratory positive airway pressure intranasal resistance valve
C9145	C9145	Injection, aprepitant, (aponvie), 1 mg
C9146	J9063	Injection, mirvetuximab soravtansine-gynx, 1 mg
C9147	J9347	Injection, tremelimumab-actl, 1 mg
C9148	J9380	Injection, teclistamab-cqyv, 0.5 mg
C9149	J9381	Injection, teplizumab-mzwv, 5 mcg
E0677	E0677	Non-pneumatic sequential compression garment, trunk
E0711	E0711	Upper extremity medical tubing/lines enclosure or covering device, restricts elbow range of motion
E1905	E1905	Virtual reality cognitive behavioral therapy device (cbt), including pre-programmed therapy software
J0208	J0208	Injection, sodium thiosulfate, 100 mg
J0218	J0218	Injection, olipudase alfa-rpcp, 1 mg
J0612	J0612	Injection, calcium gluconate (fresenius kabi), per 10 mg
J0613	J0613	Injection, calcium gluconate (wg critical care), per 10 mg
J1411	J1411	Injection, etranacogene dezaparvovec-drlb, per therapeutic dose
J1449	J1449	Injection, eflapegrastim-xnst, 0.1 mg
J1747	J1747	Injection, spesolimab-sbzo, 1 mg
J2403	J2403	Chloroprocaine hcl ophthalmic, 3% gel, 1 mg
J9196	J9196	Injection, gemcitabine hydrochloride (accord), not therapeutically equivalent to j9201, 200 mg
J9294	J9294	Injection, pemetrexed (hospira) not therapeutically equivalent to j9305, 10 mg
J9296	J9296	Injection, pemetrexed (accord) not therapeutically equivalent to j9305, 10 mg
J9297	J9297	Injection, pemetrexed (sandoz), not therapeutically equivalent to j9305, 10 mg
K1035	K1035	Molecular diagnostic test reader, nonprescription self-administered and self-collected use, fda approved, authorized or cleared
L8678	L8678	Electrical stimulator supplies (external) for use with implantable neurostimulator, per month
M0010	M0010	Enhancing oncology model (eom) monthly enhanced oncology services (meos) payment for eom enhanced services
Q4265	Q4265	Neostim tl, per square centimeter
Q4266	Q4266	Neostim membrane, per square centimeter

April 2023 HCPCS Code	CY 2024 HCPCS Code	CY 2024 Long Descriptor
Q4267	Q4267	Neostim dl, per square centimeter
Q4268	Q4268	Surgraft ft, per square centimeter
Q4269	Q4269	Surgraft xt, per square centimeter
Q4270	Q4270	Complete sl, per square centimeter
Q4271	Q4271	Complete ft, per square centimeter
Q5127	Q5127	Injection, pegfilgrastim-fpgk (stimufend), biosimilar, 0.5 mg
Q5128	Q5128	Injection, ranibizumab-eqrn (cimerli), biosimilar, 0.1 mg
Q5129	Q5129	Injection, bevacizumab-adcd (vegzelma), biosimilar, 10 mg
Q5130	Q5130	Injection, pegfilgrastim-pbbk (fylnetra), biosimilar, 0.5 mg
0364U	0364U	Oncology (hematolymphoid neoplasm), genomic sequence analysis using multiplex (PCR) and next-generation sequencing with algorithm, quantification of dominant clonal sequence(s), reported as presence or absence of minimal residual disease (MRD) with quantitation of disease burden, when appropriate
0365U	0365U	Oncology (bladder), analysis of 10 protein biomarkers (A1AT, ANG, APOE, CA9, IL8, MMP9, MMP10, PAI1, SDC1 and VEGFA) by immunoassays, urine, algorithm reported as a probability of bladder cancer
0366U	0366U	Oncology (bladder), analysis of 10 protein biomarkers (A1AT, ANG, APOE, CA9, IL8, MMP9, MMP10, PAI1, SDC1 and VEGFA) by immunoassays, urine, algorithm reported as a probability of recurrent bladder cancer
0367U	0367U	Oncology (bladder), analysis of 10 protein biomarkers (A1AT, ANG, APOE, CA9, IL8, MMP9, MMP10, PAI1, SDC1 and VEGFA) by immunoassays, urine, diagnostic algorithm reported as a risk score for probability of rapid recurrence of recurrent or persistent cancer following transurethral resection
0368U	0368U	Oncology (colorectal cancer), evaluation for mutations of APC, BRAF, CTNNB1, KRAS, NRAS, PIK3CA, SMAD4, and TP53, and methylation markers (MYO1G, KCNQ5, C9ORF50, FLI1, CLIP4, ZNF132 and TWIST1), multiplex quantitative polymerase chain reaction (qPCR), circulating cell-free DNA (cfDNA), plasma, report of risk score for advanced adenoma or colorectal cancer
0369U	0369U	Infectious agent detection by nucleic acid (DNA and RNA), gastrointestinal pathogens, 31 bacterial, viral, and parasitic organisms and identification of 21 associated antibiotic-resistance genes, multiplex amplified probe technique
0370U	0370U	Infectious agent detection by nucleic acid (DNA and RNA), surgical wound pathogens, 34 microorganisms and identification of 21 associated antibioticresistance genes, multiplex amplified probe technique, wound swab
0371U	0371U	Infectious agent detection by nucleic acid (DNA or RNA), genitourinary pathogen, semiquantitative identification, DNA from 16 bacterial organisms and 1 fungal organism, multiplex amplified probe technique via quantitative polymerase chain reaction (qPCR), urine
0372U	0372U	Infectious disease (genitourinary pathogens), antibiotic-resistance gene detection, multiplex amplified probe technique, urine, reported as an antimicrobial stewardship risk score
0373U	0373U	Infectious agent detection by nucleic acid (DNA and RNA), respiratory tract infection, 17 bacteria, 8 fungus, 13 virus, and 16 antibiotic-resistance genes, multiplex amplified probe technique, upper or lower respiratory specimen
0374U	0374U	Infectious agent detection by nucleic acid (DNA or RNA), genitourinary pathogens, identification of 21 bacterial and fungal organisms and identification of 21 associated antibiotic-resistance genes, multiplex amplified probe technique, urine

April 2023 HCPCS Code	CY 2024 HCPCS Code	CY 2024 Long Descriptor
0375U	0375U	Oncology (ovarian), biochemical assays of 7 proteins (follicle stimulating hormone, human epididymis protein 4, apolipoprotein A-1, transferrin, beta-2 macroglobulin, prealbumin [ie, transthyretin], and cancer antigen 125), algorithm reported as ovarian cancer risk score
0376U	0376U	Oncology (prostate cancer), image analysis of at least 128 histologic features and clinical factors, prognostic algorithm determining the risk of distant metastases, and prostate cancerspecific mortality, includes predictive algorithm to androgen deprivationtherapy response, if appropriate
0377U	0377U	Cardiovascular disease, quantification of advanced serum or plasma lipoprotein profile, by nuclear magnetic resonance (NMR) spectrometry with report of a lipoprotein profile (including 23 variables)
0378U	0378U	RFC1 (replication factor C subunit 1), repeat expansion variant analysis by traditional and repeat-primed PCR, blood, saliva, or buccal swab
0379U	0379U	Targeted genomic sequence analysis panel, solid organ neoplasm, DNA (523 genes) and RNA (55 genes) by nextgeneration sequencing, interrogation for sequence variants, gene copy number amplifications, gene rearrangements, microsatellite instability, and tumor mutational burden
0380U	0380U	Drug metabolism (adverse drug reactions and drug response), targeted sequence analysis, 20 gene variants and CYP2D6 deletion or duplication analysis with reported genotype and phenotype
0381U	0381U	Maple syrup urine disease monitoring by patient-collected blood card sample, quantitative measurement of alloisoleucine, leucine, isoleucine, and valine, liquid chromatography with tandem mass spectrometry (LCMS/MS)
0382U	0382U	Hyperphenylalaninemia monitoring by patient-collected blood card sample, quantitative measurement of phenylalanine and tyrosine, liquid chromatography with tandem mass spectrometry (LC-MS/MS)
0383U	0383U	Tyrosinemia type I monitoring by patient-collected blood card sample, quantitative measurement of tyrosine, phenylalanine, methionine, succinylacetone, nitisinone, liquid chromatography with tandem mass spectrometry (LC-MS/MS)
0384U	0384U	Nephrology (chronic kidney disease), carboxymethyllysine, methylglyoxal hydroimidazolone, and carboxyethyl lysine by liquid chromatography with tandem mass spectrometry (LCMS/MS) and HbA1c and estimated glomerular filtration rate (GFR), with risk score reported for predictive progression to high-stage kidney disease
0385U	0385U	Nephrology (chronic kidney disease), apolipoprotein A4 (ApoA4), CD5 antigen-like (CD5L), and insulin-like growth factor binding protein 3 (IGFBP3) by enzyme-linked immunoassay (ELISA), plasma, algorithm combining results with HDL, estimated glomerular filtration rate (GFR) and clinical data reported as a risk score for developing diabetic kidney disease
0386U*		Gastroenterology (Barrett's esophagus), P16, RUNX3, HPP1, and FBN1 methylation analysis, prognostic and predictive algorithm reported as a risk score for progression to high-grade dysplasia or esophageal cancer

*CPT code 0386U was deleted on September 30, 2023, with no replacement code.

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2. July 2023 HCPCS Codes Proposed Rule Comment Solicitation

For the July 2023 update, 97 new codes were established and made effective July 1, 2023. Through the July 2023 OPPS quarterly update CR (Transmittal 12077, Change Request 13210, dated June 13, 2023), we recognized several new codes for separate payment and assigned them to appropriate interim OPPS status indicators and APCs. We solicited public comments on the proposed APC and status indicator assignments for the codes listed in Table 7 (New HCPCS Codes Effective July 1, 2023) of the CY 2024 OPPS/ASC proposed rule (88 FR 49599–49605), which are also listed in Table 9.

We received some public comments on the proposed OPPS APC and SI assignments for the new Level II HCPCS codes implemented on July 1, 2023. The comments and our responses are addressed in their respective sections of this final rule with comment period, which include, but are not limited to: sections III.C (New Technology APCs), III.E (OPPS APC-Specific Policies), and IV (OPPS Payment for Devices). For those July 1, 2023, codes for which we received no comments, we are finalizing the proposed APC and status indicator assignments. We note that one HCPCS C-code has been replaced with a HCPCS J-code. The replacement code is listed in Table 9. Additionally, we note that in prior years we included the final OPPS status indicators and APC assignments in the coding preamble tables, however, because the same information can be found in Addendum B, we are no longer including them in Table 9. Therefore, readers are advised to refer to the OPPS Addendum B for the final OPPS status indicators, APC assignments, and payment rates for all codes reportable under the hospital OPPS. These new codes that were effective July 1, 2023, were assigned to comment indicator ''NP'' in Addendum B to the CY 2024 OPPS/ASC proposed rule to indicate that the codes are assigned to an interim APC assignment and comments would be accepted on their interim APC assignments. The complete list of status indicators and definitions used under the OPPS can be found in Addendum D1 to this final rule with comment period, while the complete list of comment indicators and definitions can be found in Addendum D2 to this final rule with comment period. We note that OPPS Addendum B (OPPS payment file by HCPCS code), Addendum D1 (OPPS Status Indicators), and Addendum D2 (OPPS Comment Indicators) are available via the internet on the CMS website.

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TABLE 9: NEW HCPCS CODES EFFECTIVE JULY 1, 2023

July 2023 HCPCS Code	CY 2024 HCPCS Code	CY 2024 Long Descriptor
C9150	C9150	Xenon Xe-129 hyperpolarized gas, diagnostic, per study dose
C9151	J2781	Injection, pegcetacoplan, intravitreal, 1 mg
C9784	C9784	Gastric restrictive procedure, endoscopic sleeve gastroplasty, with esophagogastroduodenoscopy and intraluminal tube insertion, if performed, including all system and tissue anchoring components
C9785	C9785	Endoscopic outlet reduction, gastric pouch application, with endoscopy and intraluminal tube insertion, if performed, including all system and tissue anchoring components.
C9786	C9786	Echocardiography image post processing for computer aided detection of heart failure with preserved ejection fraction, including interpretation and report
C9787	C9787	Gastric electrophysiology mapping with simultaneous patient symptom profiling
J0137	J0137	Injection, acetaminophen (hikma) not therapeutically equivalent to J0131, 10 mg
J0206	J0206	Injection, allopurinol sodium, 1 mg
J0216	J0216	Injection, alfentanil hydrochloride, 500 micrograms
J0457	J0457	Injection, aztreonam, 100 mg
J0665	J0665	Injection, bupivicaine, not otherwise specified, 0.5 mg
J0736	J0736	Injection, clindamycin phosphate, 300 mg
J0737	J0737	Injection, clindamycin phosphate (baxter), not therapeutically equivalent to J0736, 300 mg
J1440	J1440	Fecal microbiota, live - jslm, 1 ml
J1576	J1576	Injection, immune globulin (panzyga), intravenous, non-lyophilized (e.g., liquid), 500 mg
J1805	J1805	Injection, esmolol hydrochloride, 10 mg
J1806	J1806	Injection, esmolol hydrochloride (wg critical care) not therapeutically equivalent to J1805, 10 mg
J1811	J1811	Insulin (fiasp) for administration through dme (i.e., insulin pump) per 50 units
J1812	J1812	Insulin (fiasp), per 5 units
J1813	J1813	Insulin (lyumjev) for administration through dme (i.e., insulin pump) per 50 units
J1814	J1814	Insulin (lyumjev), per 5 units
J1836	J1836	Injection, metronidazole, 10 mg
J1920	J1920	Injection, labetalol hydrochloride, 5 mg
J1921	J1921	Injection, labetalol hydrochloride (hikma) not therapeutically equivalent to J1820, 5 mg
J1941	J1941	Injection, furosemide (furoscix), 20 mg
J1961	J1961	Injection, lenacapavir, 1 mg
J2249	J2249	Injection, remimazolam, 1 mg
J2305	J2305	Injection, nitroglycerin, 5 mg
J2329	J2329	Injection, ublituximab-xiiy, 1mg

July 2023 HCPCS Code	CY 2024 HCPCS Code	CY 2024 Long Descriptor
J2371	J2371	Injection, phenylephrine hydrochloride, 20 micrograms
J2372	J2372	Injection, phenylephrine hydrochloride (biorphen), 20 micrograms
J2427	J2427	Injection, paliperidone palmitate extended release (invega hafyera, or invega trinza), 1 mg
J2561	J2561	Injection, phenobarbital sodium (sezaby), 1 mg
J2598	J2598	Injection, vasopressin, 1 unit
J2599	J2599	Injection, vasopressin (american regent) not therapeutically equivalent to J2598, 1 unit
J2806	J2806	Injection, sincalide (maia) not therapeutically equivalent to j2805, 5 micrograms
J7213	J7213	Injection, coagulation factor ix (recombinant), ixinity, 1 i.u.
J9029	J9029	Injection, nadofaragene firadenovec-vncg, per therapeutic dose
J9056	J9056	Injection, bendamustine hydrochloride (vivimusta), 1 mg
J9058	J9058	Injection, bendamustine hydrochloride (apotex), 1 mg
J9059	J9059	Injection, bendamustine hydrochloride (baxter), 1 mg
J9063	J9063	Injection, mirvetuximab soravtansine-gynx, 1 mg
J9259	J9259	Injection, paclitaxel protein-bound particles (american regent) not therapeutically equivalent to j9264, 1 mg
J9322	J9322	Injection, pemetrexed (bluepoint) not therapeutically equivalent to J9305, 10 mg
J9323	J9323	Injection, pemetrexed ditromethamine, 10 mg
J9347	J9347	Injection, tremelimumab-actl, 1 mg
J9350	J9350	Injection, mosunetuzumab-axgb, 1 mg
J9380	J9380	Injection, teclistamab-cqyv, 0.5 mg
J9381	J9381	Injection, teplizumab-mzwv, 5 mcg
Q4272	Q4272	ESA no a, per square centimeter
Q4273	Q4273	Eason air, per square centimeter
Q4274	Q4274	ESA no ac, per square centimeter
Q4275	Q4275	Eason aca, per square centimeter
Q4276	Q4276	Orion, per square centimeter
Q4277	Q4277	Woundplus membrane or e-graft, per square centimeter
Q4278	Q4278	Epieffect, per square centimeter
Q4280	Q4280	Xcell amnio matrix, per square centimeter
Q4281	Q4281	Barrera sl or barrera dl, per square centimeter
Q4282	Q4282	Cygnus dual, per square centimeter
Q4283	Q4283	Biovance tri-layer or biovance 3l, per square centimeter
Q4284	Q4284	Dermabind sl, per square centimeter
Q5131	Q5131	Injection, adalimumab-aacf (idacio), biosimilar, 20 mg
0791T	0791T	Motor-cognitive, semi-immersive virtual reality–facilitated gait training, each 15 minutes (List separately in addition to code for primary procedure)

July 2023 HCPCS Code	CY 2024 HCPCS Code	CY 2024 Long Descriptor
0792T	0792T	Application of silver diamine fluoride 38%, by a physician or other qualified health care professional
0793T	0793T	Percutaneous transcatheter thermal ablation of nerves innervating the pulmonary arteries, including right heart catheterization, pulmonary artery angiography, and all imaging guidance
0794T	0794T	Patient-specific, assistive, rules-based algorithm for ranking pharmaco-oncologic treatment options based on the patient's tumor-specific cancer marker information obtained from prior molecular pathology, immunohistochemical, or other pathology results which have been previously interpreted and reported separately
0795T	0795T	Transcatheter insertion of permanent dual-chamber leadless pacemaker, including imaging guidance (eg, fluoroscopy, venous ultrasound, right atrial angiography, right ventriculography, femoral venography) and device evaluation (eg, interrogation or programming), when performed; complete system (ie, right atrial and right ventricular pacemaker components)
0796T	0796T	Transcatheter insertion of permanent dual-chamber leadless pacemaker, including imaging guidance (eg, fluoroscopy, venous ultrasound, right atrial angiography, right ventriculography, femoral venography) and device evaluation (eg, interrogation or programming), when performed; right atrial pacemaker component (when an existing right ventricular single leadless pacemaker exists to create a dual-chamber leadless pacemaker system)
0797T	0797T	Transcatheter insertion of permanent dual-chamber leadless pacemaker, including imaging guidance (eg, fluoroscopy, venous ultrasound, right atrial angiography, right ventriculography, femoral venography) and device evaluation (eg, interrogation or programming), when performed; right ventricular pacemaker component (when part of a dual-chamber leadless pacemaker system)
0798T	0798T	Transcatheter removal of permanent dual-chamber leadless pacemaker, including imaging guidance (eg, fluoroscopy, venous ultrasound, right atrial angiography, right ventriculography, femoral venography), when performed; complete system (ie, right atrial and right ventricular pacemaker components)
0799T	0799T	Transcatheter removal of permanent dual-chamber leadless pacemaker, including imaging guidance (eg, fluoroscopy, venous ultrasound, right atrial angiography, right ventriculography, femoral venography), when performed; right atrial pacemaker component
0800T	0800T	Transcatheter removal of permanent dual-chamber leadless pacemaker, including imaging guidance (eg, fluoroscopy, venous ultrasound, right atrial angiography, right ventriculography, femoral venography), when performed; right ventricular pacemaker component (when part of a dual-chamber leadless pacemaker system)
0801T	0801T	Transcatheter removal and replacement of permanent dual-chamber leadless pacemaker, including imaging guidance (eg, fluoroscopy, venous ultrasound, right atrial angiography, right ventriculography, femoral venography) and device evaluation (eg, interrogation or programming), when performed; dual-chamber system (ie, right atrial and right ventricular pacemaker components)

July 2023 HCPCS Code	CY 2024 HCPCS Code	CY 2024 Long Descriptor
0802T	0802T	Transcatheter removal and replacement of permanent dual-chamber leadless pacemaker, including imaging guidance (eg, fluoroscopy, venous ultrasound, right atrial angiography, right ventriculography, femoral venography) and device evaluation (eg, interrogation or programming), when performed; right atrial pacemaker component
0803T	0803T	Transcatheter removal and replacement of permanent dual-chamber leadless pacemaker, including imaging guidance (eg, fluoroscopy, venous ultrasound, right atrial angiography, right ventriculography, femoral venography) and device evaluation (eg, interrogation or programming), when performed; right ventricular pacemaker component (when part of a dual-chamber leadless pacemaker system)
0804T	0804T	Programming device evaluation (in person) with iterative adjustment of implantable device to test the function of device and to select optimal permanent programmed values, with analysis, review, and report, by a physician or other qualified health care professional, leadless pacemaker system in dual cardiac chambers
0805T	0805T	Transcatheter superior and inferior vena cava prosthetic valve implantation (ie, caval valve implantation [CAVI]); percutaneous femoral vein approach
0806T	0806T	Transcatheter superior and inferior vena cava prosthetic valve implantation (ie, caval valve implantation [CAVI]); open femoral vein approach
0807T	0807T	Pulmonary tissue ventilation analysis using software-based processing of data from separately captured cinefluorograph images; in combination with previously acquired computed tomography (CT) images, including data preparation and transmission, quantification of pulmonary tissue ventilation, data review, interpretation and report
0808T	0808T	Pulmonary tissue ventilation analysis using software-based processing of data from separately captured cinefluorograph images; in combination with computed tomography (CT) images taken for the purpose of pulmonary tissue ventilation analysis, including data preparation and transmission, quantification of pulmonary tissue ventilation, data review, interpretation and report
0809T*	N/A	Arthrodesis, sacroiliac joint, percutaneous or minimally invasive (indirect visualization), with image guidance, placement of transfixing device(s) and intra-articular implant(s), including allograft or synthetic device(s)
0810T	0810T	Subretinal injection of a pharmacologic agent, including vitrectomy and 1 or more retinotomies
0387U	0387U	Oncology (melanoma), autophagy and beclin 1 regulator 1 (AMBRA1) and loricrin (AMLo) by immunohistochemistry, formalinfixed paraffin-embedded (FFPE) tissue, report for risk of progression
0388U	0388U	Oncology (non-small cell lung cancer), next-generation sequencing with identification of single nucleotide variants, copy number variants, insertions and deletions, and structural variants in 37 cancer-related genes, plasma, with report for alteration detection
0389U	0389U	Pediatric febrile illness (Kawasaki disease [KD]), interferon alphainducible protein 27 (IFI27) and mast cell-expressed membrane protein 1 (MCEMP1), RNA, using reverse transcription polymerase chain reaction (RT-qPCR), blood, reported as a risk score for KD

July 2023 HCPCS Code	CY 2024 HCPCS Code	CY 2024 Long Descriptor
0390U	0390U	Obstetrics (preeclampsia), kinase insert domain receptor (KDR), Endoglin (ENG), and retinol-binding protein 4 (RBP4), by immunoassay, serum, algorithm reported as a risk score
0391U	0391U	Oncology (solid tumor), DNA and RNA by next-generation sequencing, utilizing formalin-fixed paraffin-embedded (FFPE) tissue, 437 genes, interpretive report for single nucleotide variants, splicesite variants, insertions/deletions, copy number alterations, gene fusions, tumor mutational burden, and microsatellite instability, with algorithm quantifying immunotherapy response score
0392U	0392U	Drug metabolism (depression, anxiety, attention deficit hyperactivity disorder [ADHD]), gene-drug interactions, variant analysis of 16 genes, including deletion/duplication analysis of CYP2D6, reported as impact of gene-drug interaction for each drug
0393U	0393U	Neurology (eg, Parkinson disease, dementia with Lewy bodies), cerebrospinal fluid (CSF), detection of misfolded α-synuclein protein by seed amplification assay, qualitative
0394U	0394U	Perfluoroalkyl substances (PFAS) (eg, perfluorooctanoic acid, perfluorooctane sulfonic acid), 16 PFAS compounds by liquid chromatography with tandem mass spectrometry (LC-MS/MS), plasma or serum, quantitative
0395U	0395U	Oncology (lung), multi-omics (microbial DNA by shotgun nextgeneration sequencing and carcinoembryonic antigen and osteopontin by immunoassay), plasma, algorithm reported as malignancy risk for lung nodules in early-stage disease
0396U	0396U	Obstetrics (pre-implantation genetic testing), evaluation of 300000 DNA single-nucleotide polymorphisms (SNPs) by microarray, embryonic tissue, algorithm reported as a probability for single-gene germline conditions
0397U	0397U	Oncology (non-small cell lung cancer), cell-free DNA from plasma, targeted sequence analysis of at least 109 genes, including sequence variants, substitutions, insertions, deletions, select rearrangements, and copy number variations
0398U	0398U	Gastroenterology (Barrett esophagus), P16, RUNX3, HPP1, and FBN1 DNA methylation analysis using PCR, formalin-fixed paraffin-embedded (FFPE) tissue, algorithm reported as risk score for progression to high-grade dysplasia or cancer
0399U	0399U	Neurology (cerebral folate deficiency), serum, detection of anti-human folate receptor IgGbinding antibody and blocking autoantibodies by enzyme-linked immunoassay (ELISA), qualitative, and blocking autoantibodies, using a functional blocking assay for IgG or IgM, quantitative, reported as positive or not detected
0400U	0400U	Obstetrics (expanded carrier screening), 145 genes by nextgeneration sequencing, fragment analysis and multiplex ligationdependent probe amplification, DNA, reported as carrier positive or negative
0401U	0401U	Cardiology (coronary heart disease [CAD]), 9 genes (12 variants), targeted variant genotyping, blood, saliva, or buccal swab, algorithm reported as a genetic risk score for a coronary event

*CPT code 0809T will be deleted on December 31, 2023.

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3. October 2023 HCPCS Codes Final Rule Comment Solicitation

For the October 2023 update, 64 new codes were established and made effective October 1, 2023. Through the October 2023 OPPS quarterly update CR (Transmittal 12077, Change Request 13210, dated June 13, 2023), we recognized several new codes for separate payment and assigned them to appropriate interim OPPS status indicators and APCs. For CY 2024, consistent with our established policy, we proposed in the CY 2024 OPPS/ASC

proposed rule (88 FR 49605) that the HCPCS codes that would be effective October 1, 2023, would be flagged with comment indicator ''NI'' in Addendum B in the CY 2024 OPPS/ASC final rule with comment period to indicate that we have assigned the codes to interim OPPS status indicators for CY 2024. Table 10 below lists the codes that were effective October 1, 2023. We note that several of the temporary C-codes have been replaced with permanent J-codes effective January 1, 2024. We are inviting public comments in this final rule on the interim payment indicators, which will be finalized in the CY 2025 OPPS/ASC final rule with comment period. We note these same codes will be subject to comment in the CY 2025 OPPS/ASC proposed rule with comment period, and will be finalized in the CY 2025 OPPS/ASC final rule with comment period.

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TABLE 10: NEW HCPCS CODES EFFECTIVE OCTOBER 1, 2023

October 2023 HCPCS Code	CY 2024 HCPCS Code	CY 2024 Long Descriptor
0019M	0019M	Cardiovascular disease, plasma, analysis of protein biomarkers by aptamer-based microarray and algorithm reported as 4-year likelihood of coronary event in high-risk populations
0402U	0402U	Infectious agent (sexually transmitted infection), Chlamydia trachomatis, Neisseria gonorrhoeae, Trichomonas vaginalis, Mycoplasma genitalium, multiplex amplified probe technique, vaginal, endocervical, or male urine, each pathogen reported as detected or not detected
0403U	0403U	Oncology (prostate), mRNA, gene expression profiling of 18 genes, first-catch post-digital rectal examination urine (or processed first-catch urine), algorithm reported as percentage of likelihood of detecting clinically significant prostate cancer
0404U	0404U	Oncology (breast), semiquantitative measurement of thymidine kinase activity by immunoassay, serum, results reported as risk of disease progression
0405U	0405U	Oncology (pancreatic), 59 methylation haplotype block markers, next-generation sequencing, plasma, reported as cancer signal detected or not detected
0406U	0406U	Oncology (lung), flow cytometry, sputum, 5 markers (meso-tetra [4-carboxyphenyl] porphyrin [TCPP], CD206, CD66b, CD3, CD19), algorithm reported as likelihood of lung cancer
0407U	0407U	Nephrology (diabetic chronic kidney disease [CKD]), multiplex electrochemiluminescent immunoassay (ECLIA) of soluble tumor necrosis factor receptor 1 (sTNFR1), soluble tumor necrosis receptor 2 (sTNFR2), and kidney injury molecule 1 (KIM-1) combined with clinical data, plasma, algorithm reported as risk for progressive decline in kidney function
0408U	0408U	Infectious agent antigen detection by bulk acoustic wave biosensor immunoassay, severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (coronavirus disease [COVID-19])
0409U	0409U	Oncology (solid tumor), DNA (80 genes) and RNA (36 genes), by next-generation sequencing from plasma, including single nucleotide variants, insertions/deletions, copy number alterations, microsatellite instability, and fusions, report showing identified mutations with clinical actionability
0410U	0410U	Oncology (pancreatic), DNA, whole genome sequencing with 5-hydroxymethylcytosine enrichment, whole blood or plasma, algorithm reported as cancer detected or not detected

October 2023 HCPCS Code	CY 2024 HCPCS Code	CY 2024 Long Descriptor
0411U	0411U	Psychiatry (eg, depression, anxiety, attention deficit hyperactivity disorder [ADHD]), genomic analysis panel, variant analysis of 15 genes, including deletion/duplication analysis of CYP2D6
0412U	0412U	Beta amyloid, Aβ42/40 ratio, immunoprecipitation with quantitation by liquid chromatography with tandem mass spectrometry (LC-MS/MS) and qualitative ApoE isoform-specific proteotyping, plasma combined with age, algorithm reported as presence or absence of brain amyloid pathology
0413U	0413U	Oncology (hematolymphoid neoplasm), optical genome mapping for copy number alterations, aneuploidy, and balanced/complex structural rearrangements, DNA from blood or bone marrow, report of clinically significant alterations
0414U	0414U	Oncology (lung), augmentative algorithmic analysis of digitized whole slide imaging for 8 genes (ALK, BRAF, EGFR, ERBB2, MET, NTRK1-3, RET, ROS1), and KRAS G12C and PD-L1, if performed, formalin-fixed paraffin-embedded (FFPE) tissue, reported as positive or negative for each biomarker
0415U	0415U	Cardiovascular disease (acute coronary syndrome [ACS]), IL-16, FAS, FASLigand, HGF, CTACK, EOTAXIN, and MCP-3 by immunoassay combined with age, sex, family history, and personal history of diabetes, blood, algorithm reported as a 5-year (deleted risk) score for ACS
0416U	0416U	Infectious agent detection by nucleic acid (DNA), genitourinary pathogens, identification of 20 bacterial and fungal organisms, including identification of 20 associated antibiotic-resistance genes, if performed, multiplex amplified probe technique, urine
0417U	0417U	Rare diseases (constitutional/heritable disorders), whole mitochondrial genome sequence with heteroplasmy detection and deletion analysis, nuclear-encoded mitochondrial gene analysis of 335 nuclear genes, including sequence changes, deletions, insertions, and copy number variants analysis, blood or saliva, identification and categorization of mitochondrial disorder–associated genetic variants
0418U	0418U	Oncology (breast), augmentative algorithmic analysis of digitized whole slide imaging of 8 histologic and immunohistochemical features, reported as a recurrence score
0419U	0419U	Neuropsychiatry (eg, depression, anxiety), genomic sequence analysis panel, variant analysis of 13 genes, saliva or buccal swab, report of each gene phenotype
A2022	A2022	Innovaburn or innovamatrix xl, per square centimeter
A2023	A2023	Innovamatrix pd, 1 mg
A2024	A2024	Resolve matrix, per square centimeter

October 2023 HCPCS Code	CY 2024 HCPCS Code	CY 2024 Long Descriptor
A2025	A2025	Miro3d, per cubic centimeter
A9156	A9156	Oral mucoadhesive, any type (liquid, gel, paste, etc.), per 1 ml
A9268	A9268	Programmer for transient, orally ingested capsule
A9269	A9269	Programable, transient, orally ingested capsule, for use with external programmer, per month
A9292	A9292	Prescription digital visual therapy, software-only, fda cleared, per course of treatment
A9573	A9573	Injection, gadopiclenol, 1 ml
A9603	A9603	Injection, pafolacianine, 0.1 mg
A9697	A9697	Injection, carboxydextran-coated superparamagnetic iron oxide, per study dose
B4148	B4148	Enteral feeding supply kit; elastomeric control fed, per day, includes but not limited to feeding/flushing syringe, administration set tubing, dressings, tape
C9152	J0402	Injection, aripiprazole, (abilify asimtufii), 1 mg
C9153	J0184	Injection, amisulpride, 1 mg
C9154	J0576	Injection, buprenorphine extended-release (brixadi), 1 mg
C9155	J9321	Injection, epcoritamab-bysp, 0.16 mg
C9156	A9608	Flotufolastat F 18, diagnostic, 1 millicurie
C9157	J1304	Injection, tofersen, 1 mg
C9158	J2799	Injection, risperidone, (uzedy), 1 mg
C9788	0857T	Opto-acoustic imaging, breast, unilateral, including axilla when performed, real-time with image documentation, augmentative analysis and report (List separately in addition to code for primary procedure)
C9789	C9789	Instillation of anti-neoplastic pharmacologic/biologic agent into renal pelvis, any method, including all imaging guidance, including volumetric measurement if performed
C9790	C9790	Histotripsy (ie, non-thermal ablation via acoustic energy delivery) of malignant renal tissue, including image guidance
C9791	C9791	Magnetic resonance imaging with inhaled hyperpolarized xenon-129 contrast agent, chest, including preparation and administration of agent
C9792	C9792	Blinded or nonblinded procedure for symptomatic New York Heart Association (NYHA) Class II, III, IVa heart failure; transcatheter implantation of left atrial to coronary sinus shunt using jugular vein access, including all imaging necessary to intra procedurally map the coronary sinus for optimal shunt placement (e.g., TEE or ICE ultrasound, fluoroscopy), performed under general anesthesia in an approved investigational device exemption (IDE) study)

October 2023 HCPCS Code	CY 2024 HCPCS Code	CY 2024 Long Descriptor
E0490	E0490	Power source and control electronics unit for oral device/appliance for neuromuscular electrical stimulation of the tongue muscle, controlled by hardware remote
E0491	E0491	Oral device/appliance for neuromuscular electrical stimulation of the tongue muscle, used in conjunction with the power source and control electronics unit, controlled by hardware remote, 90-day supply
J0349	J0349	Injection, rezafungin, 1 mg
J0801	J0801	Injection, corticotropin (acthar gel), up to 40 units
J0802	J0802	Injection, corticotropin (ani), up to 40 units
J0874	J0874	Injection, daptomycin (baxter), not therapeutically equivalent to j0878, 1 mg
J0889	J0889	Daprodustat, oral, 1 mg, (for esrd on dialysis)
J2359	J2359	Injection, olanzapine, 0.5 mg
J2781	J2781	Injection, pegcetacoplan, intravitreal, 1 mg
J7214	J7214	Injection, factor viii/von willebrand factor complex, recombinant (altuviiio), per factor viii i.u.
J7353	J7353	Anacaulase-bcdb, 8.8% gel, 1 gram
J7519	J7519	Injection, mycophenolate mofetil, 10 mg
J9051	J9051	Injection, bortezomib (maia), not therapeutically equivalent to j9041, 0.1 mg
J9064	J9064	Injection, cabazitaxel (sandoz), not therapeutically equivalent to j9043, 1 mg
J9345	J9345	Injection, retifanlimab-dlwr, 1 mg
K1036	K1036	Supplies and accessories (e.g., transducer) for low frequency ultrasonic diathermy treatment device, per month
L1681	L1681	Hip orthosis, bilateral hip joints and thigh cuffs, adjustable flexion, extension, abduction control of hip joint, postoperative hip abduction type, prefabricated item that has been trimmed, bent, molded, assembled, or otherwise customized to fit a specific patient by an individual with expertise
L5991	L5991	Addition to lower extremity prostheses, osseointegrated external prosthetic connector
Q4285	Q4285	Nudyn dl or nudyn dl mesh, per square centimeter
Q4286	Q4286	Nudyn sl or nudyn slw, per square centimeter
V2526	V2526	Contact lens, hydrophilic, with blue-violet filter, per lens

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4. January 2024 HCPCS Codes

a. New Level II HCPCS Codes Final Rule Comment Solicitation

Consistent with past practice, we are soliciting comments on the new Level II HCPCS codes that will be effective January 1, 2024, in this final rule with comment period, thereby allowing us to finalize the status indicators and APC assignments for the codes in the CY 2025 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 proposed new C-codes and G-codes listed in Addendum O of the CY 2024 OPPS/ASC 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. Consequently, for CY 2024, we proposed to include the new Level II HCPCS codes effective January 1, 2024 (that would be incorporated in the January 2024 OPPS quarterly update CR), in Addendum B to the CY 2024 OPPS/ASC final rule with comment period. Specifically, for CY 2024, we proposed to continue our established policy of assigning comment indicator ''NI'' in Addendum B to this final rule with comment period to the new HCPCS codes that will be effective January 1, 2024, to indicate that we are assigning them an interim status indicator, which is subject to public comment. We are inviting public comments in this final rule with comment period on the status indicators and APC assignments, which will be finalized in the CY 2025 OPPS/ASC final rule with comment period. Similar to the codes effective October 1, 2023, these new Level II HCPCS codes that will be effective January 1, 2024, will be subject to comment in the CY 2025 OPPS/ASC proposed rule with comment period, and will be finalized in the CY 2025 OPPS/ASC final rule with comment period.

b. New CY 2024 CPT Codes Proposed Rule Comment Solicitation

In the CY 2015 OPPS/ASC final rule with comment period (79 FR 66841 through 66844), we finalized a revised process of assigning APCs 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 resorting to use of 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), to solicit public comments in the final rule, and to finalize the specific APC and status indicator assignments for those codes in the following year's final rule.

For the CY 2024 OPPS update, we received the CPT codes that will be effective January 1, 2024, from the AMA in time to be included in the CY 2024 OPPS/ASC proposed rule with comment period. The new, revised, and deleted CPT codes can be found in Addendum B to the proposed rule (which is available via the internet on the CMS website). We note that the new and revised CPT codes are assigned to a proposed APC assignment and comment indicator ''NP'' in Addendum B of the 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 the current calendar year, and that comments will be accepted on the proposed APC assignment and status indicator.

Further, we reminded readers 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 included the 5-digit placeholder codes and their long descriptors for the new and revised CY 2024 CPT codes in Addendum O to the proposed rule (which is available via the internet on the CMS website) so that the public could adequately comment on the proposed APCs and SI assignments. The 5-digit placeholder codes were included in Addendum O, specifically under the column labeled ''CY 2024 OPPS/ASC Proposed Rule 5-Digit AMA Placeholder Code,'' to the proposed rule. We noted that the final CPT code numbers would be included in this CY 2024 OPPS/ASC final rule with comment period. We also noted that not every code listed in Addendum O is subject to public comment. For the new and revised Category I and III CPT codes, we requested public comments on only those codes that are assigned comment indicator ''NP.''

In summary, in the CY 2024 OPPS/ASC proposed rule, we solicited public comments on the proposed CY 2024 SI and APC assignments for the new and revised Category I and III CPT codes that would be effective January 1, 2024. The CPT codes were listed in Addendum B to the proposed rule with short descriptors only. We listed them again in Addendum O to the proposed rule with long descriptors. We also proposed to finalize the SI and APC assignments for these codes (with their final CPT code numbers) in the CY 2024 OPPS/ASC final rule with comment period. The proposed SI and APC assignments for these codes were included in Addendum B to the proposed rule (which is available via the internet on the CMS website).

We received comments on several of the new CPT codes that were assigned to comment indicator ''NP'' in Addendum B to the CY 2024 OPPS/ASC proposed rule. We have responded to those public comments in sections III.C, III.E, and IV of this CY 2024 OPPS/ASC final rule with comment period.

The final SIs, APC assignments, and payment rates for the new CPT codes that are effective January 1, 2024, can be found in Addendum B to this final rule with comment period. In addition, the SI meanings can be found in Addendum D1 (OPPS Payment Status Indicators for CY 2024) to this final rule with comment period. Addenda B and D1 are available via the internet on the CMS website.

Finally, Table 11, which is a reprint of Table 8 from the CY 2024 OPPS/ASC proposed rule (88 FR 49606), shows the comment timeframe for new and revised HCPCS codes. The table provides information on 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.

TABLE 11: COMMENT AND FINALIZATION TIMEFRAMES FOR NEW AND REVISED OPPS-RELATED HCPCS CODES

OPPS Quarterly Update CR	Type of Code	Effective Date	Comments Sought	When Finalized
April 2023	HCPCS (CPT and Level II codes)	April 1, 2023	CY 2024 OPPS/ASC proposed rule	CY 2024 OPPS/ASC final rule with comment period
July 2023	HCPCS (CPT and Level II codes)	July 1, 2023	CY 2024 OPPS/ASC proposed rule	CY 2024 OPPS/ASC final rule with comment period
October 2023	HCPCS (CPT and Level II codes)	October 1, 2023	CY 2024 OPPS/ASC final rule with comment period	CY 2025 OPPS/ASC final rule with comment period
January 2024	CPT Codes	January 1, 2024	CY 2024 OPPS/ASC proposed rule	CY 2024 OPPS/ASC final rule with comment period
	Level II HCPCS Codes	January 1, 2024	CY 2024 OPPS/ASC final rule with comment period	CY 2025 OPPS/ASC final rule with comment period

B. 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 medical devices, drugs, biologicals, therapeutic radiopharmaceuticals, and brachytherapy devices that are not packaged into the payment for the procedure.

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 final rule with comment period.

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. In the CY 2024 OPPS/ASC proposed rule (88 FR 49607), for CY 2024, we proposed 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 Advisory Panel on Hospital Outpatient Payment (also known as the HOP Panel or the Panel) recommendations for specific services for the CY 2024 OPPS update will be discussed in the relevant specific sections throughout this 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 for 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 the CY 2024 OPPS/ASC proposed rule, for CY 2024, we proposed 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 2024 OPPS update, we identified the APCs with violations of the 2 times rule; and we proposed changes to the procedure codes assigned to these APCs (with the exception of those APCs for which we proposed a 2 times rule exception) in Addendum B to the CY 2024 OPPS/ASC proposed rule. We note that Addendum B does not appear in the printed version of the **Federal Register** as part of this final rule with comment period. Rather, it is published and made available via the internet on the CMS website at: *https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient/regulations-notices.* To eliminate a violation of the 2 times rule and improve clinical and resource homogeneity in the APCs for which we did not propose a 2 times rule exception, we proposed 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 2024 included in the CY 2024 OPPS/ASC proposed rule are related to changes in costs of services that were observed in the CY 2022 claims data available for CY 2024 ratesetting. Addendum B to the CY 2024 OPPS/ASC proposed rule identifies with a comment indicator ''CH'' those procedure codes for which we proposed a change to the APC assignment or status indicator, or both, that were initially assigned in the July 1, 2023 OPPS Addendum B Update (available via the internet on the CMS website at: *https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient/addendum-a-b-updates*).

3. APC Exceptions to the 2 Times Rule

Taking into account the APC changes that we proposed to make for CY 2024, we reviewed all of the APCs for which we identified 2 times rule violations to determine whether any of the APCs would qualify for an exception. 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.

For a detailed discussion of these criteria, we refer readers to the April 7, 2000 final rule (65 FR 18457 and 18458).

Based on the CY 2022 claims data available for the CY 2024 OPPS/ASC proposed rule, we found 21 APCs with violations of the 2 times rule. We applied the criteria as described above to identify the APCs for which we proposed to make exceptions under the 2 times rule for CY 2024 and found that all of the 21 APCs we identified met the criteria for an exception to the 2 times rule based on the CY 2022 claims data available for the CY 2024 OPPS/ASC proposed rule. We note that, on an annual basis, based on our analysis of the latest claims data, we identify violations to the 2 times rule and propose changes when appropriate. Those APCs that violate the 2 times rule are identified and appear in Table 12 below. In addition, 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, where a 2 times rule violation is a relevant concept.

Table 9 of the CY 2024 OPPS/ASC proposed rule (88 FR 49608) listed the 21 APCs for which we proposed to make an exception under the 2 times rule for CY 2024 based on the criteria cited above and claims data submitted between January 1, 2022, and December 31, 2022, and processed on or before June 30, 2023, and 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 the proposed rule can be found on the CMS website at: *https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient/regulations-notices.*

Based on the updated final rule CY 2022 claims data used for this CY 2024 final rule with comment period, we found a total of 22 APCs with violations of the 2 times rule. Of these 22 total APCs, 19 were identified in the proposed rule and three are newly identified APCs. The following two APCs appeared in Table 9 of the CY 2024 OPPS/ASC proposed rule (88 FR 49608) as violating the 2 times rule, however, after conducting our data analysis for this final rule with comment period, we found that the APCs no longer violate the 2 times rule:

- APC 5303 (Level 3 Upper GI Procedures)
- APC 5822 (Health and Behavior Services)

In addition, the three newly identified APCs with violations of the 2 times rule include the following:

- APC 5734 (Level 4 Minor Procedures)

- APC 5743 (Level 3 Electronic Analysis of Devices)
- APC 5791 (Level 1 Pulmonary Treatment)

Although we did not receive any comments on Table 9 of the proposed rule, we did receive comments on APC assignments for specific HCPCS codes. The comments, and our responses, can be found in section III.E. of this final rule with comment period. In addition, we received a comment related to the application of the 2 times rule to the nuclear medicine APCs and packaged diagnostic radiopharmaceuticals. Below is the comment and our response.

Comment: A commenter stated that the statutory standard at section 1833(t)(2)(B) of the Social Security Act applies to the resources of both items and services, and if CMS continues to package diagnostic radiopharmaceuticals, the commenter suggested including the cost of the packaged radiopharmaceuticals when evaluating the nuclear medicine APCs for 2 times rule violations. The commenter added that, if needed, CMS should consider establishing additional APCs to ensure that the nuclear medicine APCs do not violate the 2 times rule when the costs of the packaged diagnostic radiopharmaceuticals are included.

Response: As we stated in the CY 2023 OPPS/ASC final rule (87 FR 71963), diagnostic radiopharmaceuticals are an integral component of many nuclear medicine and imaging procedures, and the payment for them is packaged with the primary procedure. We reiterate that the payment rates for the nuclear medicine APCs are established in a manner that uses the reported costs to furnish the procedure based on data submitted to CMS from all hospitals paid under the OPPS. The costs that are calculated for the nuclear medicine APCs reflect the average costs of items and services that are packaged into a primary procedure and will not necessarily equal the sum of the cost of the primary procedure and diagnostic radiopharmaceutical used in the procedure. Claims data that include the radiopharmaceutical packaged with the associated procedure reflect the combined cost of the procedure and the radiopharmaceutical used in the procedure. Consequently, we believe that our general standard of applying the 2 times rule to all clinical APCs, including the nuclear medicine APCs, is appropriate.

After considering the public comments we received on APC assignments and our analysis of the CY 2022 costs from hospital claims and cost report data available for this CY 2024 final rule with comment period, we are finalizing our proposals with some modifications. Specifically, we are finalizing our proposal to except 19 of the 21 proposed APCs from the 2 times rule for CY 2022 claims data and also excepting three additional APCs (APCs 5734, 5743, and 5791) for a total of 22 APCs.

In summary, Table 12 lists the 22 APCs that we are excepting from the 2 times rule for CY 2024 based on the criteria described earlier and a review of updated claims data for dates of service between January 1, 2022, and December 31, 2022, that were processed on or before June 30, 2023, and updated CCRs, if available. 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 generally accept the HOP Panel's recommendation because those recommendations are based on explicit consideration of resource use, clinical homogeneity, site of service, and the quality of the claims data used to determine the APC payment rates. The geometric mean costs for hospital outpatient services for these and all other APCs that were used in the development of this final rule with comment period can be found on the CMS website at: *https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient/regulations-notices.*

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TABLE 12: FINAL CY 2024 APC EXCEPTIONS TO THE 2 TIMES RULE

APC	APC Group Title
5012	Clinic Visits and Related Services
5071	Level 1 Excision/ Biopsy/ Incision and Drainage
5301	Level 1 Upper 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
5572	Level 2 Imaging with Contrast
5612	Level 2 Therapeutic Radiation Treatment Preparation
5627	Level 7 Radiation Therapy
5674	Level 4 Pathology
5691	Level 1 Drug Administration
5692	Level 2 Drug Administration
5721	Level 1 Diagnostic Tests and Related Services
5731	Level 1 Minor Procedures
5734	Level 4 Minor Procedures
5741	Level 1 Electronic Analysis of Devices
5743	Level 3 Electronic Analysis of Devices
5791	Pulmonary Treatment
5811	Manipulation Therapy
5821	Level 1 Health and Behavior Services
5823	Level 3 Health and Behavior Services

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C. 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.

We also adopted in the CY 2002 OPPS final rule the following criteria for assigning a complete or comprehensive service to a New Technology APC: (1) the service must be truly new, meaning it cannot be appropriately reported by an existing HCPCS code assigned to a clinical APC and does not appropriately fit within an existing clinical APC; (2) the service is not eligible for transitional pass-through payment (however, a truly new, comprehensive service could qualify for assignment to a new technology APC even if it involves a device or drug that could, on its own, qualify for a pass-through payment); and (3) the service falls within the scope of Medicare benefits under section 1832(a) of the Act and is reasonable and necessary in accordance with section 1862(a)(1)(A) of the Act (66 FR 59898 through 59903). For additional information about our New Technology APC policy, we refer readers to *https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient/pass-through-payment-status-new-technology-ambulatory-payment-classification-apc* and then follow the instructions to access the MEARIS™ system for OPPS New Technology APC applications.

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 2023, there were 52 New Technology APC levels, ranging from the lowest cost band assigned to APC 1491 (New Technology—Level 1A ($0–$10)) to 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 market basket increase reduced by the productivity adjustment. 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 payments 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.

Some services assigned to New Technology APCs have very low annual volume, which we consider to be fewer than 100 claims (86 FR 63528). 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 finalized a policy, in the CY 2019 OPPS/ASC final rule with comment period, to utilize our equitable adjustment authority at section 1833(t)(2)(E) of the Act to adjust how we determine the costs for low-volume services assigned to New Technology APCs (83 FR 58892 and 58893). Specifically, in the CY 2019 OPPS/ASC final rule with comment period (83 FR 58893), we established that, in each of our annual rulemakings, we would calculate and present the result of each statistical methodology (arithmetic mean, geometric mean, and median) based on up to 4 years of claims data and solicit public comment on which methodology should be used to establish the payment rate for the low-volume new technology service. In the CY 2022 OPPS/ASC final rule with comment period (86 FR 63529), we replaced the New Technology APC low volume policy with the universal low volume APC policy. Unlike the New Technology APC low volume policy, the universal low volume APC policy applies to clinical APCs and brachytherapy APCs, in addition to procedures assigned to New Technology APCs, and uses the highest of the geometric mean, arithmetic mean, or median based on up to 4 years of claims data to set the payment rate for the APC. We refer readers to the CY 2022 OPPS/ASC final rule with comment period (86 FR 63529) for further discussion regarding this policy.

Finally, 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 2024, we included the proposed payment rates for New Technology APCs 1491 to 1599 and 1901 through 1908 in Addendum A to the CY 2024 OPPS/ASC proposed rule (which is available on the CMS website at *https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient/regulations-notices*).

2. Procedures Assigned to New Technology APC Groups for CY 2024

As we described in the CY 2002 OPPS final rule (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 2024, we proposed to retain services within New Technology APC groups until we obtain sufficient claims data to justify reassignment of the service to an appropriate clinical APC. The flexibility associated with this policy allows us to reassign a service from a New Technology APC in less than 2 years if we have obtained sufficient claims data. It also allows us to retain a service in a New Technology APC for more than 2 years if we have not obtained sufficient claims data upon which to base a reassignment decision (66 FR 59902).

a. Administration of Subretinal Therapies Requiring Vitrectomy (APC 1563)

Effective January 1, 2021, CMS established HCPCS code C9770 (Vitrectomy, mechanical, pars plana approach, with subretinal injection of pharmacologic/biologic agent) and assigned it to a New Technology APC based on the geometric mean cost of CPT code 67036 (Vitrectomy,

mechanical, pars plana approach) due to similar resource utilization. For CY 2021, HCPCS code C9770 was assigned to APC 1561 (New Technology—Level 24 ($3001–$3500)). This code may be used to describe the administration of HCPCS code J3398 (Injection, voretigene neparvovec-rzyl, 1 billion vector genomes). This procedure was previously discussed in depth in the CY 2021 OPPS/ASC final rule with comment period (85 FR 85939 and 85940). For CY 2022, we maintained the APC assignment of APC 1561 (New Technology—Level 24 ($3001–$3500)) for HCPCS code C9770 (86 FR 63531 and 63532).

HCPCS code J3398 (Injection, voretigene neparvovec-rzyl, 1 billion vector genomes) is for a gene therapy product indicated for a rare mutation-associated retinal dystrophy. Voretigene neparvovec-rzyl (Luxturna®) was approved by FDA in December of 2017 and is an adeno-associated virus vector-based gene therapy indicated for the treatment of patients with confirmed biallelic RPE65 mutation-associated retinal dystrophy.[6] This therapy is administered through a subretinal injection, which interested parties 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.''

Interested parties, including the manufacturer of Luxturna®, recommended CPT code 67036 (Vitrectomy, mechanical, pars plana approach) for the administration of the gene therapy.[7] However, the manufacturer previously contended the administration was not accurately described by any existing codes as CPT code 67036 (Vitrectomy, mechanical, pars plana approach) does not account for the administration itself.

CMS recognized the need to accurately describe the unique procedure that is required to administer the therapy described by HCPCS code J3398. Therefore, in the CY 2021 OPPS/ASC proposed rule (85 FR 48832), we proposed to establish a new HCPCS code, C97X1 (Vitrectomy, mechanical, pars plana approach, with subretinal injection of pharmacologic/biologic agent) to describe this process. We stated that we believed this new HCPCS code accurately described the unique service associated with intraocular administration of HCPCS code J3398. We recognized that CPT code 67036 represents a clinically similar procedure and process that approximates similar resource utilization to C97X1. However, we also recognized that it is not prudent for the code that describes the administration of this unique gene therapy, C97X1, to be assigned to the same C–APC to which CPT code 67036 is assigned, as this would package the primary therapy, HCPCS code J3398, into the code that represents the process to administer the gene therapy.

Therefore, for CY 2021, we proposed to assign the services described by C97X1 to a New Technology APC with a cost band that contains the geometric mean cost for CPT code 67036. The placeholder code C97X1 was replaced by HCPCS code C9770. For CY 2021, we finalized our proposal to create HCPCS code C9770 (Vitrectomy, mechanical, pars plana approach, with subretinal injection of pharmacologic/biologic agent), and we assigned this code to APC 1561 (New Technology—Level 24 ($3001–$3500)) using the geometric mean cost of CPT code 67036. For CY 2022, we continued to assign HCPCS code C9770 to APC 1561 (New Technology—Level 24 ($3001–$3500)) using the geometric mean cost of CPT code 67036.

CY 2023 was the first year that claims data were available for HCPCS code C9770; so we proposed and finalized a policy to base the payment rate of HCPCS code C9770 on claims data for that code rather than on the geometric mean cost of CPT code 67036. Given the low number of claims for this procedure, we designated HCPCS code C9770 as a low volume procedure under our universal low volume APC policy and used the greater of the geometric mean, arithmetic mean, or median cost calculated based on the available claims data to calculate an appropriate payment rate for purposes of assigning HCPCS code C9770 to a New Technology APC.

Based on the claims data available for the CY 2023 OPPS/ASC final rule with comment period, we found the median was the statistical methodology that estimated the highest cost for the service. The payment rate calculated using this methodology fell within the cost band for New Technology APC 1562 (New Technology—Level 25 ($3501–$4000)). Therefore, we finalized our proposal to assign HCPCS code C9770 to APC 1562 for CY 2023.

CPT code 0810T (Subretinal injection of a pharmacologic agent, including vitrectomy and 1 or more retinotomies) will be effective July 1, 2023. We recognized the similarity between HCPCS code C9770 and CPT code 0810T; therefore, we proposed to delete HCPCS code C9770 effective December 31, 2023, and to recognize CPT code 0810T starting January 1, 2024. We proposed to determine the payment rate for the procedure using the claims data for HCPCS code C9770. Similar to CY 2023, for CY 2024, given that there are only 10 single frequency claims available for ratesetting, we proposed to designate CPT code 0810T as a low volume procedure under our universal low volume APC policy and to use the greater of the geometric mean, arithmetic mean, or median cost calculated based on the available claims data for HCPCS code C9770 to calculate an appropriate payment rate for purposes of assigning CPT code 0810T to a New Technology APC.

Using all available claims from the 4-year lookback period, we determined the geometric mean cost to be $3,944, the arithmetic mean cost to be $4,192, and the median cost to be $4,148. Because the arithmetic mean is the statistical methodology that estimated the highest cost for the service, we proposed to use this cost to determine the New Technology APC placement. The arithmetic mean of $4,192 falls within the cost band for New Technology APC 1563 (New Technology—Level 26 ($4001–$4500)). Therefore, we proposed to assign CPT code 0810T to APC 1563 for CY 2024. Additionally, we proposed to perform a similar analysis using updated claims data in the CY 2024 OPPS/ASC final rule with comment period and update the APC placement as needed.

Please refer to Table 13 below for the proposed OPPS New Technology APC and status indicator assignments for HCPCS code C9770 and CPT code 0810T for CY 2024. The proposed CY 2024 payment rates can be found in Addendum B to the CY 2024 OPPS/ASC proposed rule via the internet on the CMS website.

[6] Luxturna. FDA Package Insert. Available: *https://www.fda.gov/media/109906/download.*

[7] LUXTURNA REIMBURSEMENT GUIDE FOR TREATMENT CENTERS. *https://myspark generation.com/uploads/2022/09/LUXTURNA-Reimbursement-Guide-for-Treatment-Centers-ISI-Update-April-2022-P-RPE65-US-320025.pdf.*

TABLE 13: FINAL CY 2023 AND PROPOSED CY 2024 OPPS NEW TECHNOLOGY APC AND STATUS INDICATOR ASSIGNMENTS FOR HCPCS CODE C9770 AND CPT CODE 0810T

HCPCS Code	Long Descriptor	Final CY 2023 OPPS SI	Final CY 2023 OPPS APC	Proposed CY 2024 OPPS SI	Proposed CY 2024 OPPS APC
C9770	Vitrectomy, mechanical, pars plana approach, with subretinal injection of pharmacologic/biologic agent	T	1562	D	N/A
0810T	Subretinal injection of a pharmacologic agent, including vitrectomy and 1 or more retinotomies	E1	N/A	T	1563

Comment: We received three comments in support of our proposal to delete HCPCS code C9770 and reassign CPT code 0810T to APC 1563 for CY 2024.

Response: We thank the commenters for their support. After consideration of the public comment we received, we are finalizing our policy as proposed. Specifically, we are finalizing our proposal to delete HCPCS code C9770 and assign CPT code 0810T to APC 1563 (New Technology—Level 26 ($4001–$4500)) for CY 2024. We are also finalizing our proposal to designate CPT code 0810T as a low volume procedure under our universal low volume APC policy and use the greater of the geometric mean, arithmetic mean, or median cost calculated based on the available claims data for HCPCS code C9770 to calculate an appropriate payment rate for purposes of assigning CPT code 0810T to a New Technology APC.

Based on updated claims data available for this final rule with comment period from the 4-year lookback period, we found the geometric mean cost for the service to be approximately $3,901.57, the arithmetic mean cost to be approximately $4,129.91, and the median cost to be approximately $4,141.06. The median was the statistical methodology that estimated the highest cost for the service. The payment rate calculated using this methodology falls within the cost band for New Technology APC 1563 (New Technology—Level 26 ($4001–$4500)). Therefore, we are assigning HCPCS code C9770 to APC 1563 for CY 2023. Please refer to Table 14 below for the final OPPS New Technology APC and status indicator assignments for HCPCS code C9770 and CPT code 0810T for CY 2024. The final CY 2024 payment rates can be found in Addendum B to this final rule with comment period via the internet on the CMS website.

TABLE 14: PROPOSED AND FINAL CY 2024 OPPS NEW TECHNOLOGY APC AND STATUS INDICATOR ASSIGNMENTS FOR HCPCS CODE C9770 AND CPT CODE 0810T

HCPCS Code	Long Descriptor	Proposed CY 2024 OPPS SI	Proposed CY 2024 OPPS APC	Final CY 2024 OPPS SI	Final CY 2024 OPPS APC
C9770	Vitrectomy, mechanical, pars plana approach, with subretinal injection of pharmacologic/biologic agent	D	N/A	D	N/A
0810T	Subretinal injection of a pharmacologic agent, including vitrectomy and 1 or more retinotomies	T	1563	T	1563

b. Bronchoscopy with Transbronchial Ablation of Lesion(s) by Microwave Energy (APC 1562)

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 (eg, 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 the CY 2021 OPPS/ASC final rule with comment period, there were four claims reported for bronchoscopy with transbronchial ablation of lesions by microwave energy. Given the low volume of claims for the service, we proposed for CY 2021 to apply the universal low volume APC 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 determine 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 $2,693, the arithmetic mean cost to be approximately $3,086, and the median cost to be approximately $3,708. The median was the statistical methodology that estimated the highest cost for the service. The payment rate calculated using this methodology fell within the cost band for New Technology APC 1562 (New Technology—Level 25 ($3501–$4000)). Therefore, we assigned HCPCS code C9751 to APC 1562 for CY 2021.

In CY 2022, we again used the claims data from CY 2019 for HCPCS code C9751. Because the claims data was unchanged from when it was used in CY 2021, the values for the geometric mean cost ($2,693), the arithmetic mean cost ($3,086), and the median cost ($3,708) for the service described by HCPCS code C9751 remained the same. The highest cost metric using these methodologies was again the median and within the cost band for New Technology APC 1562 (New Technology—Level 25 ($3,501–$4,000)). Therefore, we continued to assign HCPCS code C9751 to APC 1562 (New Technology—Level 25 ($3,501– $4,000)), with a payment rate of $3,750.50 for CY 2022.

There were no claims reported in CY 2020, CY 2021, or CY 2022 for HCPCS code C9751. Therefore, for CY 2024, the only available claims for HCPCS code C9751 continue to be from CY 2019; and the reported claims are the same claims used to calculate the payment rate for the service in the CY 2021, CY 2022, and CY 2023 OPPS/ASC final rules with comment period. Given the low number of claims for this procedure, we proposed to continue to designate this procedure as a low volume procedure under our universal low volume policy and use the highest of the geometric mean cost, arithmetic mean cost, or median cost based on up to 4 years of claims data to assign the procedure to the appropriate New Technology APC. Because our proposal uses the same claims as we used for CY 2021, CY 2022, and CY 2023, the same values for the geometric mean cost, arithmetic mean cost, and the median cost are used to propose a payment rate for CY 2024. Once again, the median ($3,708) was the statistical methodology that estimated the highest cost for the service. The payment rate calculated using this methodology continues to fall within the cost band for New Technology APC 1562 (New Technology—Level 25 ($3501–$4000)). Therefore, we proposed to continue to assign HCPCS code C9751 to APC 1562 (New Technology—Level 25 ($3501–$4000)), with a proposed payment rate of $3,750.50 for CY 2024.

Comment: We received one comment in support of our proposal to continue to assign HCPCS code C9751 to APC 1562.

Response: We thank the commenter for their support. After consideration of the public comment we received, we are finalizing our policy as proposed. Please refer to Table 15 below for the final

OPPS New Technology APC and status indicator assignment for HCPCS code C9751 for CY 2024. The final CY 2024 payment rates can be found in Addendum B to this final rule with comment period via the internet on the CMS website.

TABLE 15: FINAL CY 2024 OPPS NEW TECHNOLOGY APC AND STATUS INDICATOR ASSIGNMENTS FOR HCPCS CODE C9751

HCPCS Code	Long Descriptor	Final CY 2024 OPPS SI	Final CY 2024 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 (e.g., aspiration[s]/biopsy[ies]	T	1562

c. Cardiac Positron Emission Tomography (PET)/Computed Tomography (CT) Studies (APCs 1520, 1521, and 1522)

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. CPT code 78431 was assigned to APC 1522 (New Technology—Level 22 ($2001–$2500)) with a payment rate of $2,250.50. CPT codes 78432 and 78433 were assigned to APC 1523 (New Technology—Level 23 ($2501–$3000)) with a payment rate of $2,750.50. We did not receive any claims data for these services for either of the CY 2021 or CY 2022 OPPS proposed or final rules. Therefore, we continued to assign CPT code 78431 to APC 1522 (New Technology—Level 22 ($2001–$2500)) with a payment rate of $2,250.50 in CY 2021 and CY 2022. Likewise, we continued to assign CPT codes 78432 and 78433 to APC 1523 (New Technology—Level 23 ($2501–$3000)) with a payment rate of $2,750.50.

For CY 2023, we used CY 2021 claims data to determine the payment rates for CPT codes 78431, 78432, and 78433. Based on our analysis of the available claims data, for CY 2023, we assigned CPT code 78431 to APC 1523 (New Technology—Level 23 ($2501–$3000)) with a payment rate of $2,750.50; CPT code 78432 to APC 1520 (New Technology—Level 20 ($1801-$1900)) with a payment rate of $1,850.50 based on the application of the universal low-volume policy; and CPT code 78433 to APC 1521 (New Technology—Level 21 ($1901–$2000)) with a payment rate of $1,950.50.

For CY 2024, the OPPS payment rates were proposed to be based on available CY 2022 claims data. CPT code 78431 had over 22,000 single frequency claims in CY 2022. The geometric mean for CPT code 78431 was approximately $2,300, which is an amount that is below the cost band for APC 1523 (New Technology—Level 23 ($2501–$3000)), where the procedure is currently assigned. We proposed, for CY 2024, that CPT code 78431 be reassigned to APC 1522 (New Technology—Level 22 ($2001–$2500)) with a payment rate of $2,250.50. Please refer to Table 16 below for the proposed New Technology APC and status indicator assignments for CPT code 78431.

There were only six single frequency claims in CY 2022 for CPT code 78432. As this is below the threshold of 100 claims for a service within a year, we proposed to apply our universal low volume APC policy and use the highest of the geometric mean cost, arithmetic mean cost, or median cost based on up to 4 years of claims data to assign CPT code 78432 to the appropriate New Technology APC. Using available claims data from CY 2021 and CY 2022, our analysis found the geometric mean cost of the service is approximately $1,658, the arithmetic mean cost of the service is approximately $1,445, and the median cost of the service is approximately $1,562. The geometric mean was the statistical methodology that estimated the highest cost for the service. The geometric mean cost of $1,658, is an amount that is below the cost band for APC 1520 (New Technology—Level 20 ($1801–$1900)), where the procedure is currently assigned. Therefore, we proposed, for CY 2024, to assign CPT code 78432 to APC 1518 (New Technology—Level 18 ($1601–$1700)) with a payment rate of $1,650.50. Please refer to Table G12 for the proposed New Technology APC and status indicator assignments for CPT code 78432.

There were over 1200 single frequency claims for CPT code 78433 in CY 2022. The geometric mean for CPT code 78433 was approximately $1,960, which is an amount that is within the cost band for APC 1521 (New Technology—Level 21 ($1901–$2000)), to which it is currently assigned. Therefore, for CY 2024, we propose to continue to assign CPT code 78433 to APC 1521 with a payment rate of $1,950.50.

Please refer to Table 16 below for the proposed OPPS New Technology APC and status indicator assignment for CPT codes 78431, 78432, and 78433 for CY 2024. The proposed CY 2024 payment rates can be found in Addendum B to the CY 2024 OPPS/ASC proposed rule via the internet on the CMS website.

TABLE 16: FINAL CY 2023 AND PROPOSED CY 2024 OPPS NEW TECHNOLOGY APC AND STATUS INDICATOR ASSIGNMENTS FOR CPT CODES 78431, 78432, AND 78433

CPT Code	Long Descriptor	Final CY 2023 OPPS SI	Final CY 2023 OPPS APC	Proposed CY 2024 OPPS SI	Proposed OPPS CY 2024 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	1523	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 (e.g., myocardial viability);	S	1520	S	1518
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 (e.g., myocardial viability); with concurrently acquired computed tomography transmission scan	S	1521	S	1521

Comment: We received several comments disagreeing with the proposed payment rates for CPT codes 78431, 78432, and 78433. Several commenters stated that the proposed APC assignments for 2024 are not consistent with the resources needed to perform these services and requested that CMS assign all three CPT codes to New Technology APC 1523 (New Technology—Level 23 ($2501–$3000)). While commenters explained differences between each service, commenters still requested that all three codes be assigned to the same New Technology APC.

Response: We thank the commenters for their input on our proposal. We do not agree that it would be appropriate to assign all three codes describing the services associated with cardiac PET/CT studies to the same New Technology APC. Since CPT codes 78431, 78432, and 78433 first became effective on January 1, 2020, they have all been assigned to different New Technology APCs based on the perceived resource expenditures stemming from clinical differences in their code descriptors. Since first receiving claims data for these codes for the CY 2023 rulemaking cycle, there are differences between the codes in terms of claims data and claims frequency that serve as further evidence for the need for variations in New Technology APC assignments. Additionally, public comments regarding the clinical and resource differences between each code further underscore the need for different New Technology APC assignments. Therefore, we are not accepting commenters' suggestion to reverse course at this time and assign the three codes describing different services associated with cardiac PET/CT studies to the same New Technology APC.

Comment: Some commenters urged that CMS maintain stable payment rates for three to five years to allow for

appropriate adoption and implementation of the cardiac PET/CT services.

Commenters explained that it takes time for hospitals to gain experience with new codes and for providers to become aware of how to appropriately bill new codes. Commenters pointed out that CPT codes 78431, 78432, and 78432 were made effective in 2020, which coincided with the COVID–19 public health emergency, and explained that there are still lingering effects of COVID–19 in terms of hospitals ordering and implementing new technology.

Response: We note that we did not change the New Technology APC assignments for CPT codes 78431, 78432, and 78433 between CY 2020 through CY 2022. Therefore, CPT codes 78431, 78432, and 78433 had the exact same payment rate for three full calendar years. We believe that the time that has already been provided is sufficient for interested parties to educate providers on coding and for hospitals to appropriately report the services performed. Additionally, it is generally not our policy to judge the accuracy of provider coding and charging for purposes of ratesetting. We rely on hospitals and providers to accurately report the use of HCPCS codes in accordance with their code descriptors, and CPT and CMS instructions, and to report services accurately on claims and charges and costs for the services on their Medicare hospital cost report.

Comment: Commenters strongly disagreed with the proposed APC reassignment for CPT code 78432 from APC 1520 to APC 1518 for CY 2024, and urged that CMS reassign CPT code 78432 to New Technology APC 1523, the New Technology APC to which it was first assigned in CY 2020 when there were no claims data yet available for the code. Commenters stated that they believed that six single frequency claims is not sufficient data to set payment rates for CPT code 78432. Other commenters explained that CPT code 78432 uses more resources than CPT code 78431 and requested that CMS consider collecting additional claims data in CY 2024 for CPT code 78432 before proposing to make an APC reassignment. Some commenters stated that they did not believe that it would benefit hospitals to adjust APC assignments year to year. These commenters stated that changes in APC assignments causes instability in payments and angst for hospitals.

Response: We thank the commenters for their input, but note that section 1833(t)(9)(A) of the Act requires that the Secretary review not less often than annually and revise the groups, the relative payment weights, and the wage and other adjustments to take into account, among other things, new cost data. For services assigned to New Technology APCs, 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). Therefore, we do not agree with commenters' suggestions that we should not regularly update the APC assignments for services like cardiac PET/CT.

With that said, we are sympathetic to comments regarding the instability of the payment rate for CPT code 78432 if we were to finalize its proposed APC assignment based on the extremely limited number of claims that exist for the code. While there have been 2 more claims processed for CPT code 78432 since the time of the publication of the CY 2024 OPPS/ASC proposed rule, the claims frequency for CPT code 78432 remains extremely low at only 7 claims. As we have stated previously, low utilization of services assigned to a New Technology APC 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 in turn limits our ability to assign the service to an appropriate clinical APC (83 FR 58893). 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, in the CY 2019 OPPS/ASC final rule with comment period (83 FR 58893) we established that, in each of our annual rulemakings, we would seek public comments on which statistical methodology (arithmetic mean, geometric mean, or median) should be used for each low-volume service assigned to a New Technology APC. In addition, we explained that we would 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. For CY 2022, we proposed to continue to utilize our equitable adjustment authority under section 1833(t)(2)(E) of the Act to calculate the geometric mean, arithmetic mean, and median using up to 4 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. Because there were fewer than 100 claims per year for CPT code 78432, we would usually apply our universal low volume APC policy to determine its New Technology APC assignment.

However, we recognize that if we utilized our universal low volume APC policy to establish a New Technology APC assignment for CY 2024 for CPT 78432, the same negative impacts caused by wide variations in payment rate that we sought to mitigate by adopting the universal low volume APC policy would result if we assigned CPT 78432 to the APC we proposed based on our universal low volume APC policy. While some payment fluctuations are expected and would not justify deviating from applying our universal low volume APC policy or making regular ratesetting changes, we have concerns that if we were to apply the universal low volume APC policy in this case to CPT code 78432 as proposed, we would see even lower utilization of CPT code 78432 compared to CPT codes 78431 and 78433, which have seen steady claims frequency increases since first being assigned to New Technology APCs. For example, for the CY 2023 OPPS/ASC final rule, we assigned CPT code 78431 to New Technology APC 1523 based on over 18,000 claims and CPT code 78433 to APC 1521 based on nearly 1,000 claims. For CY 2024, the claims volumes for both CPT code 78431 and 78433 have continued to increase to over 24,000 and 1,300 claims respectively, while utilization for CPT code 78432 has remained extremely limited. Specifically, there are only two more claims, 7 total, that we can use to set the payment rate for CPT code 78432 for CY 2024 compared to CY 2023. Because CPT code 78432 is one of three codes that describe the services associated with cardiac PET/CT studies, we have concerns that continued low claims frequency for CPT code 78432 will limit our ability to assign the service to an appropriate clinical APC. We believe that changing the APC payment rate based on an extremely low number of claims for CPT code 78432 for CY 2024 would further discourage utilization of the code as compared to CPT codes 78431 and 78433. While it is possible that patients may have a greater need for the services described by CPT code 78431 or 78433 rather than the service described by CPT code 78432, such that claims volume may always be lower for CPT code 78432 than the other codes describing cardiac PET/CT imaging

services, we would not want to make a change in payment that may further discourage utility of CPT code 78432 without first confirming that this is the case. Furthermore, we did not receive any comments on our proposal that explained that the service described by CPT code 78432 should only be furnished in extremely rare circumstances compared to CPT codes 78431 and 78433. Therefore, for CY 2024, we believe it is appropriate to utilize our equitable adjustment authority under section 1833(t)(2)(E) of the Act to maintain the New Technology APC assignment for CPT code 78432 as finalized in the CY 2023 OPPS Final Rule for one additional year by assigning the code to New Technology APC 1520.

Comment: Several commenters also disagreed with the proposal to reassign CPT code 78431 from APC 1523 to APC 1522 based on the claims data available. Although one commenter stated that with over 22,000 claims considered for CPT code 78431, the proposed APC payment for CPT code 78431 appears to be based on a large volume of information and appears to be reliable, the commenter disagreed with the proposal due to the impact a $500 reduction in payment rate may have on service lines.

Response: We disagree that it is inappropriate to change the APC assignment for CPT code 78431 based on the claims available. We based our proposal on over 22,000 claims for CPT code 78431, which demonstrate that the code had a geometric mean cost of approximately $2,300. Since the publication of the CY 2024 OPPS proposed rule (88 FR 49552), there are over 2,000 additional claims available for rate setting for CPT code 78431 for CY 2024. With the significant number of claims available for CPT code 78431, we believe it is appropriate to modify the APC assignment for CPT code 78431 based on our claims data for CY 2024.

Comment: Some commenters suggested that CMS consider alternatives to making adjustments in payment rates for services assigned to New Technology APCs that would allow for greater stability and predictability in payment rates from year to year. For example, one commenter suggested that CMS consider creating New Technology APCs with narrower cost bands between each APC or utilize several years of cost data—not unlike the low volume APC policy—to smooth the potential for large fluctuations.

Response: We appreciate the commenters' feedback and will consider the suggestions for future rulemaking.

Based on the comments received, we are finalizing our proposals for CPT codes 78431, 78432, and 78433 with modification. For CY 2024, we are finalizing the APC assignments for CPT codes 78431 and 78433 as proposed. Therefore, for CY 2024, we are assigning CPT code 78431 to New Technology APC 1522 and CPT code 78433 to New Technology APC 1521, as proposed. For CPT code 78432, we are invoking our equitable adjustment authority under section 1833(t)(2)(E) of the Act to maintain the New Technology APC assignment for CPT code 78432 as finalized in the CY 2023 OPPS final rule for an additional year. Therefore, we are assigning CPT code 78432 to APC 1520 for CY 2024.

Please refer to Table 17 below for the final OPPS New Technology APC and status indicator assignments for CPT codes 7843, 78432, and 78433 for CY 2024. The final CY 2024 payment rates can be found in Addendum B to this final rule with comment via the internet on the CMS website.

BILLING CODE 4150–28–P

TABLE 17: PROPOSED AND FINAL CY 2024 OPPS NEW TECHNOLOGY APC AND STATUS INDICATOR ASSIGNMENTS FOR CPT CODES 78431, 78432, AND 78433

CPT Code	Long Descriptor	Proposed CY 2024 OPPS SI	Proposed OPPS CY 2024 APC	Final OPPS CY 2024 SI	Final OPPS CY 2024 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 (e.g., myocardial viability);	S	1518	S	1520
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 (e.g., myocardial viability); with concurrently acquired computed tomography transmission scan	S	1521	S	1521

d. V-Wave Medical Interatrial Shunt Procedure (APC 1590)

A randomized, double-blinded, controlled 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 had 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, for CY 2020, 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 (e.g., 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)) with a payment rate of $12,500.50.

In the CY 2021 OPPS/ASC final rule with comment period (85 FR 85946), we stated that we believe similar resources and device costs are involved with the V-Wave interatrial shunt procedure and the Corvia Medical interatrial shunt procedure (HCPCS code C9760), except that payment for HCPCS codes C9758 and C9760 differs based on how often the interatrial shunt is implanted when each code is billed. An interatrial shunt is implanted one-half of the time HCPCS code C9758 is billed, whereas an interatrial shunt is implanted every time HCPCS code C9760 is billed. Accordingly, for CY 2021, we reassigned HCPCS code C9758 to New Technology APC 1590 (New Technology—Level 39 ($15,001–$20,000)), which reflects the cost of receiving the interatrial shunt one-half of the time the procedure is performed.

For CY 2022, we used the same claims data from CY 2019 that we did for the CY 2021 OPPS final rule with comment period. Because there were no claims reporting HCPCS code C9758, we continued to assign HCPCS code C9758 to New Technology APC 1590 with a payment rate of $17,500.50 for CY 2022. For CY 2023 we used claims data from CY 2019 through CY 2022. Because there were no claims reporting HCPCS code C9758, we continued to assign HCPCS code C9758 to New Technology APC 1590 with a payment rate of $17,500.50 for CY 2023.

For CY 2024, the OPPS payment rates are proposed to be based on available CY 2022 claims data. Although HCPCS code C9758 was effective January 1, 2020, we have no claims data at this time. Because we have no claims data, for CY 2024, we proposed to continue to assign HCPCS code C9758 to New Technology APC 1590 with a proposed payment rate of $17,500.50.

Please refer to Table 18 below for the proposed OPPS New Technology APC and status indicator assignment for HCPCS code C9758 for CY 2024. The proposed CY 2024 payment rates can be found in Addendum B to the CY 2024 OPPS/ASC proposed rule via the internet on the CMS website.

TABLE 18: PROPOSED CY 2024 OPPS NEW TECHNOLOGY APC AND STATUS INDICATOR ASSIGNMENTS FOR BLINDED INTRATRIAL SHUNT PROCEDURE

HCPCS Code	Long Descriptor	Proposed CY 2024 OPPS SI	Proposed CY 2024 OPPS APC
C9758	Blinded procedure for NYHA class III/IV heart failure; transcatheter implantation of interatrial shunt or placebo control, including right heart catheterization, transesophageal 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	T	1590

Comment: We received one comment on our proposal. The commenter supports our assignment of HCPCS code C9758 to APC 1590 for CY 2024.

Response: We appreciate the commenter's support for our proposal.

After consideration of the public comments we received, we are finalizing our proposal without modification. Please refer to Table 19 below for the final OPPS New Technology APC and status indicator assignments for HCPCS code C9758 for CY 2024. The final CY 2024 payment rates can be found in Addendum B to this final rule with comment via the internet on the CMS website.

BILLING CODE 4150–28–C

TABLE 19: FINAL CY 2023 AND CY 2024 OPPS NEW TECHNOLOGY APC AND STATUS INDICATOR ASSIGNMENTS FOR BLINDED INTRATRIAL SHUNT PROCEDURE

HCPCS Code	Long Descriptor	Final CY 2023 OPPS SI	Final CY 2023 OPPS SI	Final 2024 OPPS SI	Final 2024 OPPS SI
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	T	1590	T	1590

e. Corvia Medical Interatrial Shunt Procedure (APC 1592)

On July 1, 2020, we established HCPCS code 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 (*e.g.,* ultrasound, fluoroscopy), performed in an approved investigational device exemption (ide) study) to facilitate payment for the implantation of the Corvia Medical interatrial shunt.

As we stated in the CY 2021 OPPS final rule with comment period (85 FR 85947), we believe that similar resources and device costs are involved with the Corvia Medical interatrial shunt procedure and the V-Wave interatrial shunt procedure. But unlike the V-Wave interatrial shunt, which is implanted half the time the associated interatrial shunt procedure described by HCPCS code C9758 is billed, the Corvia Medical interatrial shunt is implanted every time the associated interatrial shunt procedure (HCPCS code C9760) is billed. Therefore, for CY 2021, we assigned HCPCS code C9760 to New Technology APC 1592 (New Technology—Level 41 ($25,001–$30,000)) with a payment rate of $27,500.50. We also modified the code descriptor for HCPCS code C9760 to remove the phrase ''or placebo control,'' from the descriptor. In CY 2022, we used the same claims data as was used in the CY 2021 OPPS final rule to determine the payment rate for HCPCS code C9760 because there were no claims for this service in CY 2019, the year used for ratesetting for CY 2022. Accordingly, we continued to assign HCPCS code C9760 to New Technology APC 1592 in CY 2022. For CY 2023, we used claims data from CY 2021 through CY 2022 to determine the payment rate for HCPCS code C9760. Because there were no claims for this service, we continued to assign HCPCS code C9760 to New Technology APC 1592 in CY 2023.

For CY 2024, the OPPS payment rates were proposed to be based on available CY 2022 claims data. There was only one claim for HCPCS code C9760 within this time period. As this is below the threshold of 100 claims for a service within a year, we would designate C9760 as a low volume service and apply our universal low volume APC policy. Under this policy, we would use the highest of the geometric mean cost, arithmetic mean cost, or median cost based on up to 4 years of claims data to assign HCPCS code C9760 to the appropriate New Technology APC. Using the only one claim available for HCPCS code C9760, the geometric mean, arithmetic mean, and median costs were estimated to be approximately $7,945 for this service. However, because there is only a single claim for HCPCS code C9760, its payment rate appears to be an outlier based on the cost information we received from the manufacturer. Therefore, we have concerns that the

universal low volume APC policy calculations do not accurately capture the cost of the service. Therefore, we proposed to continue assigning HCPCS code C9760 to New Technology APC 1592.

Please refer to Table 20 below for the proposed OPPS New Technology APC and status indicator assignment for HCPCS code C9760 for CY 2024. The proposed CY 2024 payment rates can be found in Addendum B to the CY 2024 OPPS/ASC proposed rule via the internet on the CMS website.

TABLE 20: PROPOSED CY 2024 OPPS NEW TECHNOLOGY APC AND STATUS INDICATOR ASSIGNMENTS FOR NON-RANDOMIZED, NON-BLINDED INTERATRIAL SHUNT PROCEDURE

HCPCS Code	Long Descriptor	Proposed CY 2024 OPPS SI	Proposed CY 2024 OPPS APC
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 (e.g., ultrasound, fluoroscopy	T	1592

Comment: We received one comment on our proposal. The commenter expressed support for finalizing the New Technology APC assignment as proposed. The commenter stated that continuing the current APC assignments is critical to ensure that HCPCS codes C9758 and C9760 can be furnished during ongoing CMS-approved IDE trials. The commenter further stated that the proposed APC assignment for HCPCS code C9760 will enable studies to proceed, preserve beneficiary access, and allow a more robust claims history to be developed on which to base permanent clinical APC assignment in the future.

Response: We appreciate the commenter's support for our proposal to assign HCPCS code C9760 to APC 1592.

First, we note that based on update claims data available for this final rule with comment period, we received one additional claim for CY 2022 since the publication of the CY 2024 OPPS proposed rule. Using the only two claims available for HCPCS code C9760, the geometric mean, arithmetic mean, and median costs are estimated to be approximately $10,520 for this service. However, because there are only two claims for HCPCS code C9760, we continue to believe its payment rate appears to be an outlier based on the cost information we received from the manufacturer. We continue to have concerns that application of the universal low volume APC policy in this case would not accurately capture the cost of the service. Therefore, after consideration of the public comment we received and our analysis of the extremely limited claims data available, we are finalizing our policy as proposed. Specifically, we are finalizing our proposal to assign HCPCS code C9760 to APC 1592 New Technology—Level 41 ($25,001–$30,000) for CY 2024.

After consideration of the public comment we received, we are finalizing our proposal without modification. Please refer to Table 21 below for the final OPPS New Technology APC and status indicator assignments for HCPCS code C9760 for CY 2024. The CY 2024 payment rates can be found in Addendum B to this final rule with comment period via the internet on the CMS website.

TABLE 21: PROPOSED AND FINAL CY 2024 OPPS NEW TECHNOLOGY APC AND STATUS INDICATOR ASSIGNMENTS FOR HCPCS CODE C9760

HCPCS Code	Long Descriptor	Proposed CY 2024 OPPS SI	Proposed CY 2024 OPPS APC	Final CY 2024 OPPS SI	Final CY 2024 OPPS APC
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 (e.g., ultrasound, fluoroscopy	T	1592	T	1592

f. Supervised Visits for Esketamine Self-Administration (APCs 1513 and 1520)

On March 5, 2019, 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)). This is the first FDA approval of esketamine for any use.

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. Each device delivers two sprays containing a total of 28 mg of esketamine. Patients would require either two (2) devices (for a 56 mg 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 esketamine nasal spray administration, and the potential for misuse or abuse 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. The Spravato™ REMS program requires the esketamine nasal spray to be dispensed and administered to enrolled patients in health care settings that are certified in the REMS. See *www.fda.gov* for more information regarding the Spravato™ REMS program compliance requirements.

A treatment session of esketamine consists of instructed nasal self-administration by the patient followed by a period of at least two (2) hours post-administration observation of the patient under direct supervision of a health care professional in the certified health care setting. Please refer to the CY 2020 PFS final rule and interim final rule for more information about supervised visits for esketamine nasal spray 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 through nasal self-administration and includes two hours of post-administration observation. For CY 2020, 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. For CY 2020, HCPCS code G2083 was assigned to New Technology APC 1511 (New Technology—Level 11 ($901–$1,000)) with a payment rate of $950.50. Updates to the APC assignments for G2082 and G2083 have been made in past rules. Please see the CY 2021 OPPS/ASC final rule with comment period (85 FR 85948), CY 2022 OPPS/ASC final rule with comment period (86 FR 63538), and the CY 2023 OPPS/ASC final rule with comment period (87 FR 71816).

For CY 2024, we proposed to use CY 2022 available claims data to determine the payment rates for HCPCS codes G2082 and G2083. Therefore, for CY 2024, we proposed to assign these two HCPCS codes to New Technology APCs based on the codes' geometric mean costs. Specifically, we proposed to assign HCPCS code G2082 to New Technology APC 1513 (New Technology—Level 13 ($1,101–$1,200)) based on its geometric mean cost of $1,123. We also proposed to assign HCPCS code G2083 to New Technology

APC 1518 (New Technology—Level 18 ($1,601–$1,700)) based on its geometric mean cost of $1,628.

The proposed New Technology APC and status indicator assignments for HCPCS codes G2082 and G2083 are shown in Table 22. The CY 2024 payment rates can be found in Addendum B to this final rule with comment period via the internet on the CMS website.

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TABLE 22: FINAL CY 2023 AND PROPOSED CY 2024 OPPS NEW TECHNOLOGY APC AND STATUS INDICATOR ASSIGNMENTS FOR HCPCS CODES G2082 AND G2083

HCPCS Code	Long Descriptor	Final CY 2023 OPPS SI	Final CY 2023 OPPS APC	Proposed CY 2024 OPPS SI	Proposed CY 2024 OPPS 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	1512	S	1513
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	1516	S	1518

Comment: We received one comment in support of our proposals to assign HCPCS code G2082 to APC 1513 and HCPCS code G2083 to APC 1518.

Response: We thank the commenter for their support.

We note the geometric mean costs for both HCPCS code G2082 and HCPCS code G2083 have changed since the proposed rule. Based on the updated claims data available for this final rule, the approximate geometric mean cost for HCPCS code G2082 is $1,189.24. Even though the geometric mean cost has increased slightly since the proposed rule, the proposed APC assignment of APC 1513 (New Technology—Level 13 ($1,101–$1,200)) is still appropriate and we are adopting this APC assignment as the final APC assignment for this HCPCS code G2082. Based on updated claims data available for this final rule with comment period, the approximate geometric mean cost for HCPCS code G2083 has increased to $1,821.48. Based on the updated claims available, we are finalizing a New Technology APC assignment for HCPCS code G2083 to APC 1520 (New Technology—Level 20 ($1,801–$1,900)) for CY 2024.

As a final note, as we have begun to gather adequate claims data, we are considering placement of HCPCS codes G2082 and G2083 into clinical APCs through future rulemaking.

Details about the New Technology APC and status indicator assignments for these HCPCS codes are shown in Table 23. The CY 2024 payment rates can be found in Addendum B to this final rule with comment period via the internet on the CMS website.

TABLE 23: CY 2024 PROPOSED AND FINAL OPPS NEW TECHNOLOGY APC AND STATUS INDICATOR ASSIGNMENTS FOR HCPCS CODES G2082 AND G2083

HCPCS Code	Long Descriptor	Proposed CY 2024 OPPS SI	Proposed CY 2024 OPPS APC	Final CY 2024 OPPS SI	Final CY 2024 OPPS 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	1513	S	1513
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	1518	S	1520

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g. DARI Motion Procedure (APC 1505)

Effective January 1, 2022, CPT code 0693T (Comprehensive full body computer-based markerless 3D kinematic and kinetic motion analysis and report) is associated with the DARI Motion Procedure, a service that provides human motion analysis to aid clinicians in pre- and post-operative surgical intervention and in making other treatment decisions, including selecting the best course of physical therapy and rehabilitation. The technology consists of eight cameras that surround a patient, which send live video to a computer workstation that analyzes the video to create a 3D reconstruction of the patient without the need for special clothing, markers, or devices attached to the patient's clothing or skin. For CY 2022, we assigned CPT code 0693T to New Technology APC 1505 (New Technology—Level 5 ($301–$400)). For CY 2023, the OPPS payment rates were based on claims submitted between January 1, 2021, and December 31, 2021, processed through June 30, 2022. Due to its effective date of January 1, 2022, there were no claims available for CPT code 0693T for rate setting in CY 2023. Therefore, in CY 2023, we continued to assign CPT code 0693T to New Technology APC 1505.

For CY 2024, the OPPS payment rates are proposed to be based on available CY 2022 claims data. Although CPT code 0693T was effective January 1, 2022, we did not have any claims data at the time of the CY 2024 OPPS/ASC proposed rule. Therefore, for CY 2024, we proposed to continue to assign CPT code 0693T to APC 1505 with a proposed payment rate of $350.50.

Please refer to Table 24 below for the proposed OPPS New Technology APC and status indicator assignment for CPT code 0693T for CY 2024. The proposed CY 2024 payment rates can be found in Addendum B to the CY 2024 OPPS/ASC proposed rule via the internet on the CMS website.

TABLE 24: PROPOSED CY 2024 OPPS NEW TECHNOLOGY APC AND STATUS INDICATOR ASSIGNMENTS FOR THE DARI MOTION PROCEDURE

CPT Code	Long Descriptor	Proposed CY 2024 OPPS SI	Proposed CY 2024 OPPS APC
0693T	Comprehensive full body computer-based markerless 3D kinematic and kinetic motion analysis and report	S	1505

We did not receive any public comments on our proposal, and we still do not have any claims for the service. Therefore, for CY 2024, we are finalizing our proposal without modification. Specifically, for CY 2024, we are assigning CPT code 0693T to APC 1505 and SI ''S.'' The final New Technology APC and status indicator assignments for CPT code 0693T for CY 2024 are found in Table 25. The CY 2024 payment rates can be found in Addendum B to this final rule with comment period via the internet on the CMS website. In addition, we refer readers to Addendum D1 of this final rule with comment period for the status indicator (SI) meanings for all codes reported under the OPPS. Addendum D1 can also be found via the internet on the CMS website.

TABLE 25: FINAL CY 2023 AND CY 2024 OPPS NEW TECHNOLOGY APC AND STATUS INDICATOR ASSIGNMENTS FOR THE DARI MOTION PROCEDURE

CPT Code	Long Descriptor	Final CY 2023 OPPS SI	Final CY 2023 OPPS APC	Final CY 2024 OPPS SI	Final CY 2024 OPPS APC
0693T	Comprehensive full body computer-based markerless 3D kinematic and kinetic motion analysis and report	S	1505	S	1505

h. Liver Histotripsy Service (APC 1576)

CPT code 0686T (Histotripsy (*i.e.,* non-thermal ablation via acoustic energy delivery) of malignant hepatocellular tissue, including image guidance) was first effective July 1, 2021, and describes the histotripsy service associated with the use of the HistoSonics system. Histotripsy is a non-invasive, non-thermal, mechanical process that uses a focused beam of sonic energy to destroy cancerous liver tumors and is currently in a non-randomized, prospective clinical trial to evaluate the efficacy and safety of the device for the treatment of primary or metastatic tumors located in the liver.[8]

When HCPCS code 0686T was first effective, the histotripsy procedure was designated as a Category A IDE clinical study (NCT04573881). Since devices in Category A IDE studies are excluded from Medicare payment, payment for CPT code 0686T only reflected the cost of the service that is performed each time it is reported on a claim. For CY 2023, we assigned CPT code 0686T to New Technology APC 1575 (New Technology—Level 38 ($10,000–$15,000) with a payment rate of $12,500. However, on March 2, 2023, the histotripsy IDE clinical study was re-designated as a Category B (Non-experimental/Investigational) IDE study. Due to this new designation, the proposed payment for CPT code 0686T in CY 2024 would reflect payment for both the service that is performed and the device used each time it is reported on a claim.

For CY 2024, the OPPS payment rates are proposed to be based on available CY 2022 claims data. There are only two claims for CPT code 0686T within this time period. We note that 0686T was still designated as a Category A IDE study for these claims and therefore, the payment for these claims only included payment for the cost of the service. As the available claims data is below the threshold of 100 claims for a service within a year, we could propose to designate CPT code 0686T as a low volume service under our universal low volume APC policy, and use the highest of the geometric mean cost, arithmetic mean cost, or median cost to assign CPT code 0686T to the appropriate New Technology APC. Based on the two available claims in CY 2022, when CPT

[8] ClinicalTrials.gov. ''The HistoSonics System for Treatment of Primary and Metastatic Liver Tumors Using Histotripsy (#HOPE4LIVER) (#HOPE4LIVER).'' Accessed May 10, 2022. *https://clinicaltrials.gov/ct2/show/study/NCT04573881.*

code 0686T was still designated as a Category A IDE study, the geometric mean is estimated to be: $4,466; the median is estimated to be: $4,480; and the arithmetic mean is estimated to be: $4,480. Because $4,480 is the greatest of these methodologies, we would use this value to set the payment rate for CPT code 0686T. However, we have concerns that the available claims data and universal low volume APC policy calculations would not accurately capture the cost of the service following its approval as a Category B IDE study in March of 2023. If 0686T were still designated as a Category A IDE study, then the two claims available would be appropriate to set its payment rate, as the claims reflect the cost of the service and exclude the cost of the device. However, because CPT code 0686T was approved as a Category B IDE study, meaning Medicare coverage and payment of the device is no longer statutorily prohibited, the two CY 2022 claims available would not accurately capture the cost of 0686T for CY 2024.

Therefore, based on the service costs reflected in the available claims and our estimates of the cost of the Category B device, for CY 2024, we proposed to maintain CPT code 0686T's current APC assignment. Specifically, we proposed to assign CPT code 0686T to APC 1575 (New Technology—Level 38 ($10,001–$15,000)) with a payment rate of $12,500.50 as shown in Table 26.

TABLE 26: PROPOSED CY 2024 OPPS NEW TECHNOLOGY APC AND STATUS INDICATOR ASSIGNMENTS FOR THE LIVER HISTOTRIPSY SERVICE

CPT Code	Long Descriptor	Proposed CY 2024 OPPS SI	Proposed CY 2024 OPPS APC
0686T	Histotripsy (i.e., non-thermal ablation via acoustic energy delivery) of malignant hepatocellular tissue, including image guidance	S	1575

Comment: Two commenters, including the developer of the liver histotripsy procedure have asked us to reassign CPT code 0686T to APC 1577 (New Technology—Level 40 ($20,001–$25,000)) with a payment rate of $22,500.50 because on March 2, 2023, the FDA changed the device classification to a Category B IDE study, which allows a device that is used in the medical procedure to receive additional payment. The developer stated that the cost of the device used in the procedure was around $7,500 and asked us to assign the liver histotripsy to a higher-paying new technology APC cost band that would reflect the cost of both the procedure and the device used in the procedure.

Response: We agree with the commenters that payment for CPT code 0686T should be increased to reflect that providers participating the Category B IDE study for the procedure may now receive payment for both the services provided and the device used to perform the procedure described by CPT code 0686T. However, we do not believe that a $10,000 payment increase for the procedure is supported by the data when the device only costs $7,500 and there are only two claims for the service. Therefore, we are assigning CPT code 0686T to APC 1576 (New Technology—Level 39 ($15,001–$20,000)) with a payment rate of $17,500.50.

HCPCS code 0686T (Histotripsy (that is, non-thermal ablation via acoustic energy delivery) of malignant hepatocellular tissue, including image guidance) will be assigned to APC 1576 (New Technology—Level 39 ($15,001–$20,000)) with a payment rate of $17,500.50. Please refer to Table 27 below for the OPPS New Technology APC and status indicator assignment for CPT code 0686T for CY 2024. The final CY 2024 payment rates can be found in Addendum B to this final rule via the internet on the CMS website.

TABLE 27: FINAL CY 2024 OPPS NEW TECHNOLOGY APC AND STATUS INDICATOR ASSIGNMENTS FOR THE LIVER HISTOTRIPSY SERVICE

CPT Code	Long Descriptor	Final CY 2024 OPPS SI	Final CY 2024 OPPS APC
0686T	Histotripsy (i.e., non-thermal ablation via acoustic energy delivery) of malignant hepatocellular tissue, including image guidance	S	1576

i. Liver Multiscan Service (APC 1511)

Effective July 1, 2021, CPT codes 0648T (Quantitative magnetic resonance for analysis of tissue composition (e.g., fat, iron, water content), including multiparametric data acquisition, data preparation and transmission, interpretation and report, obtained without diagnostic mri examination of the same anatomy (e.g., organ, gland, tissue, target structure) during the same session; single organ) and 0649T (Quantitative magnetic resonance for analysis of tissue composition (e.g., fat, iron, water content), including multiparametric data acquisition, data preparation and transmission, interpretation and report, obtained with diagnostic mri examination of the same anatomy (e.g., organ, gland, tissue, target structure); single organ (list separately in addition to code for primary procedure)) are associated with the Liver MultiScan service. LiverMultiScan is a Software as a medical Service (SaaS) that is intended to aid the diagnosis and management of chronic liver disease, the most prevalent of which is Non-Alcoholic Fatty Liver Disease (NAFLD). It provides standardized, quantitative imaging biomarkers for the characterization and assessment of inflammation, hepatocyte ballooning, and fibrosis, as well as steatosis, and iron accumulation. LiverMultiScan receives MR images acquired from patients' providers and analyzes the images using their proprietary Artificial Intelligence (AI) algorithms. It then sends the providers a quantitative metric report of the patient's liver fibrosis and inflammation. For CY 2023, we assigned CPT codes 0648T and 0649T to New Technology APC 1511 (New Technology—Level 11 ($901–$1,000) with a payment rate of $950.50.

For CY 2024, the OPPS payment rates are proposed to be based on available CY 2022 claims data. We identified only 39 claims each for CPT code 0648T and CPT code 0649T during this time period. As this is below the threshold of 100 claims for a service within a year, we proposed to apply our universal low volume APC policy and use the highest of the geometric mean cost, arithmetic mean cost, or median cost based on up to 4 years of claims data to assign CPT codes 0648T and 0649T to the appropriate New Technology APC. There are available claims data from CY 2021 and CY 2022 for CPT codes 0648T and 0649T. Our analysis of the data for CPT code 0648T found the geometric mean cost of the service is approximately $269, the arithmetic mean cost of the service is approximately $320, and the median cost of the service is approximately $313. Our analysis of the data for CPT code 0649T found the geometric mean cost of the service is approximately $102, the arithmetic mean cost of the service is approximately $136, and the median cost of the service is approximately $83. The arithmetic mean was the statistical methodology that estimated the highest cost for CPT codes 0648T and 0649T. In accordance with our SaaS Add-on Codes policy (87 FR 72032 and 72033), SaaS CPT add-on codes are assigned to the identical APCs and the same status indicator assignments as their standalone codes. Consistent with our SaaS Add-on Codes policy, CPT code 0649T, the add-on code for Liver MultiScan would be assigned to the identical APC and status indicator to CPT code 0648T, the standalone code for the same service. Therefore, we proposed, for CY 2024, to assign CPT codes 0648T and 0649T to APC 1505 (New Technology—Level 5 ($301–$400)) with a payment rate of $350.50 as shown in Table 28.

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TABLE 28: FINAL CY 2023 AND PROPOSED CY 2024 OPPS NEW TECHNOLOGY APC AND STATUS INDICATOR ASSIGNMENTS FOR THE LIVER MULTISCAN SERVICE

CPT Code	Long Descriptor	Final CY 2023 OPPS SI	Final CY 2023 OPPS APC	Proposed CY 2024 OPPS SI	Proposed CY 2024 OPPS APC
0648T	Quantitative magnetic resonance for analysis of tissue composition (e.g., fat, iron, water content), including multiparametric data acquisition, data preparation and transmission, interpretation and report, obtained without diagnostic mri examination of the same anatomy (e.g., organ, gland, tissue, target structure) during the same session; single organ	S	1511	S	1505
0649T	Quantitative magnetic resonance for analysis of tissue composition (e.g., fat, iron, water content), including multiparametric data acquisition, data preparation and transmission, interpretation and report, obtained with diagnostic MRI examination of the same anatomy (e.g., organ, gland, tissue, target structure) (List separately in addition to code for primary procedure)	S	1511	S	1505

Comment: Multiple commenters asked that we not change the APC assignment for both Liver Multiscan procedures. Many commenters stated that the cost of each of the services is at least $950, which is the current payment rate for these services. Other commenters noted that only 40 claims have been received for each service, which they believe is an insufficient number of claims to estimate the cost for these services.

Response: We recognize that software-based technologies are rapidly evolving, like the product used for both CPT code 0648 and CPT code 0649T. As noted in our comment solicitation on payment policy for software as a service (SaaS) procedures in the CY 2023 OPPS final rule (87 FR 72035 and 72036), we are considering for future rulemaking whether specific adjustments to payment policies and rate calculations are necessary to more accurately and appropriately pay for these products and services across settings of care. CMS remains open to feedback on these issues and welcomes engagement from interested parties, including from manufacturers, providers, and beneficiaries. We agree with the commenters that for both CPT code 0648 and CPT code 0649T, we should wait for more claims data before adjusting the current payment rates for these services.

Comment: One commenter supported our proposal because it would help lower the cost of non-invasive liver evaluations performed for liver fibrosis and liver fat quantification by encouraging providers to use a broader array of diagnostic approaches.

Response: We appreciate the support of the commenter for our original proposal, but we are adopting a final policy not to change the payment rates for CPT code 0648T and CPT code 0649T in CY 2024.

After consideration of the public comments we received, we are implementing our proposal with modifications. We will use our equitable adjustment authority under section 1833(t)(2)(E) to continue to assign CPT codes 0648T and 0649T to New Technology APC 1511 (New Technology—Level 11 ($901–$1,000) with a payment rate of $950.50. Please refer to Table 29 below for the final OPPS New Technology APC and status indicator assignments for CPT codes 0648T and 0649T for CY 2024. The final CY 2024 payment rates can be found in Addendum B to this final rule via the internet on the CMS website.

TABLE 29: FINAL CY 2024 OPPS NEW TECHNOLOGY APC AND STATUS INDICATOR ASSIGNMENTS FOR THE LIVER MULTISCAN SERVICE

CPT Code	Long Descriptor	Final CY 2024 OPPS SI	Final CY 2024 OPPS APC
0648T	Quantitative magnetic resonance for analysis of tissue composition (e.g., fat, iron, water content), including multiparametric data acquisition, data preparation and transmission, interpretation and report, obtained without diagnostic mri examination of the same anatomy (e.g., organ, gland, tissue, target structure) during the same session; single organ	S	1511
0649T	Quantitative magnetic resonance for analysis of tissue composition (e.g., fat, iron, water content), including multiparametric data acquisition, data preparation and transmission, interpretation and report, obtained with diagnostic MRI examination of the same anatomy (e.g., organ, gland, tissue, target structure) (List separately in addition to code for primary procedure)	S	1511

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j. Minimally Invasive Glaucoma Surgery (MIGS) (APC 5493)

Prior to CY 2022, extracapsular cataract removal with insertion of intraocular lens was reported using CPT codes describing cataract removal alongside a CPT code for device insertion. Specifically, the procedure was described using CPT codes 66982 (Extracapsular cataract removal with insertion of intraocular lens prosthesis (1-stage procedure), manual or mechanical technique (e.g., irrigation and aspiration or phacoemulsification), complex, requiring devices or techniques not generally used in routine cataract surgery (e.g., iris expansion device, suture support for intraocular lens, or primary posterior capsulorrhexis) or performed on patients in the amblyogenic developmental stage; without endoscopic cyclophotocoagulation) or 66984 (Extracapsular cataract removal with insertion of intraocular lens prosthesis (1-stage procedure), manual or mechanical technique (e.g., irrigation and aspiration or phacoemulsification); without endoscopic cyclophotocoagulation) and 0191T (Insertion of anterior segment aqueous drainage device, without extraocular reservoir, internal approach, into the trabecular meshwork; initial insertion).

For CY 2022, the AMA's CPT Editorial Panel created two new Category I CPT codes describing extracapsular cataract removal with insertion of intraocular lens prosthesis, specifically, CPT codes 66989 (Extracapsular cataract removal with insertion of intraocular lens prosthesis (1-stage procedure), manual or mechanical technique (e.g., irrigation and aspiration or phacoemulsification), complex, requiring devices or techniques not generally used in routine cataract surgery (e.g., iris expansion device, suture support for intraocular lens, or primary posterior capsulorrhexis) or performed on patients in the amblyogenic developmental stage; with insertion of intraocular (e.g., trabecular meshwork, supraciliary, suprachoroidal) anterior segment aqueous drainage device, without extraocular reservoir, internal approach, one or more) and 66991 (Extracapsular cataract removal with insertion of intraocular lens prosthesis (1 stage procedure), manual or mechanical technique (e.g., irrigation and aspiration or phacoemulsification); with insertion of intraocular (e.g., trabecular meshwork, supraciliary, suprachoroidal) anterior segment aqueous drainage device, without extraocular reservoir, internal approach, one or more); deleted a Category III CPT code, specifically, CPT code 0191T, describing insertion of anterior segment aqueous drainage device; and created a new Category III CPT code, specifically, CPT code 0671T, describing anterior segment aqueous drainage device without concomitant cataract removal.

For CY 2022, we finalized the assignment of CPT codes 66989 and 66991 to New Technology APC 1563 (New Technology—Level 26 ($4,001–$4,500)). We stated that we believed that the change in coding for MIGS is significant in that it changes longstanding billing for the service from reporting two separate CPT codes to reporting a single bundled code. Without claims data, and given the magnitude of the coding change, we explained that we did not believe we had the necessary information on the costs associated with CPT codes 66989 and 66991 to assign them to a clinical APC at that time. We maintained these APC assignments for CY 2023.

For CY 2023, the payment rates were based on claims data submitted between January 1, 2021, and December 31, 2021, and processed on or before June 30, 2022, and CCRs, if available. Because CPT codes 66989 and 66991 were

effective January 1, 2022, and we had no claims data for CY 2022, we finalized continued assignment of CPT codes 66989 and 66991 to New Technology APC 1563.

For CY 2024, the OPPS payment rates are proposed to be based on available CY 2022 claims data. For CY 2024, based on our analysis of claims data, we found a total of 898 single frequency claims and an estimated geometric mean cost of $5,241.55 for CPT code 66989 and a total of 5,576 single frequency claims and an estimated geometric mean cost of $4,957.01 for CPT code 66991. Given the claims volume, we believe it is appropriate to reassign the service to a clinical APC using our regular process of using the most recent year of claims data for a procedure. Upon review, we determined that the most appropriate clinical APC family for CPT codes 66989 and 66991 would be the Intraocular Procedures APC family (APC 5491 through 5495). However, there was a large payment rate difference between the level 2 Intraocular Procedures APC (APC 5492), which has a payment rate of $3,970.62, and the level 3 Intraocular Procedures APC (APC 5493), which has a payment rate of $14,067.62. Assigning CPT codes 66989 and 66991 to either APC 5492 or 5493 would result in a payment rate that would not reflect the cost for these procedures.

Therefore, given the significant difference in payment between APC 5492 and APC 5493, we believe it is appropriate to restructure the Intraocular Procedures APC family. Specifically, we proposed to create a sixth level in the Intraocular Procedures APC family by dividing APC 5492 into two APCs—an APC for services with a geometric mean cost of less than $5,000 and an APC for services with a geometric mean cost of greater than, or equal to, $5000. We believe that the creation of an additional level in the Intraocular APC family will create a smoother distribution of the costs between the different levels based on their resource costs and clinical characteristics. See section III.E. of the CY 2024 OPPS/ASC proposed rule for a detailed discussion of our proposal to restructure the Intraocular Procedures APC family. Reorganizing the Intraocular Procedures APCs would create a proposed Level 3 APC to be referred to as ''Proposed APC 5493'' with a payment rate of approximately $5,110.58, which is closer to the geometric mean of CPT codes 66989 and 66991. We note that, although these services have different estimated geometric mean costs, interested parties have indicated that it is preferable that they be placed within the same APC due to clinical similarity; therefore, we propose to reassign CPT codes 66989 and 66991 to Proposed APC 5493 for CY 2024.

The proposed clinical APC and status indicator assignments for CPT codes 66989 and 66991 are found in Table 30.

TABLE 30: CY 2023 FINAL AND CY 2024 PROPOSED OPPS NEW TECHNOLOGY APC AND STATUS INDICATOR ASSIGNMENTS FOR CPT CODES 66989 AND 66991

HCPCS Code	Long Descriptor	Final CY 2023 OPPS SI	Final CY 2023 OPPS APC	Proposed CY 2024 OPPS SI	Proposed CY 2024 OPPS APC
66989	Extracapsular cataract removal with insertion of intraocular lens prosthesis (1-stage procedure), manual or mechanical technique (eg, irrigation and aspiration or phacoemulsification), complex, requiring devices or techniques not generally used in routine cataract surgery (eg, iris expansion device, suture support for intraocular lens, or primary posterior capsulorrhexis) or performed on patients in the amblyogenic developmental stage; with insertion of intraocular (eg, trabecular meshwork, supraciliary, suprachoroidal) anterior segment aqueous drainage device, without extraocular reservoir, internal approach, one or more	S	1563	S	5493
66991	Extracapsular cataract removal with insertion of intraocular lens prosthesis (1 stage procedure), manual or mechanical technique (eg, irrigation and aspiration or phacoemulsification); with insertion of intraocular (eg, trabecular meshwork, supraciliary, suprachoroidal) anterior segment aqueous drainage device, without extraocular reservoir, internal approach, one or more	S	1563	S	5493

Comment: We received three comments in support of our proposal to reassign CPT codes 66989 and 66991 to Proposed APC 5493 for CY 2024.

Response: We appreciate the commenters' support for our proposals.

After consideration of the public comments we received, we are finalizing our proposal without modification. Please refer to Table 31 below for the final OPPS New Technology APC and status indicator assignment for CPT codes 66989 and 66991. The final CY 2024 payment rates can be found in Addendum B to this final rule with comment via the internet on the CMS website.

TABLE 31: CY 2023 FINAL AND CY 2024 FINAL OPPS NEW TECHNOLOGY APC AND STATUS INDICATOR ASSIGNMENTS FOR CPT CODES 66989 AND 66991

HCPCS Code	Long Descriptor	Final CY 2023 OPPS SI	Final CY 2023 OPPS APC	Final CY 2024 OPPS SI	Final CY 2024 OPPS APC
66989	Extracapsular cataract removal with insertion of intraocular lens prosthesis (1-stage procedure), manual or mechanical technique (eg, irrigation and aspiration or phacoemulsification), complex, requiring devices or techniques not generally used in routine cataract surgery (eg, iris expansion device, suture support for intraocular lens, or primary posterior capsulorrhexis) or performed on patients in the amblyogenic developmental stage; with insertion of intraocular (eg, trabecular meshwork, supraciliary, suprachoroidal) anterior segment aqueous drainage device, without extraocular reservoir, internal approach, one or more	S	1563	S	5493
66991	Extracapsular cataract removal with insertion of intraocular lens prosthesis (1 stage procedure), manual or mechanical technique (eg, irrigation and aspiration or phacoemulsification); with insertion of intraocular (eg, trabecular meshwork, supraciliary, suprachoroidal) anterior segment aqueous drainage device, without extraocular reservoir, internal approach, one or more	S	1563	S	5493

k. Scalp Cooling (APC 1514)

CPT code 0662T (Scalp cooling, mechanical; initial measurement and calibration of cap) became effective on July 1, 2021, to describe initial measurement and calibration of a scalp cooling device for use during chemotherapy administration to prevent hair loss. According to Medicare's National Coverage Determination (NCD) policy, specifically, NCD 110.6 (Scalp Hypothermia During Chemotherapy to Prevent Hair Loss), the scalp cooling cap itself is classified as an incident to supply to a physician service, and would not be paid under the OPPS; however, interested parties have indicated that there are substantial resource costs of around $1,900 to $2,400 associated with calibration and fitting of the cap. CPT guidance states that CPT code 0662T should be billed once per chemotherapy session, which we interpret to mean once per course of chemotherapy. Therefore, if a course of chemotherapy involves, for example, 6 or 18 sessions, HOPDs should report CPT 0662T only once for that 6 or 18 therapy sessions. For CY 2022, we assigned CPT code 0662T to APC New Technology 1520 (New Technology—Level 20 ($1801–$1900)) with a payment rate of $1,850.50. For CY 2023, we did not have any claims data; so, we continued to assign CPT code 0662T to APC 1520.

For CY 2024, the OPPS payment rates are proposed to be based on available

CY 2022 claims data. The Scalp Cooling service became effective in the OPPS in CY 2022, and we have identified 11 single frequency paid claims for CPT code 0662T for CY 2022. As this is below the threshold of 100 claims for a service within a year, we proposed to designate CPT code 0662T as a low volume service under our universal low volume APC policy and to use the highest of the geometric mean cost, arithmetic mean cost, or median cost based on up to 4 years of claims data to assign the service to the appropriate New Technology APC. Based on our review of the available claims, the geometric mean cost for CPT code 0662T is $831.16; the median is $797.63; and the arithmetic mean is $1,284.59. Therefore, for CY 2024, we proposed to designate this service as a low volume service under our universal low volume APC policy and reassign CPT code 0662T to APC 1514 (New Technology—Level 14 ($1201–$1300)) with a payment rate of $1,250.50 for CY 2024 based on the arithmetic mean of $1,284.59 as shown in Table 32.

TABLE 32: FINAL CY 2023 AND PROPOSED CY 2024 NEW TECHNOLOGY APC AND STATUS INDICATOR ASSIGNMENTS FOR THE SCALP COOLING PROCEDURE

CPT Code	Long Descriptor	Final CY 2023 OPPS SI	Final CY 2023 OPPS APC	Proposed CY 2024 OPPS SI	Proposed CY 2024 OPPS APC
0662T	Scalp cooling, mechanical; initial measurement and calibration of cap	S	1520	S	1514

Comment: Multiple commenters asked that we continue to assign CPT code 0662T to APC New Technology 1520 (New Technology—Level 20 ($1801–$1900)) with a payment rate of $1,850.50 for CY 2024. The commenters believe that 12 claims are not enough data to determine the cost of the procedure and that we should wait for more paid claims for the service before reducing payment for the service. Commenters stated that they had concerns with how hospital outpatient departments were billing CPT code 0662T and believed that they were incorrectly billing for the service.

Response: We disagree with the commenters. First, it is generally not our policy to judge the accuracy of provider coding and charging for purposes of ratesetting. We rely on hospitals and providers to accurately report the use of HCPCS codes in accordance with their code descriptors, and CPT and CMS instructions, and to report services accurately on claims and charges and costs for the services on their Medicare hospital cost report. The 12 claims for CPT code 0662T have a geometric mean of around $833 which is over $1,000 below the current $1,850.50 payment rate for the service. While there may be some future variation with the geometric mean for this service, it is likely to be closer to $830 than $1,850. CPT code 0662T is eligible to be evaluated through the new technology service low volume APC policy and has a median of $780.47, an arithmetic mean of $1,217.74, and a geometric mean of $832.96. Therefore, we will assign CPT code 0662T to the APC we proposed, APC 1514 (New Technology—Level 14 ($1201–$1300)) with a payment rate of $1,250.50 based on the updated arithmetic mean for the service of $1,217.74.

After consideration of the public comments we received, we are implementing our proposal without modification. Please refer to Table 33 below for the final OPPS New Technology APC and status indicator assignment for CPT code 0662T. The final CY 2024 payment rates can be found in Addendum B to this final rule with comment via the internet on the CMS website.

TABLE 33: FINAL CY 2024 NEW TECHNOLOGY APC AND STATUS INDICATOR ASSIGNMENTS FOR THE SCALP COOLING PROCEDURE

CPT Code	Long Descriptor	Final CY 2024 OPPS SI	Final CY 2024 OPPS APC
0662T	Scalp cooling, mechanical; initial measurement and calibration of cap	S	1514

l. Optellum Lung Cancer Prediction (LCP) (APC 1508)

CPT codes 0721T (Quantitative computed tomography (CT) tissue characterization, including interpretation and report, obtained without concurrent CT examination of any structure contained in previously acquired diagnostic imaging) and 0722T (Quantitative computed tomography (CT) tissue characterization, including interpretation and report, obtained with concurrent CT examination of any structure contained in the concurrently acquired diagnostic imaging dataset (list separately in addition to code for primary procedure)) became effective July 1, 2022, and are associated with the Optellum LCP technology. The Optellum LCP applies an algorithm to a patient's CT scan to produce a raw risk score for a patient's pulmonary nodule. The physician uses the risk score to quantify the risk of lung cancer and to determine what the next management step should be for the patient (for example, CT surveillance versus invasive procedure). For CY 2023, we assigned CPT codes 0721T and 0722T to APC New Technology 1508 (New Technology—Level 8 ($601–$700)).

For CY 2024, the OPPS payment rates are proposed to be based on available CY 2022 claims data. There are no claims available for CPT codes 0721T and 0722T. Therefore, for CY 2024, we proposed to continue assigning CPT codes 0721T and 0722T to New Technology APC 1508.

Please refer to Table 34 below for the proposed OPPS New Technology APC and status indicator assignment for HCPCS codes 0721T and 0722T for CY 2024. The proposed CY 2024 payment rates can be found in Addendum B to the CY 2024 OPPS/ASC proposed rule via the internet on the CMS website.

TABLE 34: PROPOSED CY 2024 NEW TECHNOLOGY APC AND STATUS INDICATOR ASSIGNMENTS FOR THE OPTELLUM LCP PROCEDURE

CPT Code	Long Descriptor	Proposed CY 2024 OPPS SI	Proposed CY 2024 OPPS APC
0721T	Quantitative computed tomography (CT) tissue characterization, including interpretation and report, obtained without concurrent CT examination of any structure contained in previously acquired diagnostic imaging	S	1508
0722T	Quantitative computed tomography (CT) tissue characterization, including interpretation and report, obtained with concurrent CT examination of any structure contained in the concurrently acquired diagnostic imaging dataset (list separately in addition to code for primary procedure)	S	1508

We did not receive any public comments on our proposal and are finalizing it without modification. HCPCS codes 0721T and 0722T will be assigned to New Technology APC 1508 with a status indication of ''S'' for CY 2024. Please refer to Table 35 below for the final OPPS New Technology APC and status indicator assignment for CPT

codes 0721T and 0722T. The final CY 2024 payment rates can be found in Addendum B to this final rule with comment via the internet on the CMS website.

TABLE 35: FINAL CY 2023 NEW TECHNOLOGY APC AND STATUS INDICATOR ASSIGNMENTS FOR THE OPTELLUM LCP PROCEDURE

CPT Code	Long Descriptor	Final CY 2024 OPPS SI	Final CY 2024 OPPS APC
0721T	Quantitative computed tomography (CT) tissue characterization, including interpretation and report, obtained without concurrent CT examination of any structure contained in previously acquired diagnostic imaging	S	1508
0722T	Quantitative computed tomography (CT) tissue characterization, including interpretation and report, obtained with concurrent CT examination of any structure contained in the concurrently acquired diagnostic imaging dataset (list separately in addition to code for primary procedure)	S	1508

m. Quantitative Magnetic Resonance Cholangiopancreatography (QMRCP) (APC 1511)

Effective July 1, 2022, CPT codes 0723T (Quantitative magnetic resonance cholangiopancreatography (QMRCP) including data preparation and transmission, interpretation and report, obtained without diagnostic magnetic resonance imaging (MRI) examination of the same anatomy (eg, organ, gland, tissue, target structure) during the same session) and 0724T (Quantitative magnetic resonance cholangiopancreatography (QMRCP), including data preparation and transmission, interpretation and report, obtained with diagnostic magnetic resonance imaging (MRI) examination of the same anatomy (eg, organ, gland, tissue, target structure) (list separately in addition to code for primary procedure)) are associated with the QMRCP Software as a medical Service (SaaS). The service performs quantitative assessment of the biliary tree and gallbladder. It uses a proprietary algorithm that produces a three-dimensional reconstruction of the biliary tree and pancreatic duct and also provides precise quantitative information of biliary tree volume and duct metrics. For CY 2023, we assigned CPT codes 0723T and 0724T to New Technology APC 1511 (New Technology—Level 11 ($900–$1,000)).

For CY 2024, the OPPS payment rates are proposed to be based on available CY 2022 claims data. For CPT code 0723T, there were no claims during this time period. Because there are no claims available, we proposed to continue to assign CPT code 0723T to New Technology APC 1511 with a payment rate of $950.50.

For CPT code 0724T, there was only one claim for CY 2022. As this is below the threshold of 100 claims for a service within a year, we explained that we could propose to designate CPT code 0724T as a low volume service under our universal low volume APC policy and use the highest of the geometric mean cost, arithmetic mean cost, or median cost based on up to 4 years of claims data to assign the service to an appropriate New Technology APC. Because there is only one claim available, the geometric mean, arithmetic mean, and median costs are estimated to be $26 for this service. However, we explained that because there is only a single claim for CPT code 0724T, the single claim available appears to be an outlier based on the cost information we received from the manufacturer. Therefore, we stated that we had concerns that the universal low volume APC policy calculations would not accurately capture the cost of the service. Therefore, for CY 2024, we proposed to continue assigning CPT code 0724T to New Technology APC 1511 with a payment rate of $950.50.

Please refer to Table 36 below for the proposed OPPS New Technology APC and status indicator assignment for HCPCS codes 0723T and 0724T for CY 2024. The proposed CY 2024 payment rates can be found in Addendum B to the CY 2024 OPPS/ASC proposed rule via the internet on the CMS website.

TABLE 36: PROPOSED CY 2024 OPPS NEW TECHNOLOGY APC AND STATUS INDICATOR ASSIGNMENTS FOR THE QMRCP PROCEDURE

CPT Code	Long Descriptor	Proposed CY 2024 OPPS SI	Proposed CY 2024 OPPS APC
0723T	Quantitative magnetic resonance cholangiopancreatography (QMRCP) including data preparation and transmission, interpretation and report, obtained without diagnostic magnetic resonance imaging (MRI) examination of the same anatomy (e.g., organ, gland, tissue, target structure) during the same session	S	1511
0724T	Quantitative magnetic resonance cholangiopancreatography (QMRCP), including data preparation and transmission, interpretation and report, obtained with diagnostic magnetic resonance imaging (MRI) examination of the same anatomy (e.g., organ, gland, tissue, target structure) (list separately in addition to code for primary procedure)	S	1511

We did not receive any public comments on our proposal and are finalizing it without modification. HCPCS codes 0723T and 0724T will be assigned to New Technology APC 1511 with a status indication of ''S'' for CY 2024. Please refer to Table 37 below for the final OPPS New Technology APC and status indicator assignment for HCPCS codes 0723T and 0724T. The final CY 2024 payment rates can be found in Addendum B to this final rule with comment via the internet on the CMS website.

TABLE 37: FINAL CY 2024 OPPS NEW TECHNOLOGY APC AND STATUS INDICATOR ASSIGNMENTS FOR THE QMRCP PROCEDURE

CPT Code	Long Descriptor	Final CY 2024 OPPS SI	Final CY 2024 OPPS APC
0723T	Quantitative magnetic resonance cholangiopancreatography (QMRCP) including data preparation and transmission, interpretation and report, obtained without diagnostic magnetic resonance imaging (MRI) examination of the same anatomy (e.g., organ, gland, tissue, target structure) during the same session	S	1511
0724T	Quantitative magnetic resonance cholangiopancreatography (QMRCP), including data preparation and transmission, interpretation and report, obtained with diagnostic magnetic resonance imaging (MRI) examination of the same anatomy (e.g., organ, gland, tissue, target structure) (list separately in addition to code for primary procedure)	S	1511

n. CardiAMP (APC 1590)

The CardiAMP cell therapy IDE studies are two randomized, double-blinded, controlled IDE studies: the CardiAMP Cell Therapy Chronic Myocardial Ischemia Trial[9] and the CardiAMP Cell Therapy Heart Failure Trial.[10] The two trials are designed to investigate the safety and efficacy of autologous bone marrow mononuclear cells treatment for the following: (1) patients with medically refractory and symptomatic ischemic cardiomyopathy; and (2) patients with refractory angina pectoris and chronic myocardial ischemia. On April 1, 2022, we established HCPCS code C9782 to describe the CardiAMP cell therapy IDE studies and assigned HCPCS code C9782 to APC 1574 (New Technology—Level 37 ($9,501–$10,000)) with the status indicator ''T.'' We subsequently revised the descriptor for HCPCS code C9782 to: (Blinded procedure for New York Heart Association (NYHA) Class II or III heart failure, or Canadian Cardiovascular Society (CCS) Class III or IV chronic refractory angina; transcatheter intramyocardial transplantation of autologous bone marrow cells (*e.g.,* mononuclear) or placebo control, autologous bone marrow harvesting and preparation for transplantation, left heart catheterization including ventriculography, all laboratory services, and all imaging with or without guidance (*e.g.,* transthoracic echocardiography, ultrasound, fluoroscopy), all device(s), performed in an approved Investigational Device Exemption (IDE) study) to clarify the inclusion of the Helix transendocardial injection catheter device in the descriptor. Additionally, we determined that APC 1590 (New Technology—Level 39 ($15,001–$20,000)) most accurately accounted for the resources associated with furnishing the procedure described by HCPCS code C9782.

For CY 2024, the OPPS payment rates are proposed to be based on available CY 2022 claims data. There are no available claims for ratesetting for CY 2024. Therefore, for CY 2024, we proposed to continue assigning HCPCS code C9782 to New Technology APC 1590 with a payment rate of $17,050.50.

Please refer to Table 38 below for the proposed OPPS New Technology APC and status indicator assignment for HCPCS code C9782 for CY 2024. The proposed CY 2024 payment rates can be found in Addendum B to the CY 2024 OPPS/ASC proposed rule via the internet on the CMS website.

[9] ClinicalTrials.gov. ''Randomized Controlled Pivotal Trial of Autologous Bone Marrow Cells Using the CardiAMP Cell Therapy System in Patients With Refractory Angina Pectoris and Chronic Myocardial Ischemia.'' Accessed May 10, 2022. *https://clinicaltrials.gov/ct2/show/NCT03455725?term=NCT03455725&rank=1.*

[10] ClinicalTrials.gov. ''Randomized Controlled Pivotal Trial of Autologous Bone Marrow Mononuclear Cells Using the CardiAMP Cell Therapy System in Patients With Post Myocardial Infarction Heart Failure.'' Accessed May 10, 2022. *https://clinicaltrials.gov/ct2/show/NCT02438306.*

TABLE 38: PROPOSED CY 2024 NEW TECHNOLOGY APC AND STATUS INDICATOR ASSIGNMENTS FOR THE CARDIAMP CELL THERAPY IDE STUDIES

HCPCS Code	Long Descriptor	Proposed CY 2024 OPPS SI	Proposed CY 2024 OPPS APC
C9782	Blinded procedure for New York Heart Association (NYHA) Class II or III heart failure, or Canadian Cardiovascular Society (CCS) Class III or IV chronic refractory angina; transcatheter intramyocardial transplantation of autologous bone marrow cells (e.g., mononuclear) or placebo control, autologous bone marrow harvesting and preparation for transplantation, left heart catheterization including ventriculography, all laboratory services, and all imaging with or without guidance (e.g., transthoracic echocardiography, ultrasound, fluoroscopy), all device(s), performed in an approved Investigational Device Exemption (IDE) study	T	1590

We did not receive any public comments on our proposal and are finalizing it without modification. HCPCS code C9782 will be assigned to New Technology APC 1590 with a status indication of ''T'' for CY 2024. Please refer to Table 39 below for the final OPPS New Technology APC and status indicator assignment for CPT code C9782. The final CY 2024 payment rates can be found in Addendum B to this final rule with comment via the internet on the CMS website.

TABLE 39: FINAL CY 2024 NEW TECHNOLOGY APC AND STATUS INDICATOR ASSIGNMENTS FOR THE CARDIAMP CELL THERAPY IDE STUDIES

HCPCS Code	Long Descriptor	Final CY 2024 OPPS SI	Final CY 2024 OPPS APC
C9782	Blinded procedure for New York Heart Association (NYHA) Class II or III heart failure, or Canadian Cardiovascular Society (CCS) Class III or IV chronic refractory angina; transcatheter intramyocardial transplantation of autologous bone marrow cells (e.g., mononuclear) or placebo control, autologous bone marrow harvesting and preparation for transplantation, left heart catheterization including ventriculography, all laboratory services, and all imaging with or without guidance (e.g., transthoracic echocardiography, ultrasound, fluoroscopy), all device(s), performed in an approved Investigational Device Exemption (IDE) study	T	1590

o. Surfacer® Inside-Out® Access Catheter System (APC 1534)

HCPCS code C9780 (Insertion of central venous catheter through central venous occlusion via inferior and superior approaches (*e.g.,* inside-out technique), including imaging guidance) describes the procedure associated with the use of the Surfacer® Inside-Out® Access Catheter System that is designed to address central venous occlusion. HCPCS code C9780 was established on October 1, 2021, and since its establishment the code has been assigned to New Technology APC 1534 (New Technology—Level 34 ($8001–$8500)).

For CY 2024, the OPPS payment rates are proposed to be based on available CY 2022 claims data. Although HCPCS code C9780 was effective October 1, 2021, we have no claims data at this time. Because we have no claims data available, for CY 2024, we proposed to continue to assign HCPCS code C9780 to APC 1534 with a proposed payment rate of $8,250.50 as shown in Table 40.

TABLE 40: PROPOSED CY 2024 NEW TECHNOLOGY APC AND STATUS INDICATOR ASSIGNMENT FOR SURFACER® INSIDE-OUT® ACCESS CATHETER SYSTEM PROCEDURE

HCPCS Code	Long Descriptor	Proposed CY 2024 OPPS SI	Proposed CY 2024 OPPS APC
C9780	Insertion of central venous catheter through central venous occlusion via inferior and superior approaches (e.g., inside-out technique), including imaging guidance	S	1534

We did not receive any public comments on our proposal and are finalizing it without modification. There are no paid claims for the service described by HCPCS code 9780 for CY 2024. Therefore, we will continue to assign this service to APC 1534 with a proposed payment rate of $8,250.50. Please refer to Table 41 below for the final OPPS New Technology APC and status indicator assignment for HCPCS code C9780 for CY 2024. The final CY 2024 payment rates can be found in Addendum B to this final rule via the internet on the CMS website.

TABLE 41: FINAL CY 2024 NEW TECHNOLOGY APC AND STATUS INDICATOR ASSIGNMENT FOR SURFACER® INSIDE-OUT® ACCESS CATHETER SYSTEM PROCEDURE

HCPCS Code	Long Descriptor	Final CY 2024 OPPS SI	Final CY 2024 OPPS APC
C9780	Insertion of central venous catheter through central venous occlusion via inferior and superior approaches (e.g., inside-out technique), including imaging guidance	S	1534

p. Insertion or Replacement of Neurostimulator System for Treatment of Central Sleep Apnea; Complete System (APC 1580)

HCPCS code 0424T (Insertion or replacement of a neurostimulator system for treatment of central sleep apnea; complete system (transvenous placement of right or left stimulation lead, sensing lead, implantable pulse generator)) is associated with the use of the Remede® System, which is used to treat adult patients with moderate to severe Central Sleep Apnea. HCPCS code 0424T was first effective in January 1, 2016, and subsequently assigned to Comprehensive APC 5464 (Neurostimulator and Related Procedures APC—Level 4). For CY 2021, we created a 5-level structure for the Neurostimulator and Related Procedure APC series, and consequently, assigned HCPCS code 0424T to the highest level in the series: Comprehensive APC 5465 (Neurostimulator & Related Procedures APC—Level 5). For CY 2023, we proposed to continue the 5-level structure for the Neurostimulator and Related Procedure APC series, while also soliciting comment on the creation of an additional Level 6 APC in the series. In the CY 2023 final rule with comment period, we finalized our proposal to continue the 5-level APC structure based on a determination that

the existing structure remained appropriate based on clinical and cost characteristics. However, we also recognized that CPT code 0424T was not appropriately assigned to the Comprehensive APC 5465 based on a significant difference between its geometric mean cost and that of the APC. Therefore, for CY 2023, we finalized the assignment of HCPCS code 0424T to New Technology APC 1581 (New Technology—Level 44 ($50,001–$60,000)).

For CY 2024, the OPPS payment rates are proposed to be based on available CY 2022 claims data. There are only 30 claims for HCPCS code 0424T available during this time period. As this is below the threshold of 100 claims for a service within a year, we propose to apply our universal low volume APC policy and use the highest of the geometric mean cost, arithmetic mean cost, or median cost based on up to 4 years of claims data to assign HCPCS code 0424T to the appropriate New Technology APC. Considering the available claims data for HCPCS code 0424T, the arithmetic mean is $49,468; the median is $48,285; and the geometric mean cost is $44,287. Of these, the arithmetic mean is the statistical methodology that estimates the highest cost for the service. The payment rate calculated using this methodology falls within the cost band for New Technology APC 1580 (New Technology—Level 43 ($40,001–$50,000)) with a payment rate of $45,000.50. Therefore, for CY 2024, we proposed to assign HCPCS code 0424T to New Technology APC 1580. We note that for the CY 2024 update, the CPT Editorial Panel is deleting HCPCS code 0424T and replacing it with placeholder code 3X008 effective January 1, 2024. Consequently, we proposed to assign HCPCS code 0424T to status indicator ''D'' to indicate the code will be deleted and assigning its replacement code, specifically, placeholder code 3X008, to APC 1580 for CY 2024. For placeholder code 3X008, we stated the final 5-digit CPT code number would be listed in the CY 2024 OPPS/ASC final rule with comment period. This information is summarized in Table 42.

TABLE 42: PROPOSED CY 2024 NEW TECHNOLOGY APC AND STATUS INDICATOR ASSIGNMENT FOR HCPCS 0424T/3X008

HCPCS Code	Long Descriptor	Final CY 2023 OPPS SI	Final CY 2023 OPPS APC	Proposed CY 2024 OPPS SI	Proposed CY 2024 OPPS APC
0424T	Insertion or replacement of a neurostimulator system for treatment of central sleep apnea; complete system (transvenous placement of right or left stimulation lead, sensing lead, implantable pulse generator	S	1581	D	N/A
3X008	Insertion of phrenic nerve stimulator system (pulse generator and stimulating lead[s]), including vessel catheterization, all imaging guidance, and pulse generator initial analysis with diagnostic mode activation, when performed	N/A	N/A	S	1580

Comment: One commenter, the manufacturer, claimed that in CY 2022 two of the 21 paid claims for CPT code 0424T were inappropriately billed by hospitals that according to the manufacturer's records could not have purchased the device used in the procedure described by CPT code 0424T. The manufacturer asked that we exclude the two claims from our analysis to determine the payment rate for the procedure.

Response: We appreciate the comment, but as have regularly stated since the establishment of the OPPS, it is the responsibility of providers and other interested parties to work with the MACs to fix any claims that may have been billed or paid inappropriately for a service. In this case, and in most cases, we assume that if a paid claim has been present on the claims file for several months that the claim as been paid appropriately. Therefore, we will not remove the two claims in question when performing our new technology low volume analyses to determine the payment rate for HCPCS code 0424T.

After consideration of the public comments we received, we are implementing our proposal without modification. Our updated low volume analysis for HCPCS code 0424T finds that the median for paid claims for the service is $47,387.06, the arithmetic mean is $47,967.41, and the geometric mean is $43,063.94. The highest amount of the three values is the arithmetic mean of $47,967.41. Therefore, the service described by 0424T and placeholder code 3X008 will be assigned to New Technology APC 1580

(New Technology—Level 43 ($40,001–$50,000)) with a payment rate of $45,000.50. In addition, placeholder code 3X008 has been replaced with CPT code 33276 (Insertion of phrenic nerve stimulator system (pulse generator and stimulating lead[s]), including vessel catheterization, all imaging guidance, and pulse generator initial analysis with diagnostic mode activation, when performed).

Please refer to Table 43 below for the final OPPS New Technology APC and status indicator assignment for CPT code 33276 for CY 2024. The final CY 2024 payment rates can be found in Addendum B to this final rule via the internet on the CMS website.

TABLE 43: FINAL CY 2024 NEW TECHNOLOGY APC AND STATUS INDICATOR ASSIGNMENT FOR HCPCS 0424T/33276

CPT Code	Long Descriptor	Final CY 2024 OPPS SI	Final CY 2024 OPPS APC
0424T	Insertion or replacement of a neurostimulator system for treatment of central sleep apnea; complete system (transvenous placement of right or left stimulation lead, sensing lead, implantable pulse generator	D	N/A
33276/ 3X008	Insertion of phrenic nerve stimulator system (pulse generator and stimulating lead[s]), including vessel catheterization, all imaging guidance, and pulse generator initial analysis with diagnostic mode activation, when performed	S	1580

q. Cleerly Labs (APC 1511)

Cleerly Labs is a Software as a Service (SaaS) that assesses the extent of coronary artery disease severity using Atherosclerosis Imaging-Quantitative Computer Tomography (AI–QCT). This procedure is performed to quantify the extent of coronary plaque and stenosis in patients who have undergone coronary computed tomography analysis (CCTA). The AMA CPT Editorial Panel established the following four codes associated with this service, effective January 1, 2021:

0623T: Automated quantification and characterization of coronary atherosclerotic plaque to assess severity of coronary disease, using data from coronary computed tomographic; angiography; data preparation and transmission, computerized analysis of data, with review of computerized analysis output to reconcile discordant data, interpretation and report.

0624T: Automated quantification and characterization of coronary atherosclerotic plaque to assess severity of coronary disease, using data from coronary computed tomographic angiography; data preparation and transmission.

0625T: Automated quantification and characterization of coronary atherosclerotic plaque to assess severity of coronary disease, using data from coronary computed tomographic angiography; computerized analysis of data from coronary computed tomographic angiography.

0626T: Automated quantification and characterization of coronary atherosclerotic plaque to assess severity of coronary disease, using data from coronary computed tomographic angiography; review of computerized analysis output to reconcile discordant data, interpretation and report.

In the CY 2021 OPPS/ASC final rule with comment period, we assigned the CPT codes 0623T, 06234T, 0625T, and 0626T to status indicator ''E1'' to indicate that the codes are not payable by Medicare when submitted on outpatient claims because the service had not received FDA clearance at the time of the assignment.

For the October 2022 update, based on our review of the New Technology application submitted to CMS for OPPS payment consideration, we evaluated the current status indicator assignments for CPT codes 0623T–0626T. Based on the technology and its potential utilization in the HOPD setting, our evaluation of the service, as well as input from our medical advisors, we assigned CPT code 0625T to a separately payable status. Specifically, in the October 2022 OPPS Update CR (Change Request 12885, Transmittal 11594, dated September 9, 2022), we reassigned CPT code 0625T to status indicator ''S'' (Significant Procedures, Not Discounted when Multiple. Paid under OPPS; separate APC payment) and APC 1511 (New Technology—Level 11 ($900–$1000)) with a payment rate of $950.50, effective October 1, 2022, following our review of the manufacturer's New Technology APC application.

For CY 2024, the OPPS payment rates were proposed to be based on available CY 2022 claims data. There are 90 claims for CPT code 0625T during this time period. As this is below the threshold of 100 claims for a service within a year, we explained that we could propose to designate CPT code 0625T as a low volume service under our universal low volume APC policy and use the highest of the geometric mean cost, arithmetic mean cost, or median cost based on up to 4 years of claims data to assign code 0625T to the appropriate New Technology APC. We found the geometric mean cost for the service to be approximately $3.70, the

arithmetic mean cost to be approximately $4.10, and the median cost to be approximately $3.50. Under our universal low volume APC policy, we would use the greatest of the statistical methodologies, the arithmetic mean, to assign CPT code 0625T to New Technology 1491 (New Technology Level 1A—(0–$10)) with a payment rate of $5.00. However, we acknowledged that, because CPT code 0625T was only made separately payable as part of the OPPS in October 2022, and, therefore, the claims available only reflect two months of data, we were concerned that we do not have sufficient claims data to justify reassignment to another New Technology APC (66 FR 69902). Therefore, consistent with our current policy to retain services within New Technology APC groups until we obtain sufficient claims data to justify reassignment (66 FR 59902), for CY 2024 we proposed to maintain CPT code 0625T's current assignment. Specifically, for CY 2024, we proposed to continue to assign CPT code 0625T to New Technology APC 1511 with a payment rate of $950.50.

Please refer to Table 44 below for the proposed OPPS New Technology APC and status indicator assignment for CPT code 0625T for CY 2024. The proposed CY 2024 payment rates can be found in Addendum B to the CY 2024 OPPS/ASC proposed rule via the internet on the CMS website.

TABLE 44: PROPOSED CY 2024 NEW TECHNOLOGY APC AND STATUS INDICATOR ASSIGNMENTS FOR CLEERLY LABS HCPCS CODE 0625T

HCPCS Code	Long Descriptor	Proposed CY 2024 OPPS SI	Proposed CY 2024 OPPS APC
0625T	Automated quantification and characterization of coronary atherosclerotic plaque to assess severity of coronary disease, using data from coronary computed tomographic angiography; computerized analysis of data from coronary computed tomographic angiography	S	1511

Comment: We received comments supporting our proposal for 0625T. Commenters stated that they agree with our reasoning that there are limited claims data available because CPT code 0625T was only made separately payable as part of the OPPS in October 2022. One commenter noted that there may also be a limited number of claims in CY 2023 and urged CMS to be cognizant of that in developing the CY 2025 payment rate for CPT code 0625T. The commenter also stated that there will likely be sufficient CY 2024 claims data for CMS to consider a different APC assignment for CPT code 0625T for CY 2026 with the availability of a new device that may be utilized with service described by CPT code 0625T.

Response: We thank the commenters for their support of our proposal. We note that the policy being finalized in this final rule with comment with regard to CPT code 0625T applies only for CY 2024. Regarding the APC assignments for CPT code 0625T for future years, we will similarly consider the claims data available and public comments received in selecting the APC assignment for the code.

We note that based on updated claims data available for this final rule with comment period, the low volume policy calculations have changed slightly. However, the concerns stated in the CY 2024 OPPS/ASC proposed rule regarding having insufficient claims data to justify reassignment to another New Technology APC remain. Therefore, after consideration of the public comments we received and the limited claims data available, we are finalizing the APC assignment for CPT code 0625T as proposed.

Please refer to Table 45 below for the final OPPS New Technology APC and status indicator assignment for CPT code 0625T. The final CY 2024 payment rates can be found in Addendum B to this final rule with comment via the internet on the CMS website.

TABLE 45: PROPOSED AND FINAL CY 2024 OPPS NEW TECHNOLOGY APC AND STATUS INDICATOR ASSIGNMENTS FOR CPT CODE 0625T

HCPCS Code	Long Descriptor	Proposed CY 2024 OPPS SI	Proposed CY 2024 OPPS APC	Final CY 2024 OPPS SI	Final CY 2024 OPPS APC
0625T	Automated quantification and characterization of coronary atherosclerotic plaque to assess severity of coronary disease, using data from coronary computed tomographic angiography; computerized analysis of data from coronary computed tomographic angiography	S	1511	S	1511

D. Universal Low Volume APC Policy for Clinical and Brachytherapy APCs

In the CY 2022 OPPS/ASC final rule with comment period (86 FR 63743 through 63747), we adopted a policy to designate clinical and brachytherapy APCs as low volume APCs if they have fewer than 100 single claims that can be used for ratesetting purposes in the claims year used for ratesetting for the prospective year. For the CY 2024 OPPS/ASC proposed rule, CY 2022 claims are generally the claims used for ratesetting; and clinical and brachytherapy APCs with fewer than 100 single claims from CY 2022 that can be used for ratesetting would be low volume APCs subject to our universal low volume APC policy. As we stated in the CY 2022 OPPS/ASC final rule with comment period, we adopted this policy to reduce the volatility in the payment rate for those APCs with fewer than 100 single claims. Where a clinical or brachytherapy APC has fewer than 100 single claims that can be used for ratesetting, under our low volume APC payment adjustment policy, we determine the APC cost as the greatest of the geometric mean cost, arithmetic mean cost, or median cost based on up to 4 years of claims data. We excluded APC 5853 (Partial Hospitalization for CMHCs) and APC 5863 (Partial Hospitalization for Hospital-based PHPs) from our universal low volume APC policy given the different nature of policies that affect the partial hospitalization program. We also excluded APC 2698 (Brachytx, stranded, nos) and APC 2699 (Brachytx, non-stranded, nos) as our current methodology for determining payment rates for non-specified brachytherapy sources is appropriate.

Based on claims data available for the CY 2024 OPPS/ASC proposed rule, we proposed to designate five brachytherapy APCs and five clinical APCs as low volume APCs under the OPPS. The five brachytherapy APCs and five clinical APCs meet our criteria of having fewer than 100 single claims in the claims year used for ratesetting (CY 2022 for the CY 2024 OPPS/ASC proposed rule). Eight of the ten APCs were designated as low volume APCs in CY 2023. Based on data for the CY 2024 OPPS/ASC proposed rule, APC 2642 (Brachytx, stranded, C–131) now meets our criteria to be designated a Low Volume APC; and we proposed to designate it as such for CY 2024. Further, with the proposed addition of Level 6 Intraocular APC (APC 5496), as discussed in section III.E of the CY 2024 OPPS/ASC proposed rule, and the reassignment of certain intraocular procedures from Level 2 to Level 3, the Level 4 Intraocular APC (which was the Level 3 Intraocular APC in CY 2023), now meets our criteria to be designated a Low Volume APC; and we proposed to designate it as such for CY 2024.

Table 46 includes the APC geometric mean cost without the low volume APC designation, that is, if we calculated the geometric mean cost based on CY 2022 claims data available for ratesetting; the median, arithmetic mean, and geometric mean cost using up to 4 years of claims data based on the APC's designation as a low volume APC; and the statistical methodology we proposed to use to determine the APC's cost for ratesetting purposes for CY 2024. As discussed in our CY 2022 OPPS/ASC final rule with comment period (86 FR 63751 through 63754), given our concerns with CY 2020 claims data as a result of the PHE, the 4 years of claims data we proposed to use to calculate the costs for these APCs are CYs 2018, 2019, 2021, and 2022.

TABLE 46: COST STATISTICS FOR FINAL LOW VOLUME APCS USING COMPREHENSIVE (OPPS) RATESETTING METHODOLOGY FOR CY 2024

APC	APC Description	CY 2022 Claims Available for Ratesetting	Geometric Mean Cost without Low Volume APC Designation	Final Median Cost	Final Arithmetic Mean Cost	Final Geometric Mean Cost	Final CY 2024 APC Cost
2632	Iodine I-125 sodium iodide	0	---*	$31.74	$61.83	$41.06	$61.83
2635	Brachytx, non-str, HA, P-103	21	$97.56	$58.38	$60.78	$54.74	$60.78
2636	Brachy linear, non-str, P-103	1	$60.16	$22.17	$55.57	$32.95	$55.57
2642	Brachytx, stranded, C-131	82	$93.94	$76.36	$100.23	$79.27	$100.23
2647	Brachytx, NS, Non-HDRIr-192	2	$415.40	$201.69	$358.12	$166.75	$358.12
5244	Level 4 Blood Product Exchanges and Related Services	66	$69,452.75	$45,702.69	$53,516.13	$45,639.70	$53,516.13
5494	Level 4 Intraocular Procedures	55	$13,367.49	$11,993.21	$12,140.88	$11,065.60	$12,140.88
5495	Level 5 Intraocular Procedures	91	$7,548.24	$15,457.23	$14,722.07	$11,025.70	$15,457.23
5496	Level 6 Intraocular Procedures	26	$11,541.28	$16,990.74	$15,263.22	$12,931.30	$16,990.74

* For this rule, there are no CY 2022 claims that contain the HCPCS code assigned to APC 2632 that are available for CY 2024 OPPS/ASC ratesetting.

Comment: One commenter requested clarification about the meaning of the statement ''using up to four years of data'' regarding the calculation of the geometric mean, arithmetic mean, and median for the universal low volume APC policy for clinical and brachytherapy APCs (88 FR 49627). The commenter also requested more information on why there was a difference in the geometric mean amount reported in the CY 2024 OPPS proposed rule in Table 27 for APC 5244 (Level 4 Blood Product Exchanges and Related Services), which was $52,105 based on claims from CY 2022 as compared to the geometric mean reported for APC 5244 in the 2 times rule discussion for the CY 2024 OPPS proposed rule, which was $71,154 and also based on claims from CY 2022 (88 FR 49628).

Response: When we state that we are using up to four years of data for the universal low volume APC policy for clinical and brachytherapy APCs, we mean that we will use four years of data

if four years of data is available for an APC, but we may need to use between one and three years of data if fewer years of data are available. We will use the greatest number of years of data available, unless there is a substantial reason not to use a particular year of data. The data will also be for consecutive years unless, again, there is substantial reason not to use a particular year of data. For example, we stated in the CY 2024 OPPS proposed rule (88 FR 49627) that we had concerns with CY 2020 claims data as a result of the COVID–19 PHE, and that we were therefore using data from CYs 2018, 2019, 2021, and 2022.

The commenter correctly noted that we inadvertently provided an outdated geometric mean cost for APC 5244 based on only CY 2022 claims data. Based on data available for the proposed rule, the correct geometric mean cost without low volume APC designation that should have been displayed in Table 27 for APC 5244 was $71,154.

Comment: One commenter supports the universal low volume APC policy for clinical and brachytherapy APCs in general but requests that the policy only be invoked when application of the universal low volume policy would increase the payment amount for the low-volume APC.

Response: The purpose of the universal low volume APC policy for clinical and brachytherapy APCs is to bring payment stability to these low-volume APCs rather than to ensure higher payment rates. With payment stability, whether it is limiting annual increases or decreases in the payment rate, providers are better able to plan what their expenses and compensation will be for performing certain low-volume services, and they can use that information to help budget for the cost of these low-volume services over several years.

After consideration of the public comments we received, we are implementing our proposals without modification except where we are updating the payment rates for low-volume clinical and brachytherapy APCs with claims data updated through June 20, 2023.

E. APC-Specific Policies

1. Ablation of Bone Tumors CPT Code 20982 (APC 5115)

CPT code 20982 (Ablation therapy for reduction or eradication of 1 or more bone tumors (eg, metastasis) including adjacent soft tissue when involved by tumor extension, percutaneous, including imaging guidance when performed; radiofrequency) describes a primarily palliative procedure that reduces the size of bone tumors and lessens the pain from the tumors. For the CY 2024 OPPS proposed rule, CPT code 20982 had a geometric mean of around $11,773 and we proposed to assign the procedure to APC 5114 (Level 4 Musculoskeletal Procedures), which has a payment rate of around $6,974.

Comment: One commenter asked that we reassign CPT code 20982 from APC 5114 to APC 5115 (Level 5 Musculoskeletal Procedures) with a payment rate of around $13,421. The commenter noted that this bone tumor ablation procedure was one of the highest cost procedures assigned to APC 5114 and that the payment rate for APC 5114 only covered around 60 percent of the cost of CPT code 20982. The commenter also noted that while the bone tumor ablation procedure would be overpaid in APC 5115, the additional payment was only 13 percent of the cost of CPT code 20982.

Response: We agree with the commenter. In addition to the underpayment and overpayment amounts cited by the commenter, we also found that if CPT code 20982 had enough claims to be a significant procedure in APC 5114, it would be in violation of the 2 times rule by over $1,000 as two times the lowest cost significant procedure in that APC was around $10,700 while the payment rate for CPT code 20982 is around $11,773.

After consideration of the public comments we received, we are assigning CPT code 20982 to APC 5115 (Level 5 Musculoskeletal Procedures). Table 47 shows the finalized status indicator and APC assignment for this procedure code. We refer readers to Addendum B of this final rule with comment period for the payment rates for all codes reportable under the OPPS. Addendum B is available via the internet on the CMS website.

TABLE 47: FINAL CY 2024 OPPS APC STATUS INDICATOR ASSIGNMENTS FOR CPT CODE 20982

CPT Code	Long Descriptor	Final CY 2024 OPPS SI	Final CY 2024 OPPS APC
20982	Ablation therapy for reduction or eradication of 1 or more bone tumors (eg, metastasis) including adjacent soft tissue when involved by tumor extension, percutaneous, including imaging guidance when performed; radiofrequency	J1	5115

2. Administration of Lacrimal Ophthalmic Insert Into Lacrimal Canaliculus (APC 5503)

Dextenza, which is described by HCPCS code J1096 (Dexamethasone, lacrimal ophthalmic insert, 0.1 mg), is a drug indicated for ''the treatment of ocular inflammation and pain following ophthalmic surgery'' and for ''the treatment of ocular itching associated with allergic conjunctivitis.'' [11]

The manufacturer of the drug previously asserted that this drug is administered and described by CPT code 0356T (Insertion of drug-eluting implant (including punctal dilation and implant removal when performed) into lacrimal canaliculus, each). Interested parties also previously stated that Dextenza is inserted in a natural opening in the eyelid (called the punctum) and that the drug is designed

[11] Dextenza. FDA Package Insert. *https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/208742s007lbl.pdf.*

to deliver a tapered dose of dexamethasone to the ocular surface for up to 30 days. CPT code 0356T was deleted December 31, 2021, and replaced with CPT code 68841 (Insertion of drug-eluting implant, including punctal dilation when performed, into lacrimal canaliculus, each), effective January 1, 2022. Interested parties currently assert that the drug, Dextenza, is administered and described by CPT code 68841. We refer readers to the CY 2023 OPPS/ASC final rule with comment period for a detailed history on CMS payment assignments for CPT code 0356T and CPT code 68841 (87 FR 71840).

In the CY 2024 OPPS/ASC proposed rule (87 FR 49765), we proposed that Dextenza (HCPCS code J1096) continues to function as a surgical supply that meets the criteria described at § 416.174, and we proposed to continue to make separate payment for Dextenza as a non-opioid pain management drug that functions as a supply in a surgical procedure under the ASC payment system for CY 2024. We proposed that payment for Dextenza would continue to be packaged when furnished in the HOPD but paid separately when furnished in an ASC. We proposed to package HCPCS code J1096 under the OPPS and assign the code to a status indicator of ''N'' (packaged). This is consistent with our packaging policy outlined at 42 CFR 419.2(b), which lists the types of items and services for which payment is packaged under the OPPS. Specifically, § 419.2(b)(16) includes drugs and biologicals that function as supplies when used in a surgical procedure as packaged costs. Historically, we have stated that 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).

For CY 2024, we proposed to continue to assign CPT code 68841 to APC 5503 (Level 3 Extraocular, Repair, and Plastic Eye Procedures) with a proposed payment rate of $2,249.64. We also proposed to continue to assign CPT code 68841 OPPS status indicator ''Q1'' and an ASC payment indicator of ''N1.''

The issue of payment for CPT code 68841 was brought to the Advisory Panel on Hospital Outpatient Payment (also known as HOP Panel) in 2023 for CY 2024 rulemaking. At the August 2023 meeting, based on the information presented, the Panel recommended that CMS assign HCPCS code 68841 a status indicator (SI) of ''J1'' (Hospital Part B Services Paid Through a Comprehensive APC) as they believed this assignment would treat CPT code 68841 similarly to other clinically related codes.

Comment: Several commenters stated that increased payment, and separate payment, for CPT code 68841, the code that describes the administration of the drug, was required to ensure continued beneficiary access to the drug Dextenza (HCPCS code J1096) in both the HOPD and ASC settings. Some commenters did not make a specific suggestion as to the final APC assignment but contended that the proposed payment was inadequate. Commenters cited various payment rates, such as $500, $1,200, $2,350, and $2,500 as potential appropriate payment rates for CPT 68841 under the OPPS and ASC payment system. Commenters emphasized that a change was needed to ensure adequate payment in the ASC setting, where the commenters stated the majority of these Dextenza administrations occur.

Several commenters argued for a change in the OPPS status indicator and the ASC payment indicator to allow separate payment for CPT code 68841. Some commenters stated that a ''Q1'' status indicator (STV-Packaged Codes) was inappropriate but did not provide an alternative suggestion. However, some other commenters suggested assignment to a ''J1''(Hospital Part B Services Paid Through a Comprehensive APC) status indicator. One commenter contended that a status indicator of ''S'' (Procedure or Service, Not Discounted When Multiple) or ''T'' (Procedure or Service, Multiple Procedure Reduction Applies) would also be appropriate but believed that ''J1'' would be the most accurate and would generate consistency among APC 5503, as all other codes within APC 5503 are assigned to status indicator ''J1.''

Several commenters pointed to the clinical importance of providing Dextenza to patients, noting that it reduces ocular pain and inflammation and reduces the burden of topical eyedrop application. Additionally, commenters stated that they usually perform the procedure to administer Dextenza in conjunction with ophthalmic surgeries. Commenters believed the procedure is a distinct surgical procedure that requires additional operating room time and resources. These commenters believed that the cataract surgery is conducted and concluded, as evidenced by the removal of the surgical drape and speculum, and then the Dextenza administration procedure begins. The commenters further mentioned that additional payment was needed to compensate for a variety of tasks associated with the administration of Dextenza, such as ordering, billing, counting inventory, technician training, surgical tools, and instrument sterilization, among others. Commenters also pointed to the fact that there are 112 single frequency claims as evidence that both Dextenza and its administration should be paid separately as there is no other procedure on the claim.

Overall, commenters were concerned that the lack of increased or separate payment may reduce access to Dextenza, particularly in the ASC setting.

Response: We thank commenters for their feedback. We agree with commenters that it is still appropriate to assign CPT code 68841 to APC 5503 (Level 3 Extraocular, Repair, and Plastic Eye Procedures).

For the CY 2024 OPPS update, based on claims submitted between January 1, 2022, and December 30, 2022, processed through June 30, 2023, our analysis of the latest claims data for this final rule with comment period shows a geometric mean cost of approximately $1,993.20 for predecessor CPT code 68841 based on 172 single claims, which is comparable to the geometric mean cost of about $2,288.49 for APC 5503. Based on the data, we continue to believe that assignment to APC 5503 for CPT code 68841 is appropriate.

We also continue to believe that assignment of CPT code 68841 to an OPPS status indicator of ''Q1'' and an associated ASC payment indicator of ''N1,'' is appropriate. We continue to believe that CPT code 68841 is mostly performed during ophthalmic surgeries, such as cataract surgeries. A status indicator ''Q1,'' indicating 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. Although stakeholders state this is an independent surgical procedure and should not be packaged into the primary ophthalmic procedure in which the drug and drug administration are associated, based on observed clinical patterns as to how the drug is used, we do not agree. Based on claims data, out of over 7,000 total frequency claims, CPT code 68841 is used independently only about 2 percent of the time,

meaning that the other 98 percent of the time CPT code 68841 has its payment packaged into the primary procedure with which it is associated. These data reinforce our belief that Dextenza and CPT code 68841 are not furnished independent of a surgical procedure and should be packaged into the primary ophthalmic procedure with which the drug and drug administration are associated.

While we recognize that there are some claims that may only include CPT code 68841 without a primary ophthalmic surgery on the claim, we do not believe that this is a frequent occurrence based on our claims data and clinical use patterns; as previously mentioned, our claims data shows that only 172 out of 7,327 claims are performed independently of another primary procedure (only about 2 percent of claims).

After consideration of the public comments, we are finalizing our proposal, without modification, to assign CPT code 68841 to APC 5503 with OPPS status indicator ''Q1'' (STVPackaged Codes) for CY 2024, which typically means there will be a packaged APC payment if this code is billed on the same claims as a HCPCS code assigned to status indictor ''S,'' ''T,'' or ''V'' (Clinic or Emergency Department Visit). In addition, based on the OPPS assignments, we are finalizing an ASC payment indicator of ''N1'' (Packaged service/item; no separate payment made) for CPT code 68841 for CY 2024.

For the final CY 2024 OPPS payment rates, we refer readers to OPPS Addendum B to this final rule with comment period. In addition, we refer readers to OPPS Addendum D1 to this final rule with comment period for the status indicator definitions for all codes reported under the OPPS. For the final CY 2024 ASC payment rates and payment indicators, we refer readers to Addendum AA and Addendum BB for the ASC payment rates, and Addendum DD1 for the ASC payment indicator and their definitions. The OPPS Addenda B and D1 and ASC Addenda AA, BB, and DD1 are available via the internet on the CMS website.[12]

Please refer to Table 48 for the code descriptor, APC assignment, status indicator assignment, and payment indicator assignment for CPT code 68841 for CY 2024.

TABLE 48: FINAL CY 2024 OPPS AND ASC PAYMENT ASSIGNMENTS FOR CPT CODE 68841

HCPCS Code	Descriptor	Final CY 2024 OPPS APC	Final CY 2024 OPPS SI	Final CY 2024 ASC PI
68841	Insertion of drug-eluting implant, including punctal dilation when performed, into lacrimal canaliculus, each	5503	Q1	N1

Similar to our rationale outlined for CPT code 68841, we also find it appropriate to package Dextenza (HCPCS code J1096) based on its clinical use patterns. Consistent with our clinical review and commenters' input, we believe this drug is mostly administered during ophthalmic surgeries, such as cataract surgeries. The packaging of this drug is consistent with our regulations at 42 CFR 419.2(b). Specifically, 42 CFR 419.2(b)(16) includes among the items and services for which payment is packaged under the OPPS, drugs and biologicals that function as supplies when used in a surgical procedure. Historically, we have stated that 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). We therefore believe packaging of HCPCS code J1096 is appropriate in the HOPD setting for CY 2024.

Although packaged under the OPPS, as discussed in section XIII.E. of this final rule with comment period, we believe Dextenza (HCPCS code J1096), meets the criteria described at § 416.174; and we are finalizing our proposal to make separate payment for Dextenza as a non-opioid pain management drug that functions as a supply in a surgical procedure under the ASC payment system for CY 2024. For more information on the ASC payment for HCPCS code J1096 for CY 2024, refer to section XIII.E. of this final rule with comment period.

As a reminder, for OPPS billing, because charges related to packaged services are used for outlier and future rate setting, hospitals are advised to report both CPT code 68841, the administration service, and HCPCS code J1096, the Dextenza drug, on the claim whenever Dextenza is provided in the HOPD setting. It is extremely important that hospitals report all HCPCS codes consistent with their descriptors, CPT and/or CMS instructions and correct coding principles, and all charges for all services they furnish, whether payment for the services is made separately or is packaged.

Finally, for the final CY 2024 OPPS payment rates, we refer readers to OPPS Addendum B to this final rule with comment period. In addition, we refer readers to OPPS Addendum D1 to this final rule with comment period for the status indicator definitions for all codes reported under the OPPS. For the final CY 2024 ASC payment rates and payment indicators, we refer readers to Addendum AA and Addendum BB for the ASC payment rates and Addendum DD1 for the ASC payment indicator and their definitions. The OPPS Addenda B and D1 and ASC Addenda AA, BB, and DD1 are available via the internet on the CMS website.[13]

[12] *https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient/regulations-notices.*

[13] *https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient/regulations-notices.*

3. Aquabeam Waterjet Ablation Service CPT Code 0421T (APC 5376)

CPT code 0421T (Transurethral waterjet ablation of prostate, including control of post-operative bleeding, including ultrasound guidance, complete (vasectomy, meatotomy, cystourethroscopy, urethral calibration and/or dilation, and internal urethrotomy are included when performed) describes the Aquabeam waterjet ablation service. According to the manufacturer, Aquabeam is for treating lower urinary tract symptoms (LUTS) due to benign prostatic hyperplasia (BPH) by using a high-velocity water stream to ablate and remove tissue from enlarged prostates.

For the OPPS CY 2024 proposed rule, we calculated the geometric mean for CPT code 0421T to be $9,609.07, and we assigned the service to APC 5376 (Level 6 Urology and Related Services), which has a payment rate of $8,947.91. There were 2,375 claims used to calculate the geometric mean for CPT code 0421T.

Comment: One commenter, the manufacturer of the Aquabeam system, requested that we assign CPT code 0421T to APC 5377 (Level 7 Urology and Related Services) with a payment rate of $12,712.15 instead of assigning the service to APC 5376 with a payment rate of $8,947.91. The commenter asserts that the Aquabeam procedure has more clinical and resource similarity to procedures in APC 5377 than in APC 5376 because, according to the commenter, the procedures in APC 5377 are device-intensive procedures similar to how the Aquabeam procedure is a device-intensive procedure. The commenter also notes that the Aquabeam procedure is one of the highest cost procedures assigned to APC 5376.

Response: We disagree with the commenter. CPT code 0421T is one of the more costly procedures in APC 5376 but it is not the costliest. The cost of the procedure is around $800 more than the payment rate of APC 5376, but it is over $2,700 less than the payment rate of APC 5377. The Aquabeam procedure also does not violate the 2 times rule in its current assignment in APC 5376, and several of the procedures with similar cost to the Aquabeam procedure are device-intensive procedures with a similar percentage device offset as the Aquabeam procedure. Finally, if CPT code 0421T were to be reassigned into APC 5377, its cost would be over $2,000 less than the lowest-cost significant procedure in that APC.

After consideration of the public comments we received, we are finalizing our proposal without modification for CPT code 0421T. Table 49 shows the finalized status indicator and APC assignment for all of the procedure codes. We refer readers to Addendum B of this final rule with comment period for the payment rates for all codes reportable under the OPPS. Addendum B is available via the internet on the CMS website.

TABLE 49: FINAL CY 2024 OPPS APC STATUS INDICATOR ASSIGNMENTS FOR CPT CODE 0421T

CPT Code	Long Descriptor	Final CY 2024 OPPS SI	Final CY 2024 OPPS APC
0421T	Transurethral waterjet ablation of prostate, including control of post-operative bleeding, including ultrasound guidance, complete (vasectomy, meatotomy, cystourethroscopy, urethral calibration and/or dilation, and internal urethrotomy are included when performed	J1	5376

4. Aquadex® Ultrafiltration (APC 5241)

CPT code 0692T (Therapeutic ultrafiltration) describes an apheresis procedure through which plasma water and sodium are removed from the blood using the Aquadex® SmartFlow System. The procedure is indicated in patients who are diagnosed with hypervolemia and are non-responsive to the more traditional treatments such as diuretic medications. CPT code 0692T was established effective January 1, 2022, and since its establishment, the code has been assigned to APC 5241 (Level 1 Blood Product Exchange and Related Services). At the August 21, 2023, HOP Panel Meeting, a presenter provided information to the Panel on the description of the service and the cost of the Aquadex® Ultrafiltration device and procedure. At the conclusion of the presentation, the presenter advised the Panel to request that CMS reassign CPT code 0692T from APC 5241 to APC 5242. The HOP Panel had no recommendations. For CY 2024, we proposed to maintain the assignment to APC 5241, with a payment rate of $417.32.

Comment: We received one comment from the manufacturer requesting that CMS reassign CPT code 0692T from APC 5241 with a payment of $426.24 to APC 5242 (Level 2 Blood Product Exchange and Related Services) with a payment of $1,504.13. The commenter stated that the proposed APC assignment and payment does not accurately reflect the resources, time, and costs necessary to complete the therapeutic ultrafiltration procedure. The commenter pointed out that the current APC assignment consists of mostly transfusion procedures, with CPT code 36430 (Transfusion, blood or blood components) accounting for 99 percent of the more than 200,000 single frequency claims for services assigned to this APC. They also note that there are several apheresis procedures assigned to APC 5242.

Response: Under the OPPS, we review our claims data on an annual basis to determine the payment rates. For CY 2024, the OPPS payment rates are based on claims submitted between January 1, 2022, and December 31, 2022, processed through June 30, 2023. Because the code was new in 2022, we have very limited claims data (1 claim). However, we note that with all new codes for which we lack pricing information, our policy has been to assign the service to an existing APC based on input from a variety of sources, including, but not limited to, review of the clinical similarity of the

service to existing procedures, input from CMS medical advisors, and review of all other information available to us. The OPPS is a prospective payment system that provides payment for groups of services that share clinical and resource use characteristics. Based on our understanding of the service and input from our medical advisors, we do not agree that CPT code 0692T is dissimilar to other services in APC 5241 such that it should be assigned to a different APC. In particular, our medical advisors noted the similarities between platelet apheresis (CPT code 36513) and the therapeutic ultrafiltration procedure. For CY 2024, based on our evaluation, we are finalizing our proposal to continue the assignment to APC 5241 for CPT code 0692T.

In summary, after consideration of the public comment, we are finalizing our proposal, without modification, to assign CPT code 0692T to APC 5241 for CY 2024. The final CY 2024 payment rate for the code can be found in Addendum B to this final rule with comment period. In addition, we refer readers to Addendum D1 of this final rule with comment period for the SI meanings for all codes reported under the OPPS. Addenda B and D1 are available via the internet on the CMS website.

5. Aqueous Shunt Procedure (APC 5492)

For CY 2023, we assigned CPT code 66180 (Aqueous shunt to extraocular equatorial plate reservoir, external approach; with graft) to APC 5492 (Level 2 Intraocular Procedures) with a payment of $3,995.58. For CY 2024, as shown in OPPS Addendum B that was released with the CY 2024 OPPS/ASC proposed rule with comment period, we proposed to maintain the APC assignment to APC 5492 with a payment rate of $3,970.62 for CPT code 66180.

Comment: One commenter suggested reassigning CPT code 66180 to APC 5493 (Level 3 Intraocular Procedures, with a payment rate of $5,110.58, based on its similarity to CPT code 66179 (Aqueous shunt to extraocular equatorial plate reservoir, external approach; without graft), which is proposed in APC 5493. The commenter explained that CPT code 66180 and CPT code 66179 are very similar procedures but clarified that CPT code 66180 requires additional time and resources to affix the scleral patch graft used in the procedure. Based on their similarity, the commenter urged CMS to reassign CPT code 66179 to APC 5493.

Response: While the procedures may be the same, our claims data for this final rule with comment period shows that the resources to perform the procedures are significantly different. For 2024, the OPPS payment rates are based on claims submitted between January 1, 2022, and December 31, 2022, processed through June 30, 2023. Based on our evaluation of the claims data, the geometric mean cost for CPT code 66180 is lower than CPT code 66179. Specifically, our claims data show a geometric mean cost of about $4,595 for CPT code 66180 based on 3,124 single claims (out of 3,140 total claims). In contrast, the geometric mean cost for CPT code 66179 is slightly higher at approximately $4,988 based on 134 single claims (out of 135 total claims). The cost range for the significant procedures assigned to APC 5492 is between approximately $3,138 (for CPT code 65820) and $4,694 (for CPT code 66183), while the cost range for the significant procedures assigned to APC 5493 is between about $4,943 (for CPT code 66991) and $5,357 (for CPT code 66989). Based on the cost range for APC 5492 and 5493, we believe that the resource costs and clinical homogeneity for CPT code 66180 are consistent with those procedures in APC 5492, rather than APC 5493. Therefore, we believe we should continue to assign CPT code 66180 to APC 5492.

In summary, after consideration of the public comment we received, we are finalizing our proposal, without modification, to continue to assign CPT code 66180 to APC 5492 for CY 2024. We refer readers to Addendum B of this final rule with comment period for the payment rates for all codes reported under the OPPS. In addition, we refer readers to Addendum D1 of this final rule with comment period for the status indicator meanings for all codes reported under the OPPS. Addenda D1 and Addendum B are available via the internet on the CMS website.

6. Arthrodesis, Sacroiliac Joint, Percutaneous, with Image Guidance, Including Placement of Intra-Articular Implant(s) (*e.g.,* Bone Allograft[s], Synthetic Device[s]), Without Placement of Transfixation Device (APC 5116)

The CPT Editorial Panel established CPT code 27278, to describe arthrodesis, sacroiliac joint, percutaneous, with image guidance, including placement of intra-articular implant(s) (*e.g.,* bone allograft[s], synthetic device[s]), without placement of transfixation device, effective January 1, 2024. Because the final CY 2024 CPT code numbers were not available when we published the proposed rule, the code was listed as placeholder code 2X000 in the OPPS Addendum B of the CY 2024 OPPS/ASC proposed rule.

For CY 2024, we proposed to assign CPT code 27278 to status indicator ''J1'' and APC 5116 (Level 6 Musculoskeletal Procedures) with a proposed payment rate of $20,692.25 based on clinical similarity and resource use to the predecessor code 0775T.

Comment: One commenter supported our proposal to assign CPT code 27278 to APC 5116 due to clinical similarity and resource use to the predecessor code 0775T.

Response: We appreciate the commenter's feedback on this new CPT code and we agree with the commenter's recommendation to finalize the APC assignment.

In summary, after reviewing the public comment for the proposal, we are adopting as final our proposal to assign CPT code 27278 to APC 5116. The final CY 2024 payment rate for this code can be found in Addendum B to this final rule with comment period. In addition, we refer readers to Addendum D1 of this final rule with comment period for the status indicator meanings for all codes reported under the OPPS. Addenda B and D1 are available via the internet on the CMS website.

7. Artificial Iris Insertion Procedures (APC 5496)

For the July 2020 update, the AMA's CPT Editorial Panel established three CPT codes to describe the CustomFlex Artificial Iris device implantation procedure. Table 50 below lists the long descriptors for the codes. In addition to the surgical CPT codes, as discussed in the CY 2021 OPPS/ASC final rule with comment period (85 FR 85990 through 85992), we approved the associated device, specifically, the CustomFlex Artificial Iris, for pass-through status effective January 1, 2021, and established a new category for this device, specifically, HCPCS code C1839 (Iris prosthesis). The designation of pass-through status for the device indicates that, under the OPPS, the device is paid separately in addition to the surgical CPT codes.

In the CY 2023 OPPS/ASC final rule with comment period (87 FR 71889), we listed device category HCPCS code C1839 in Table 52 (Devices with Pass-Through Status (Or Adjusted Separate Payment) Expiring At The End of the Fourth Quarter of 2022, In 2023, or In 2024), as one of the device codes whose pass-through status would expire on December 31, 2022. However, section 4141 (Extension of Pass-Through Status Under the Medicare Program for Certain Devices Impacted by COVID–19) of the Consolidated Appropriations Act, 2023 extended pass-through status for a 1-year period beginning on January 1,

2023, for devices whose pass-through status would have ended on December 31, 2022. Consequently, pass-through for HCPCS code C1839 will now expire on December 31, 2023.

As listed in Table 50 below, for CY 2023, we assigned HCPCS code C1839 to status indicator ''H'' to indicate that the device is on pass-through status. In addition, we assigned CPT codes 0616T–0618T to APC 5495 (Level 5 Intraocular Procedures) with a payment rate of $18,089.98. For CY 2024, we proposed to reassign device category code C1839 from status indicator ''H'' (device pass-through) to status indicator ''N'' (packaged) since its pass-through status expires on December 31, 2023. With the additional costs from the expired pass-through device, we proposed to reassign CPT codes 0616T, 0617T, and 0618T from APC 5495 to APC 5496 (Level 6 Intraocular APC), which is a Low Volume APC and is discussed in further detail in section III.D of this final rule with comment period. In addition, the discussion related to device HCPCS code C1839 can be found in section IV.b of this final rule with comment period.

TABLE 50: CY 2023 AND PROPOSED CY 2024 OPPS SI AND APCS FOR THE ARTIFICIAL IRIS INSERTION PROCEDURES

HCPCS Code	Long Descriptor	CY 2023 OPPS SI	CY 2023 OPPS APC	Proposed CY 2024 OPPS SI	Proposed CY 2024 OPPS APC
C1839	Iris prosthesis	H		N	
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	J1	5495	J1	5496
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	J1	5495	J1	5496
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	J1	5495	J1	5496

Comment: Some commenters applauded our proposal to reassign CPT codes 0616T, 0617T, and 0618T to APC 5496, and requested that CMS finalize the APC assignment.

Response: As listed in Table 46 in section III.D. of this final rule with comment period, APC 5496 is designated as one of the low volume APCs for CY 2024. Based on our review of the claims data for APC 5496, we found the cost for CPT code 0616T to be about $18,080 based on 15 single claims, approximately $12,873 for CPT code 0617T based on 7 claims, and about $17,733 for CPT code 1618T based on 13 single claims. Based on our analysis of the updated data for this final rule, we identified APC 5496 as a Low Volume APC with a cost of $16,990.74, and a final payment amount of $16,547.60 for CY 2024. We believe that APC 5496 is the appropriate assignment for CPT codes 0616T, 0617T, and 0618T based on their clinical characteristic and resource similarity to the procedure in the APC.

In summary, after consideration of the public comments, we are finalizing our proposal, without modification, and assigning CPT codes 0616T, 0617T, and 0618T to APC 5496 for CY 2024. Table 51 list the final OPPS SIs and APC for the codes. The final CY 2024 OPPS payment rate for the codes can be found in Addendum B to this final rule with comment period. In addition, we refer readers to Addendum D1 of this final rule with comment period for the status indicator (SI) meanings for all codes reported under the OPPS. Addenda B and D1 are available via the internet on the CMS website.

TABLE 51: FINAL CY 2024 OPPS SI AND APCS FOR THE ARTIFICIAL IRIS INSERTION PROCEDURES

HCPCS Code	Long Descriptor	CY 2023 OPPS SI	CY 2023 OPPS APC	Final CY 2024 OPPS SI	Final CY 2024 OPPS APC
C1839	Iris prosthesis	H		N	
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	J1	5495	J1	5496
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	J1	5495	J1	5496
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	J1	5495	J1	5496

8. Autologous Adipose-Derived Regenerative Cell (ADRC) Therapy for Partial Thickness Rotator Cuff Tear (APC 5055)

Effective July 1, 2022, the AMA's CPT Editorial Panel created two new Category III CPT codes to describe autologous adipose-derived regenerative cell (ADRC) therapy for partial thickness rotator cuff tear:

- 0717T: Autologous adipose-derived regenerative cell (ADRC) therapy for partial thickness rotator cuff tear; adipose tissue harvesting, isolation and preparation of harvested cells, including incubation with cell dissociation enzymes, filtration, washing, and concentration of ADRCs
- 0718T: Autologous adipose-derived regenerative cell (ADRC) therapy for partial thickness rotator cuff tear; injection into supraspinatus tendon including ultrasound guidance, unilateral

These codes describe a prospective, randomized multicenter pivotal trial of autologous adult adipose-derived regenerative cell (ADRC) injection into partial-thickness rotator cuff tears that is currently in progress. The purpose of this investigation is to evaluate the safety and superior effectiveness in functional improvement in patients with partial-thickness rotator cuff tears (PTRCTs) after the administration of a single injection of adipose-derived regenerative cells (ADRCs) into the partial-thickness rotator cuff tear compared to the administration of a single corticosteroid injection into the associated subacromial space. For CY 2024, we proposed to assign CPT codes 0717T and 0718T to status indicator ''E1'' to indicate that these codes are not paid by Medicare when submitted on outpatient claims (any outpatient bill type) since, at the time, the clinical trial had not been approved by CMS as IDE Category B study.

Comment: One commenter requested that we reassign CPT codes 0717T and 0718T from status indicator ''E1'' to status indicator ''J1'' and assign them to APC 5114 (Level 4 Musculoskeletal Procedures) with a proposed payment rate of $6,895.06. The commenter stated that this was the best placement based on clinical and resource coherence. The commenter also stated that this was consistent with their calculation that the total cost of the device was $3,186.11. The commenter stated that the cost of their procedure including the device was $6,316 in 2022. The commenter noted that on August 24, 2023, the CMS Coverage and Analysis Group (CAG) approved their Category B IDE study and included it on the approved list of covered Category B IDE trials.

Response: We thank the commenter for the recommendation. Because the clinical trial was approved by CMS as a Category B IDE study on August 24, 2023, we are assigning CPT codes 0717T and 0718T to separate payment under OPPS. Based on input from our medical advisors, we are assigning both CPT codes 0717T and 0718T to status indicator ''T'' and APC 5055 (Level 5 Skin Procedures) based on clinical similarity with CPT code 15771 (Grafting of autologous fat harvested by liposuction technique to trunk, breasts, scalp, arms, and/or legs; 50 cc or less injectate).

The final 2024 payment rates for the codes can be found in Addendum B to this final rule with comment period. In addition, we refer readers to Addendum D1 of this final rule with comment period for the status indicator (SI) meanings for all codes reported under the OPPS. Addenda B and D1 are available via the internet on the CMS website.

9. Barostim CPT Code 0266T (APC 1580)

Barostim is a fully implantable neurostimulator system with an indication to treat heart failure symptoms in a limited number of patients who meet the FDA-approved eligibility criteria. Barostim received device pass-through status in the OPPS starting in January 2021 and its device pass-through status is scheduled to end on December 31, 2023. In the OPPS, once pass-through status ends for a device, the cost of the device is packaged into its associated procedure, which for Barostim is CPT code 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)).

Claims from CY 2022 will be used to set the payment rate for the Barostim implant procedure. There are 123 claims for the Barostim implant procedure in CY 2022, and all claims report using Barostim as a part of the Barostim implant procedure. Therefore, the geometric mean cost of the Barostim implant procedure reflects the full cost of the device and the resources used to implant it. The Neurostimulator and Related Procedures APC has five payment levels. The estimated payment amount for CY 2024 for Level 5, which is the highest level, is around $30,700. The geometric mean cost of the Barostim implant procedure is nearly $46,000. In the CY 2024 OPPS proposed rule, we proposed to assign the Barostim implant procedure to APC 5465 (Level 5 Neurostimulator and Related Procedures).

Comment: The HOP Panel and multiple commenters including the manufacturer requested that CPT code 0266T be assigned to APC 1580 (New Technology—Level 43 ($40,001–$50,000)) with a payment rate of around $45,000. The commenters noted that in the CY 2023 OPPS/ASC final rule we assigned a different neurostimulator procedure whose geometric mean cost was over $25,000 more than the payment rate for APC 5465, CPT code 0424T (Insertion or replacement of neurostimulator system for treatment of central sleep apnea; complete system (transvenous placement of right or left stimulation lead, sensing lead, implantable pulse generator)), to New Technology APC 1581 (New Technology—Level 44 ($50,001–$60,000) with a payment rate of around $55,000 as APC 1581 more closely reflected the cost of the service.

Response: We agree with the commenters. The updated geometric mean for CPT code 0266T is around $47,300 which is nearly $17,000 more than the updated payment rate for APC 5465 of around $30,500. Also as noted by the commenters, we had in CY 2023 moved another neurostimulator procedure described by CPT code 0424T to a new technology APC when its geometric mean was found to be substantially higher than the payment rate for APC 5465.

After consideration of the public comments we received, we are not adopting our proposal as final. Instead, we are adopting a final APC assignment for CPT code 0266T to APC 1580 (New Technology—Level 43 ($40,001–$50,000)). Table 52 shows the finalized status indicator and APC assignment for all of the procedure codes. We refer readers to Addendum B of this final rule with comment period for the payment rates for all codes reportable under the OPPS. Addendum B is available via the internet on the CMS website.

TABLE 52: FINAL CY 2024 OPPS APC STATUS INDICATOR ASSIGNMENTS FOR CPT CODE 0266T

CPT Code	Long Descriptor	Final CY 2024 OPPS SI	Final CY 2024 OPPS APC
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	S	1580

10. Barricaid® Spine/Lumbar Disk Surgery (APC 5115)

For CY 2024, we proposed to assign HCPCS code C9757 (Laminotomy (hemilaminectomy), with decompression of nerve root(s), including partial facetectomy, foraminotomy and excision of herniated intervertebral disc, and repair of annular defect with implantation of bone anchored annular closure device, including annular defect measurement, alignment and sizing assessment, and image guidance; 1 interspace, lumbar) to APC 5115 (Level 5 Musculoskeletal Procedures) with a proposed payment rate of $13,269.40. The proposed short descriptor for HCPCS code C9757 was ''spine/lumbar disk surgery.''

Comment: We received a comment from the manufacturer of the Barricaid® device, which is the bone-anchored annular closure device that is implanted during the procedure described by HCPCS code C9757. Specifically, the commenter requested that we revise the short descriptor for HCPCS code C9757 from ''spine/lumbar disk surgery'' to ''spine bone-anchor implant surgery,'' which could help limit erroneous claims for HCPCS code C9757 that do not include the Barricaid® device. The commenter also requested that CMS issue a transmittal or Medicare Learning Network® (MLN) Matters article to educate hospital outpatient departments that a bone-anchored implant must be used to report HCPCS code C9757, and that the code cannot be reported using any other type of non-FDA approved technology or when a suture-based supply is used.

Response: We thank the commenter for their input. First, we note that coders are generally aware that they need to read the entire long descriptors, and not rely on short descriptors alone, for the codes they are billing to ensure they are

reporting the procedures, services, and items accurately. In addition, it is generally not our policy to judge the accuracy of provider coding and charging for purposes of ratesetting. We rely on hospitals and providers to accurately report the use of HCPCS codes in accordance with their code descriptors and CPT and CMS instructions, and to report services accurately on claims and charges and costs for the services on their Medicare hospital cost report. Nonetheless, we are sympathetic to the commenter's concern regarding the descriptor, and consequently, we believe that a slight modification to the short descriptor may be helpful to ensuring that a device is used every time the HCPCS code C9757 is billed on a claim. We note that there is a maximum number of characters that can be used for the short descriptor field. In light of this character field limitation and to further clarify that a device should be implanted each time HCPCS code C9757 is billed, for CY 2024 we are revising the short descriptor for the code from ''Spine/lumbar disk surgery'' to ''Spine device implant surgery.''

After consideration of the public comment, we are finalizing our proposal to assign HCPCS code C9757 to APC 5115 with one modification to the code's short descriptor. For CY 2024, the short descriptor for HCPCS code C9757 is ''Spine device implant surgery'' to clarify that a device must be implanted each time the service is performed. The final CY 2024 short descriptor for HCPCS code C9757 can be found in Addendum B to this final rule with comment period. Addendum B is available via the internet on the CMS website. We also refer readers to Addendum D1 of this final rule with comment period for the SI meanings for all codes reported under the OPPS. Addenda B and D1 are available via the internet on the CMS website.

11. Biliary Endoscopy CPT Codes 47539 and 47564 (APCs 5361 and 5362)

CPT code 47539 (Placement of stent(s) into a bile duct, percutaneous, including diagnostic cholangiography, imaging guidance (eg, fluoroscopy and/or ultrasound), balloon dilation, catheter exchange(s) and catheter removal(s) when performed, and all associated radiological supervision and interpretation; new access, without placement of separate biliary drainage catheter) with a geometric mean cost of around $7,576 and CPT code 47564 (Laparoscopy, surgical; cholecystectomy with exploration of common duct) with a geometric mean cost of around $7,576 describe procedures that are performed when a patient has a blockage of their bile duct. For the CY 2024 OPPS proposed rule, we proposed to assign both procedures to APC 5361 (Level 1 Laparoscopy and Related Services) with a payment rate of around $5,608.

Comment: One commenter requested that we assign both CPT code 47539 and CPT code 47564 to APC 5362 (Level 2 Laparoscopy and Related Services) with a payment rate of around $9,984. The commenter noted that both of these procedures had a geometric mean cost that was more than 2-times the lowest-cost significant procedure assigned to APC 5361 (CPT code 49587), with a 2-times limit of around $7,207, which is less than the $7,576 geometric mean rate for both procedures. The commenters contended the only reason there is not a 2-times violation is neither CPT code 47539 nor CPT code 47564 is a significant procedure for determining the payment rate for APC 5361. The commenter also noted that the procedures described by CPT codes 47539 and 47564 have clinical and resource similarities to both the procedures in the higher-cost portion of APC 5361 and the lower-cost portion of APC 5362, which was another reason the commenters believed the procedures should be moved to APC 5362.

Response: We appreciate the request of the commenter. Since the release of the CY 2024 OPPS proposed rule, we have updated our 2-times analysis of claims from CY 2022 that are used to set rates for CY 2024. Our updated results find that the 2-times limit for APC 5361 based on CPT code 49587 as the lowest-cost significant procedure is around $7,318. The updated geometric mean cost for CPT code 47539 is around $7,316, which means by just $2 there would not be a 2 times rule violation if CPT code 47539 was a significant procedure in determining the payment rate for APC 5361. For CPT code 47564, the updated geometric mean cost for the procedure is $7,557, which means there would be a 2 times rule violation if the procedure was significant in APC 5361. Our review of the procedures assigned to APC 5361 and APC 5362 found the procedure described by CPT code 47539 had more clinical and resource similarities with the procedures in APC 5361, while the procedure described by CPT code 47564 appeared to have more clinical and resource similarities with the procedures in APC 5362.

After consideration of the public comments we received, we are implementing our proposal without modification for CPT code 47539 to assign the procedure to APC 5361 (Level 1 Laparoscopy and Related Services). We also are implementing our proposal with modification for CPT code 47564 by assigning the procedure to APC 5362 (Level 2 Laparoscopy and Related Services). Table 53 shows the finalized status indicator and APC assignment for all of the procedure codes. We refer readers to Addendum B of this final rule with comment period for the payment rates for all codes reportable under the OPPS. Addendum B is available via the internet on the CMS website.

TABLE 53: FINAL CY 2024 OPPS APC STATUS INDICATOR ASSIGNMENTS FOR CPT CODES 47539 AND 47564

CPT Code	Long Descriptor	Final CY 2024 OPPS SI	Final CY 2024 OPPS APC
47539	Placement of stent(s) into a bile duct, percutaneous, including diagnostic cholangiography, imaging guidance (eg, fluoroscopy and/or ultrasound), balloon dilation, catheter exchange(s) and catheter removal(s) when performed, and all associated radiological supervision and interpretation; new access, without placement of separate biliary drainage catheter	J1	5361
47564	Laparoscopy, surgical; cholecystectomy with exploration of common duct	J1	5362

12. Bone Density Tests/Bone Mass Measurement: Biomechanical Computed Tomography (BCT) Analysis and Digital X-ray Radiogrammetry-Bone Mineral Density (DXR–BMD) Analysis) (APCs 5521, 5523, and 5731)

CPT code 0743T (Bone strength and fracture risk using finite element analysis of functional data and bone mineral density (BMD), with concurrent vertebral fracture assessment, utilizing data from a computed tomography scan, retrieval and transmission of the scan data, measurement of bone strength and BMD and classification of any vertebral fractures, with overall fracture-risk assessment, interpretation and report) became effective January 1, 2023. This code describes the service associated with BCT analysis with concurrent vertebral fracture assessment (VFA).

In addition to new CPT code 0743T, there are five existing CPT codes describing BCT analysis that were effective July 1, 2019. The codes and their long descriptors are listed below.

- 0554T: Bone strength and fracture risk using finite element analysis of functional data and bone-mineral density utilizing data from a computed tomography scan; retrieval and transmission of the scan data, assessment of bone strength and fracture risk and bone-mineral density, interpretation and report.
- 0555T: Bone strength and fracture risk using finite element analysis of functional data and bone-mineral density utilizing data from a computed tomography scan; retrieval and transmission of the scan data.
- 0556T: Bone strength and fracture risk using finite element analysis of functional data and bone-mineral density utilizing data from a computed tomography scan; assessment of bone strength and fracture risk and bone mineral density.
- 0557T: Bone strength and fracture risk using finite element analysis of functional data and bone-mineral density utilizing data from a computed tomography scan; interpretation and report.
- 0558T: Computed tomography scan taken for the purpose of biomechanical computed tomography analysis.

In the CY 2023 OPPS/ASC notice of proposed rulemaking (NPRM), we proposed to reassign CPT codes 0554T–0558T to status indicator E1. In response to public comment on the proposal, in the CY 2023 OPPS/ASC final rule (87 FR71844 through 71846), we stated that, based on our review and understanding of the service, BCT analysis does not meet Medicare's definition of bone mass measurement, as specified in § 410.31(a), which specifies the coverage of, and payment for, bone mass measurements for Medicare beneficiaries. Therefore, we assigned CPT codes 0554T–0558T and CPT code 0743T to status indicator ''E1'' to indicate that these codes are not covered by Medicare, and not paid by Medicare when submitted on outpatient claims (any outpatient bill type).

In the CY 2024 OPPS/ASC proposed rule, we proposed to continue to assign CPT codes 0554T–0558T and CPT code 0743T to status indicator ''E1.''

Comment: Several commenters stated that they disagree with the status indicator assignment of ''E1'' and that the BCT CPT codes 0554–0558T and CPT Code 0743T (BCT+VFA) meet the regulatory definition of Bone Mass Measurement (BMM). Commenters contended that the BCT and BCT+VFA procedures are reasonable and necessary diagnostic tests that meet all aspects of both the statutory and regulatory definitions of BMM.

Another commenter stated that they urge CMS to restore coverage for BCT codes and BCT with concurrent VFA as covered bone mass measurement and assign them to status indicators ''S.''

Response: We appreciate these comments. While CMS further considers this issue, we will not finalize, as proposed, the status indicator of ''E1'' for these codes, but instead are assigning certain BCT codes describing HOPD services to clinical APCs. Specifically, for CY 2024, we are assigning CPT code 0555T to APC 5731 (Level 1 Minor Procedures) and SI ''S,'' CPT code 0556T to APC 5523 (Level 3 Imaging without Contrast) and SI ''S,'' and CPT code 0558T to APC 5521 (Level 1 Imaging without Contrast) with SI of ''S,'' which were the same APC assignments for the codes between CY 2019 and CY 2022. In addition, we are assigning CPT codes 0554T, 0557T, and 0743T to SI ''M'' (Items and Services Not Billable to the MAC. Not paid under OPPS.) to indicate that these codes are not payable under the OPPS since they describe physician-only services. As we have consistently stated in past rules (87 FR 71879) and quarterly change requests to assign new codes to APCs (see, *e.g.,* Pub 100–04 Medicare Claims Processing, Transmittal 11937), the fact that a drug, device, procedure or service is assigned a HCPCS code and a payment rate under the OPPS does not imply coverage by the Medicare program, but indicates only how the product, procedure, or service may be paid if covered by the program.

Medicare Administrative Contractors (MACs) determine whether a drug, device, procedure, or other service meets all program requirements and conditions for coverage and payment. Accordingly, we emphasize that HOPDs would only receive payment for these services when the appropriate MAC determines that the service meets the relevant conditions for coverage and payment.

In summary, after consideration of the public comments, we are not finalizing our proposal for CPT codes 0554T–0558T and CPT code 0743T. The final payment rates for the separately payable codes can be found in Addendum B to this final rule with comment period. In addition, we refer readers to Addendum D1 of this final rule with comment period for the status indicator (SI) meanings for all codes reported under the OPPS. Addenda B and D1 are available via the internet on the CMS website.

13. Cardiac Computed Tomography Angiography (CCTA) (APC 5571)

For the 2006 update, the AMA's CPT Editorial Panel established six Category III CPT codes to describe cardiac computed tomography angiography with contrast materials effective January 1, 2006. The codes were active and separately payable under the OPPS between January 1, 2006, through December 31, 2009. The CPT Editorial Panel deleted the Category III CPT codes and replaced them with Category I CPT codes 75572 through 75574 effective January 1, 2010. With the deletion of the Category III CPT codes on December 31, 2009, we crosswalked the APC assignments from the Category III CPT codes (predecessor codes) to the new Category I CPT codes effective January 1, 2010. Since 2010, the Category I CPT codes describing cardiac computed tomography angiography with contrast materials are CPT codes 75572, 75573, and 75574. The codes and their long descriptors are listed below.

- 75572: Computed tomography, heart, with contrast material, for evaluation of cardiac structure and morphology (including 3D image postprocessing, assessment of cardiac function, and evaluation of venous structures, if performed)
- 75573: Computed tomography, heart, with contrast material, for evaluation of cardiac structure and morphology in the setting of congenital heart disease (including 3D image postprocessing, assessment of left ventricular (LV) cardiac function, right ventricular (RV) structure and function and evaluation of vascular structures, if performed)
- 75574: Computed tomographic angiography, heart, coronary arteries and bypass grafts (when present), with contrast material, including 3D image postprocessing (including evaluation of cardiac structure and morphology, assessment of cardiac function, and evaluation of venous structures, if performed)

For CY 2023, as we indicated in the CY 2023 OPPS/ASC final rule with comment period (87 FR 71847 through 71850), we assigned the codes to APC 5571 (Level 1 Imaging with Contrast). As listed in the OPPS Addendum A (OPPS APCs) that was released with the CY 2023 OPPS/ASC final rule with comment period, APC 5571 was assigned a payment rate of $180.34 effective January 1, 2023. We note that the OPPS payment rate applies only to the hospital outpatient facility and does not include the physician service payment. Physician services are paid under Medicare's Physician Fee Schedule (PFS). For reference, the 54 below shows the total CY 2023 Medicare reimbursement for CPT codes 75572, 75573, and 75574.

TABLE 54: CY 2023 OPPS AND PFS Payment FOR CPT CODES 75572, 75573, AND 75574

HCPCS Code	CY 2023 OPPS (hospital outpatient facility)	CY 2023 PFS (physician service)	CY 2023 Total Medicare Reimbursement
75572	$ 180.34	$ 83.02	$ 263.36
75573	$ 180.34	$ 120.98	$ 301.32
75574	$ 180.34	$ 113.86	$ 294.20

For CY 2024, based on the latest claims data, we proposed to continue to assign the codes to APC 5571 with a proposed payment rate of $177.09. As a reminder, we update the OPPS payment rates on an annual basis consistent with the requirements set forth in section 1833(t)(9)(A) of the Act that requires the HHS Secretary to review, not less often than annually, and revise the APC groups, the relative payment weights, and the wage and other adjustments 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. We received several comments related to our proposed payment for the CCTA codes. Many of the comments, which were form letters, addressed the same issues that were brought to our attention in the CY 2021 OPPS/ASC final rule (85 FR 85956 through 85959). Below is a summary of the public comments to the CY 2024 OPPS/ASC proposed rule and our responses to the comments.

Comment: Several commenters noted that the payment for the CCTA codes has declined since 2017 and expressed concern with the continued assignment to APC 5571. They indicated that the reimbursement amount is insufficient to cover the cost of providing the service and argued that the payment amount does not take into account the hospital resources required to perform the test, including the use of the equipment, medication administration, staff time, and scanner time. To pay appropriately for the service, many of the commenters requested the reassignment of CPT codes 75572 and 75573 to APC 5572 (Level 2 Imaging with Contrast), with a proposed payment of $369.86. These same commenters also requested the reassignment of CPT code 75574 to APC 5573 (Level 3 Imaging with Contrast), with a proposed payment rate of $775.83.

Response: Under the OPPS, we use the latest claims data to set the annual payment rates. Payment rates for CY 2024 are based on claims with dates of service between January 1, 2022, and December 31, 2022, processed through June 30, 2023. As illustrated in Table 55

below, analysis of our claims data shows that the geometric mean cost for the codes range between $150.58 and $219.06. Specifically, the geometric mean cost for CPT code 75572 is $150.57 based on 22,575 single claims (out of 40,066 total claims), $219.06 for CPT code 75573 based on 437 single claims (out of 678 total claims), and $193.29 for CPT code 75574 based on 55,871 single claims (out of 78,932 total claims). Based on our analysis, the geometric mean costs for all three codes are consistent with the geometric mean cost for APC 5571, whose geometric mean cost is $179.94. In contrast, the geometric mean costs for APCs 5572 and 5573 are $376.62 and $784.12, respectively. Based on the geometric mean costs for CPT codes 75572 (GMC $150.57) and 75573 (GMC $219.06), we do not believe that reassigning the codes to APC 5572 (GMC $376.62) would be appropriate. Similarly, based on the latest claims data for CPT code 75574 (GMC $193.29), we do not believe that reassigning the code to APC 5573 (GMC $784.11) would be appropriate. We believe that reassigning the codes to either APC 5572 or 5573 would significantly overpay for the service. Based on the claims data, we believe that assigning CPT codes 75572, 75573, and 75574 to APC 5571 remains appropriate based on clinical characteristics and resource homogeneity to the other services in the APC. In addition, because the CCTA CPT codes have been in existence since 2010, we do not believe that hospital outpatient facilities have been coding these services inappropriately. Consequently, we believe our claims data reflect the cost of providing the service.

TABLE 55: VOLUME FOR CCTA EXAMS (CLAIMS SUBMITTED BETWEEN 1/1/2013 THROUGH 12/31/2022)

Final Rule	Claim Submission Timeframe	75572 Single Freq	75572 Geometric Mean Cost	75573 Single Freq	75573 Geometric Mean Cost	75574 Single Freq	75574 Geometric Mean Cost
CY 2015	1/1/2013-12/31/2013	3,855	$205.23	164	$222.17	10,820	$231.29
CY 2016	1/1/2014-12/31/2014	4,188	$196.60	275	$231.58	10,481	$231.45
CY 2017	1/1/2015-12/31/2015	4,905	$195.81	256	$201.90	11,154	$237.58
CY 2018	1/1/2016-12/31/2016	5,703	$185.82	177	$166.19	12,848	$239.04
CY 2019	1/1/2017-12/31/2017	7,256	$185.70	143	$205.35	14,785	$230.69
CY 2020	1/1/2018-12/31/2018	12,299	$158.74	323	$185.26	25,434	$195.62
CY 2021/ CY 2022	1/1/2019-12/31/2019	14,262	$157.27	317	$193.55	32,502	$196.53
CY 2023	1/1/2021-12/31/2021	19,245	$159.60	371	$237.59	46,352	$208.47
CY 2024	1/1/2022-12/31/2022	22,575	$150.57	437	$219.06	55,871	$193.29

Comment: A commenter suggested discontinuing payment for CPT code 75573 and instead reassigning the current payment rate for CPT code 75573 for CPT codes 75574, 93571, and 93572. The commenter noted that in addition to CPT code 75574, CPT codes 93571 and 93572 are under-reimbursed.

Response: Under the OPPS, we cannot reallocate or remove the reimbursement from one active/existing code and distribute to other codes. In cases where

a code is deleted and replaced with another code, we will crosswalk the payment for the deleted code/predecessor code to the new code. However, in this case, CPT code 75573 is an active code under the OPPS, and its payment cannot be removed and reassigned to another code. Payment determination under the OPPS is based on analysis of the latest claims data. For CY 2024, OPPS payments are based on our analysis of claims with dates of service between January 1, 2022, and December 31, 2022, processed through June 30, 2023. As stated above, we have claims data for CPT code 75573, which indicates that the service is performed in the HOPD setting.

With regard to CPT codes 93571 and 93572 codes, we note these codes are assigned status indicator ''N'' to indicate that their payment is packaged in the primary code. Below are the complete long descriptors for CPT codes 93571 and 93572:

- 93571: Intravascular doppler velocity and/or pressure derived coronary flow reserve measurement (coronary vessel or graft) during coronary angiography including pharmacologically induced stress; initial vessel (list separately in addition to code for primary procedure)
- 93572: Intravascular doppler velocity and/or pressure derived coronary flow reserve measurement (coronary vessel or graft) during coronary angiography including pharmacologically induced stress; each additional vessel (list separately in addition to code for primary procedure)

The words ''list separately in addition to code for primary procedure'' are included in the long descriptors for CPT code 93571 and 93572 to indicate that that the codes are considered ''add-ons'' to another primary code that cannot be reported independently. Specifically, add-on codes must always be reported with another primary code on the same day. The AMA states in the CPT 2024 Professional Edition (page xviii) that ''add-on codes are always performed in addition to the primary service or procedure and must never be reported as a stand-alone code.'' In most cases, add-on codes are typically ancillary and supportive to a primary diagnostic or therapeutic modality and are an integral part of the primary service they support. As specified under regulation 42 CFR 419.2(b)(18), add-on codes are generally packaged under the OPPS, and payment for the codes are bundled with the primary codes. Consequently, CPT codes 93571 and 93572 are not paid separately under the OPPS, but instead, their payment is packaged into the primary code.

In addition, because we have claims data for CPT code 75573, we would not reallocate the payment for the code to CPT codes 93571, 93572, and 75574. As stated above, our claims data show a geometric mean cost of $219.06 for CPT code 75573 based on 437 single claims (out of 678 total claims). Therefore, we believe that CPT code 75573 should continue to be paid separately under APC 5571.

Comment: Many commenters urged CMS to allow hospitals the flexibility to submit charges for cardiac CT procedures with other than the general CT revenue code (0350) or the general MRI revenue code (0610), thereby allowing future estimates to reflect the true cost of providing the service. Some commenters suggested that the Medicare Administrative Contractors (MACs) have made it mandatory to report only the general CT revenue code (0350) for the CCTA codes. Another commenter reported that MACs have applied edits to the CCTA codes that prevent hospitals from reporting a cardiac revenue code for cardiac CT services when appropriate.

Response: Based on our evaluation, we have not found any MAC edits that prevent hospitals from reporting the appropriate revenue code for the CCTA codes. We analyzed our claims data and based on claims with dates of service between January 1, 2022, and December 31, 2022, processed through June 30, 2023, we found seven revenue codes reported with CPT codes 75572, 75573, and 75574, specifically, revenue codes 0320, 0321, 0329, 0350, 0351, 0352, and 0359. Of these seven revenue codes, four apply to CT services, specifically, revenue codes 0350, 0351, 0352, and 0359. As evidenced by the claims data, hospital outpatient facilities are reporting revenue codes that describe CT services for the CCTA codes. We note that the general MRI revenue code, specifically, revenue code 0610, was not reported with the CCTA codes. Moreover, as listed in Table 56 below, we included the costs for these revenue codes in the CY 2024 ratesetting. That is, the costs attributed to the CCTA codes are included in the payment for CPT codes 75572, 75573, and 75574.

TABLE 56: REVENUE CODES REPORTED WITH CCTA EXAMS CPT CODES 75572, 75573, AND 75574

2022 Revenue center ID	Description (applicable to CY 2022 claims)	Used in 2024 OPPS (2022 claims)	2552-96 Primary cost center source for CCR	2552-96 Primary cost center name	2552-10 Primary cost center source for CCR	2552-10 Primary cost center name
0320	Radiology - Diagnostic	Y	4100	Radiology-Diagnostic	0320	Radiology - Diagnostic
0321	Radiology - Diagnostic: Angiocardiography	Y	3030	Angiocardiography	0321	Radiology - Diagnostic: Angiocardiography
0329	Radiology - Diagnostic: Other	Y	4100	Radiology-Diagnostic	0329	Radiology - Diagnostic: Other
0350	CT Scan	Y	3230	CAT Scan	0350	CT Scan
0351	CT Scan: Head	Y	3230	CAT Scan	0351	CT Scan: Head
0352	CT Scan: Body	Y	3230	CAT Scan	0352	CT Scan: Body
0359	CT Scan: Other CT scans	Y	3230	CAT Scan	0359	CT Scan: Other CT scans

Furthermore, as we stated in the CY 2023 OPPS/ASC final rule (87 FR 71849), hospital outpatient facilities are responsible for reporting the appropriate cost centers and revenue codes. As stated in section 20.5 in Chapter 4 (Part B Hospital) of the Medicare Claims Processing, CMS ''does not instruct hospitals on the assignment of HCPCS codes to revenue codes for services provided under OPPS since hospitals' assignment of cost vary. Where explicit instructions are not provided, HOPDs should report their charges under the revenue code that will result in the charges being assigned to the same cost center to which the cost of those services are assigned in the cost report.'' Therefore, hospital outpatient facilities must determine the most appropriate cost center and revenue code for the CCTA codes. This instruction is reiterated in the Medicare Administrative Contractor (MAC) instructions for revenue code reporting for CCT and CCTA services, as noted in the various articles listed in Table 57. As stated in Table 57, MACs ''may specify revenue codes to help providers identify those revenue codes typically used'' to report a service, however, the guidance is purely advisory, and not mandatory, which is in contrast to statements made by several commenters. The MAC instructions can be found on the CMS.gov website, specifically, on the Medicare Coverage Database website.

TABLE 57: MEDICARE ADMINISTRATIVE CONTRACTORS (MAC) REVENUE CODE INSTRUCTION FOR CPT CODES 75572, 75573, AND 75574

Medicare Administrative Contractors (MACs) Instructions for Revenue Code Reporting for CCT and CCTA			
Medicare Coverage Database: https://www.cms.gov/medicare-coverage-database/search.aspx			
Contractors may specify revenue codes to help providers identify those revenue codes typically used to report this service. In most instances revenue codes are purely advisory. Unless specified in the article, services reported under other revenue codes are equally subject to this coverage determination. Complete absence of all revenue codes indicates that coverage is not influenced by revenue code and the article should be assumed to apply equally to all revenue codes.			
Article ID	Title	Medicare Administrative Contractor (MAC)	Revenue Code Suggestion
A56451	Billing and Coding: Cardiac Computed Tomography (CCT) and Coronary Computed Tomography Angiography (CCTA)	CGS Administrators, LLC	0321: Radiology - Diagnostic - Angiocardiography; 0359: CT Scan - CT - Other
A56691	Billing and Coding: Cardiac Computed Tomography & Angiography (CCTA)	Palmetto GBA	
A56737	Billing and Coding: Cardiac Computed Tomography (CCT) and Coronary Computed Tomography Angiography (CCTA)	National Government Services, Inc.	
A57552	Billing and Coding: Coronary Computed Tomography Angiography (CCTA)	Wisconsin Physicians Service Insurance Corporation	

In summary, after consideration of the public comments, we are finalizing our proposal, without modification, and assigning the CCTA CPT codes 75572, 75573, and 75574 to APC 5571. The final CY 2024 OPPS payment rates for the codes can be found in Addendum B to this final rule with comment period. In addition, we refer readers to Addendum D1 of this final rule with comment period for the status indicator (SI) meanings for all codes reported under the OPPS. Addenda B and D1 are available via the internet on the CMS website.

14. Cardiac Leadless Pacemaker Procedures (APCs 5183, 5224, and 5741)

For the July 2023 update, the CPT Editorial Panel established 10 new codes effective July 1, 2023, to describe the various procedures related to three new leadless pacemaker systems, specifically, the Aveir VR, Aveir AR, and Aveir DR leadless pacemaker systems. The codes describe the insertion, removal and replacement, removal-only, and programming associated with the new devices. The codes, and their long descriptors are listed in Table 58. Based on our evaluation of the codes, we determined that the Aveir VR received FDA approval, however, the Aveir AR and Aveir DR Systems were still pending FDA approval. Because the Aveir VR System received FDA premarket approval (PMA) in March 2022 and was approved by CMS for Medicare coverage under Coverage with Evidence Development (CED) on June 21, 2022 (Study Title: Aveir VR Coverage With Evidence Development Post-Approval Study; Clinicaltrials.gov number: NCT05336877), we assigned the related CPT codes to specific status indicator and APC assignments effective July 1, 2023. For the Aveir AR, and Aveir DR Systems that were still pending FDA approval, we assigned the codes to status indicator ''E1'' to indicate that they were not payable by Medicare when submitted on outpatient claims (any outpatient bill type) because the services associated with these codes are either not covered by any Medicare outpatient benefit category, statutorily excluded by Medicare, or not reasonable and necessary. These codes, and their OPPS SI and APC assignments were listed in the July 2023 OPPS quarterly update CR (Transmittal 12077, Change Request 13210, dated June 13, 2023). Table 58 below list the codes, long descriptors, status indicators, and APC assignments for the 10 codes that were listed in the July 2023 OPPS quarterly update CR.

BILLING CODE 4150–28–P

TABLE 58: JULY 2023 OPPS SI AND APC ASSIGNMENTS FOR THE LEADLESS PACEMAKER CPT CODES 0795 – 0804T

CPT Code	Long Descriptor	July 2023 OPPS SI	July 2023 OPPS APC	July 2023 APC Group Title
0795T	Transcatheter insertion of permanent dual-chamber leadless pacemaker, including imaging guidance (eg, fluoroscopy, venous ultrasound, right atrial angiography, right ventriculography, femoral venography) and device evaluation (eg, interrogation or programming), when performed; complete system (ie, right atrial and right ventricular pacemaker components)	E1		
0796T	Transcatheter insertion of permanent dual-chamber leadless pacemaker, including imaging guidance (eg, fluoroscopy, venous ultrasound, right atrial angiography, right ventriculography, femoral venography) and device evaluation (eg, interrogation or programming), when performed; right atrial pacemaker component (when an existing right ventricular single leadless pacemaker exists to create a dual-chamber leadless pacemaker system)	E1		
0797T	Transcatheter insertion of permanent dual-chamber leadless pacemaker, including imaging guidance (eg, fluoroscopy, venous ultrasound, right atrial angiography, right ventriculography, femoral venography) and device evaluation (eg, interrogation or programming), when performed; right ventricular pacemaker component (when part of a dual-chamber leadless pacemaker system)	J1	5194	Level 4 Endovascular Procedures
0798T	Transcatheter removal of permanent dual-chamber leadless pacemaker, including imaging guidance (eg, fluoroscopy, venous ultrasound, right atrial angiography, right ventriculography, femoral venography), when performed; complete system (ie, right atrial and right ventricular pacemaker components)	E1		
0799T	Transcatheter removal of permanent dual-chamber leadless pacemaker, including imaging guidance (eg, fluoroscopy, venous ultrasound, right atrial angiography, right ventriculography, femoral	E1		

CPT Code	Long Descriptor	July 2023 OPPS SI	July 2023 OPPS APC	July 2023 APC Group Title
	venography), when performed; right atrial pacemaker component			
0800T	Transcatheter removal of permanent dual-chamber leadless pacemaker, including imaging guidance (eg, fluoroscopy, venous ultrasound, right atrial angiography, right ventriculography, femoral venography), when performed; right ventricular pacemaker component (when part of a dual-chamber leadless pacemaker system)	J1	5183	Level 3 Vascular Procedures
0801T	Transcatheter removal and replacement of permanent dual-chamber leadless pacemaker, including imaging guidance (eg, fluoroscopy, venous ultrasound, right atrial angiography, right ventriculography, femoral venography) and device evaluation (eg, interrogation or programming), when performed; dual-chamber system (ie, right atrial and right ventricular pacemaker components)	E1		
0802T	Transcatheter removal and replacement of permanent dual-chamber leadless pacemaker, including imaging guidance (eg, fluoroscopy, venous ultrasound, right atrial angiography, right ventriculography, femoral venography) and device evaluation (eg, interrogation or programming), when performed; right atrial pacemaker component	E1		
0803T	Transcatheter removal and replacement of permanent dual-chamber leadless pacemaker, including imaging guidance (eg, fluoroscopy, venous ultrasound, right atrial angiography, right ventriculography, femoral venography) and device evaluation (eg, interrogation or programming), when performed; right ventricular pacemaker component (when part of a dual-chamber leadless pacemaker system)	J1	5194	Level 4 Endovascular Procedures
0804T	Programming device evaluation (in person) with iterative adjustment of implantable device to test the function of device and to select optimal permanent programmed values, with analysis, review, and report, by a physician or other qualified health care professional, leadless pacemaker system in dual cardiac chambers	Q1	5741	Level 1 Electronic Analysis of Devices

BILLING CODE 4150–28–C

For CY 2024, as listed in the OPPS Addendum B that was released with the CY 2024 OPPS/ASC proposed rule, we proposed to continue to assign the 10

codes to the same status indicator and APC assignments listed in Table 58. In addition to the codes effective July 1, 2023, we also listed the four Aveir AR-related CPT codes, specifically, CPT codes 0823T, 0824T, 0825T, and 0826T, that are effective January 1, 2024, in OPPS Addendum B, and proposed to assign them to status indicator ''E1'' since the device had not received FDA approval. The codes were listed in OPPS Addendum B with their placeholder codes since we had not received the final CPT code numbers from AMA in time for publication of the proposed rule.

- 0823T (placeholder code X125T): Insertion of permanent right atrial single-chamber leadless pacemaker
- 0824T (placeholder code X126T): Removal of permanent right atrial single-chamber leadless pacemaker
- 0825T (placeholder code X127T): Removal and replacement of permanent right atrial single-chamber leadless pacemaker
- 0826T (placeholder code X128T): Programming device evaluation, single chamber

We note a commenter provided background information on the technology associated with the new codes, the FDA approval for the three leadless pacemaker systems, and the cost of the complete system. First, the commenter clarified that the new codes relate to the Aveir DR dual-chamber leadless pacemaker, which is a modular system, that consists of two implanted leadless pacemakers, specifically, the Aveir VR single-chamber right ventricular component, and the Aveir AR single-chamber right atrial component. Secondly, the commenter clarified that the Aveir VR received FDA PMA approval in March 2022, and the Aveir DR and Aveir AR were approved by the FDA for commercial use through a PMA supplement on June 29, 2023. Additionally, the commenter reported that the price for the Aveir DR dual chamber leadless pacemaker is $24,000 and includes the following components: one Aveir VR right ventricular leadless pacemaker, one Aveir AR right atrial leadless pacemaker, two delivery catheters, and one introducer. The commenter indicated that the Aveir VR and Aveir AR devices may be implanted at the same time, thus representing the complete Aveir DR dual-chamber leadless pacemaker. Alternatively, the single-chamber components (Aveir VR and Aveir AR) may be implanted separately.

We received several comments related to our proposal. Below are the responses to the comments.

Comment: A commenter disagreed with the proposed APC assignment for the codes describing insertion of a leadless pacemaker for the complete system and single-chamber devices. Specifically, the commenter disagreed with the proposed assignment of APC 5194 (Level 4 Endovascular Procedures; proposed payment of $17,195.36) for CPT codes 33274 and 0797T, and suggested assignment to APC 5524 (Level 4 Pacemaker and Similar Procedures; proposed payment of $18,718.23). This same commenter disagreed with the status indicator assignment of ''E1'' for CPT codes 0795T, 0796T, and 0823T, and recommended revision to APC 5524. Another device manufacturer also disagreed with the proposed status indicator assignment of ''E1'' for CPT codes 0795T, 0796T, and 0823T, and recommended assignment to either APC 5231 (Level 1 ICD and Similar Procedures; proposed payment of $23,075.10) or APC 5224. This same device manufacturer recommended reassignment from status indicator ''E1'' to APC 5194 (Level 4 Endovascular Procedures; proposed payment of $17,195.36) for CPT codes 0796T and 0823T.

Response: Because the codes are new, specifically, CPT codes 0795T, 0796T, 0797T, and 0823T, we have no claims data. In determining the appropriate APC placement for new codes, we generally rely on input from a variety of sources, including, but not limited to, review of the resource costs and clinical similarity of the service to existing procedures; input from CMS medical advisors; information from interested specialty societies; and review of all other information available to us. Based on our evaluation of the codes, we agree that these insertion codes are more appropriate in APC 5224 (Level 4 Pacemaker and Similar Procedures) based on clinical similarity and resource homogeneity to the procedures in the APC. Therefore, we are assigning CPT codes 0795T, 0796T, 0797T, and 0823T, to APC 5224 for CY 2024.

With respect to CPT code 33274, which was effective January 1, 2019, our analysis of the claims data for this final rule shows a geometric mean cost of about $19,560 based on 4,349 single claims (out of 4,408 total claims), which we believe is consistent with the geometric mean cost of approximately $19,082 for APC 5224. Therefore, we agree with the commenter that CPT code 33274 fits more appropriately in APC 5224 rather than APC 5194, whose geometric mean cost is about $17,173. Consequently, we are reassigning CPT code 33274 from APC 5194 to APC 5224 for CY 2024.

Comment: For the removal and replacement codes, specifically, CPT codes 0801T, 0802T, 0803T, and 0825T, some commenters disagreed with the proposed status indicator assignment of ''E1.'' For CPT code 0801T, the commenters recommended assignment to either APC 5224 or 5231, and for CPT code 0803T, they disagreed with assignment to APC 5194 and suggested assignment to APC 5224. For CPT codes 0802T and 0825T, the commenters recommended assignment to APC 5224.

Response: Because these removal and replacement codes are new, we have no claims data. However, based on our review of the codes, input from our clinicians, and their clinical similarity to the procedures in APC 5224, we believe these codes should be assigned to APC 5224 and the corresponding status indicator ''J1.'' Therefore, for CY 2024, we are assigning CPT codes 0801T, 0802T, 0803T, and 0825T to APC 5224 and SI ''J1.''

Comment: For the removal-only codes, specifically, CPT codes 0798T, 0799T, and 0824T, the commenters disagreed with the proposed status indicator assignment of ''E1.'' For CPT code 0798T, one commenter recommended assignment to APC 5183 (Level 3 Vascular Procedures; proposed payment of $3,054.97), while another commenter suggested assignment to APC 5184 (Level 4 Vascular Procedures; proposed payment of $5,284.18). Similarly, the commenters agreed that CPT codes 0799T and 0824T should be reassigned from status indicator ''E1'' to APC 5183. Another commenter suggested assigning the new leadless pacemaker removal-only codes, specifically, CPT codes 0798T, 0799T, 0800T, and 0824T, to the same APC as CPT code 33275 (APC 5183) since they all describe the same procedure.

Response: With the exception of CPT code 33275, which was effective January 1, 2019, we have no claims data for the removal-only codes, specifically, 0798T, 0799T, 0800T, and 0824T. However, based on input from our clinicians, and their similarity to CPT code 33275, we agree that all five codes should be placed in APC 5183. Therefore, for CPT codes 0798T, 0799T, and 0824T, we are reassigning the codes from status indicator ''E1'' to APC 5183 for CY 2024. We note that we did not receive any alternative APC recommendations for CPT codes 33275 and 0800T, therefore, we are finalizing their APC assignments as proposed.

Comment: For the programming code, specifically, CPT code 0826T, the commenters disagreed with the

proposed status indicator assignment of ''E1,'' and suggested assignment to APC 5741 (Level 1 Electronic Analysis of Devices; proposed payment of $36.79). One commenter recommended the assignment of CPT codes 0804T and 0826T to the same APC as existing CPT code 93279 (APC 5741) since they describe the same service.

Response: Because the code is new, we have no claims data. However, based on recommendations from our clinicians, and suggestions from the commenters, we are reassigning CPT code 0826T from status indicator ''E1'' to APC 5741 for CY 2024. Similarly, for CPT code 0804T, because the code is new, we have no claims data. However, based on input from the commenters, and suggestions from our clinicians, we are finalizing our proposal, without modification, to assign the code to APC 5741. For CPT code 93279, our analysis of the claims data for this final rule shows a geometric mean cost of approximately $34 based on 13,655 single claims (out of 22,664 total claims), which is in line with the geometric mean cost of approximately $37 for APC 5741. Therefore, for CPT code 93279, we are finalizing our proposal, without modification, to assign the code to APC 5741.

Comment: A device manufacturer reported that their suggested APCs for the new leadless pacemaker CPT codes do not include the device cost since they intend to submit a device pass-through application to CMS. They note that approval of the pass-through application would enable hospital outpatient facilities to receive separate payment for the device for a period of two to three years.

Response: We appreciate the clarification, and suggest the commenter refer to the Medicare Electronic Application Request Information System (MEARIS), specifically, at *https://mearis.cms.gov/public/home,* to submit their device pass-through application.

Comment: A commenter mentioned that in OPPS Addendum B of the CY 2024 OPPS/ASC proposed rule, CMS proposed to continue to assign HCPCS code G2066 (Interrogation device evaluation(s), (remote) up to 30 days; implantable cardiovascular physiologic monitor system, implantable loop recorder system, or subcutaneous cardiac rhythm monitor system, remote data acquisition(s), receipt of transmissions and technician review, technical support and distribution of results) to APC 5741, however, in the CY 2024 PFS proposed rule (88 FR 52321), CMS proposed to delete the code, and assign the direct practice expense inputs to CPT codes 93297 and 93298. The commenter requested clarification on whether HCPCS code G2066 will remain active for CY 2024, and if not, what alternative codes should be reported by the hospital outpatient facilities.

Response: HCPCS code G2066 will be deleted December 31, 2023, with no replacement code. We note that HCPCS code G2066 does not describe an interrogation device evaluation associated with a leadless pacemaker system, rather, it describes an interrogation device evaluation for an implantable cardiovascular physiologic monitor system, implantable loop recorder system, or subcutaneous cardiac rhythm monitor system. Under the OPPS, the interrogation device evaluation code that should be reported for the leadless pacemaker systems is CPT code 93296. The code was effective January 1, 2009, and is assigned to APC 5741. Below is the complete long descriptor for the code:

- 93296: Interrogation device evaluation(s) (remote), up to 90 days; single, dual, or multiple lead pacemaker system, leadless pacemaker system, or implantable defibrillator system, remote data acquisition(s), receipt of transmissions and technician review, technical support and distribution of results.

In addition, we did not receive any comments on our proposed APC assignment for CPT code 93296. Therefore, for CY 2024, we are finalizing our proposed APC for this code. In summary, after consideration of the comments that we received, we are finalizing our proposal to the status indicator and APC assignments for the 18 codes listed in Tables 59, 60, 61, 62, and 63 below. Because the codes for the leadless pacemaker are new, we have no claims data. We believe that the assignment to APC 5224 for the insertion, as well as for the removal and replacement procedure codes, is the best approach at this time. Similarly, we believe that the assignment to APC 5183 for the removal-only codes are appropriate. We also believe that the assignment to APC 5741 for the programming and the interrogation device evaluation codes is appropriate at this time. We reiterate that we analyze our claims data on an annual basis to establish the annual OPPS payment rates. Once we have data, we will reevaluate and, if necessary, reassign the codes to appropriate APCs based on the latest claims data. Finally, the final payment rates for the codes can be found in Addendum B to this final rule with comment period. In addition, we refer readers to Addendum D1 of this final rule with comment period for the status indicator (SI) meanings for all codes reported under the OPPS. Addenda B and D1 are available via the internet on the CMS website.

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TABLE 59: FINAL CY 2024 OPPS SIs AND APCs FOR THE INSERTION LEADLESS PACEMAKER CODES

CPT Code	Description	Proposed CY 2024 OPPS SI	Proposed CY 2024 OPPS APC	Proposed CY 2024 OPPS APC Group Title	Suggested APC	Final CY 2024 OPPS SI	Final CY 2024 OPPS APC
33274	Insertion or replacement; right ventricle	J1	5194	Level 4 Endovascular Procedures	5224: Level 4 Pacemaker and Similar Procedures	J1	5224
0795T	Insertion; dual chamber/ complete system	E1			5224: Level 4 Pacemaker and Similar Procedures OR 5231: Level 1 ICD and Similar Procedures	J1	5224
0796T	Insertion; dual chamber/ right atrial	E1			5224: Level 4 Pacemaker and Similar Procedures OR 5194: Level 4 Endovascular Procedures	J1	5224
0797T	Insertion; dual chamber/ right ventricle	J1	5194	Level 4 Endovascular Procedures	5224: Level 4 Pacemaker and Similar Procedures	J1	5224
0823T	Insertion; single-chamber/ right atrial	E1			5224: Level 4 Pacemaker and Similar Procedures OR 5194: Level 4 Endovascular Procedures	J1	5224

TABLE 60: FINAL CY 2024 OPPS SIs AND APCs FOR THE REMOVAL AND REPLACEMENT LEADLESS PACEMAKER CODES

CPT Code	Description	Proposed CY 2024 OPPS SI	Proposed CY 2024 OPPS APC	Proposed CY 2024 OPPS APC Group Title	Suggested APC	Final CY 2024 OPPS SI	Final CY 2024 OPPS APC
0801T	Removal and replacement; dual-chamber system/ complete system	E1			5224: Level 4 Pacemaker and Similar Procedures	J1	5224
0802T	Removal and replacement; dual-chamber system/ right atrial	E1			5224: Level 4 Pacemaker and Similar Procedures	J1	5224
0803T	Removal and replacement; dual-chamber/ right ventricle	J1	5194	Level 4 Endovascular Procedures	5224: Level 4 Pacemaker and Similar Procedures	J1	5224
0825T	Removal and replacement; single-chamber/ right atrial	E1			5224: Level 4 Pacemaker and Similar Procedures	J1	5224

TABLE 61: FINAL CY 2024 OPPS SIs AND APCs FOR THE REMOVAL-ONLY LEADLESS PACEMAKER CODES

CPT Code	Description	Proposed CY 2024 OPPS SI	Proposed CY 2024 OPPS APC	Proposed CY 2024 OPPS APC Group Title	Suggested APC	Final CY 2024 OPPS SI	Final CY 2024 OPPS APC
33275	Removal; right ventricle	J1	5183	Level 3 Vascular Procedures	N/A	J1	5183
0798T	Removal; dual chamber/ complete system	E1			5183: Level 3 Vascular Procedures OR 5184: Level 4 Vascular Procedures	J1	5183
0799T	Removal; dual chamber/ right atrial	E1			5183: Level 3 Vascular Procedures	J1	5183
0800T	Removal; dual chamber/ right ventricle	J1	5183	Level 3 Vascular Procedures	N/A	J1	5183
0824T	Removal; single-chamber - right atrial	E1			5183: Level 3 Vascular Procedures	J1	5183

TABLE 62: FINAL CY 2024 OPPS SIs AND APCs FOR THE IN-PERSON PROGRAMMING LEADLESS PACEMAKER CODES

CPT Code	Description	Proposed CY 2024 OPPS SI	Proposed CY 2024 OPPS APC	Proposed CY 2024 OPPS APC Group Title	Suggested APC	Final CY 2024 OPPS SI	Final CY 2024 OPPS APC
93279	In person programming device evaluation; single lead or leadless pacemaker one cardiac chamber	Q1	5741	Level 1 Electronic Analysis of Devices	N/A	Q1	5741
0804T	In person programming device evaluation; leadless pacemaker dual-chamber	Q1	5741	Level 1 Electronic Analysis of Devices	N/A	Q1	5741
0826T	In person programming device evaluation; leadless pacemaker single-chamber	E1			5741	Q1	5741

TABLE 63: FINAL CY 2024 OPPS SI AND APC FOR THE REMOTE INTERROGATION DEVICE EVALUATION LEADLESS PACEMAKER CODE

CPT Code	Description	Proposed CY 2024 OPPS SI	Proposed CY 2024 OPPS APC	Proposed CY 2024 OPPS APC Group Title	Suggested APC	Final CY 2024 OPPS SI	Final CY 2024 OPPS APC
93296	Remote interrogation device eval	Q1	5741	Level 1 Electronic Analysis of Devices	N/A	Q1	5741

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15. Cardiac Magnetic Resonance Imaging (APC 5572)

For CY 2023, we assigned CPT code 75561 (Cardiac magnetic resonance imaging for morphology and function without contrast material(s), followed by contrast material(s) and further sequences) to APC 5572 (Level 2 Imaging with Contrast) with a payment rate of $368.43. For CY 2024, as listed in OPPS Addendum B that was released with the CY 2024 OPPS/ASC proposed rule, we proposed to maintain the assignment to APC 5572 with a payment rate of $369.86.

Comment: A commenter disagreed with the assignment to APC 5572 for CPT code 75561 and requested a change to APC 5573. The commenter indicated that the service described by the code is clinically similar to the service described by CPT code 75563 (Cardiac magnetic resonance imaging for morphology and function without contrast material(s), followed by contrast material(s) and further sequences; with stress imaging), which is proposed to be assigned to APC 5573 (Level 3 Imaging with Contrast), with a payment of $775.83.

Response: We reviewed our claims data for this final rule, which is based on claims submitted between January 1, 2022, and December 31, 2022, processed through June 30, 2023, and found that the resource costs associated with CPT codes 75561 and 75563 are very different. Specifically, our claims data show a geometric mean cost of about $440 for CPT code 75561 based on

23,451 single claims (out of 27,479 total claims), which is significantly lower than the geometric mean cost of approximately $833 for CPT code 75563 based on 3,377 single claims (out of 3,818 total claims). We believe that the geometric mean cost of about $440 for CPT code 75561 is consistent with the geometric mean cost of approximately $377 for APC 5572, rather than APC 5573, whose geometric mean cost is approximately $784. Based on the data, we believe that the clinical and resource characteristics of CPT code 75561 are sufficiently similar to the other procedures assigned to APC 5572 and should continue to be assigned to the APC.

In summary, after consideration of the public comment, we are finalizing our proposal, without modification, to assign CPT code 75561 to APC 5572 for CY 2024. The final CY 2024 payment rate for the code can be found in Addendum B to this final rule with comment period. In addition, we refer readers to Addendum D1 of this final rule with comment period for the SI definitions for all codes reported under the OPPS. Addenda B and D1 are available via the internet on the CMS website.

16. Cardiac Resynchronization Therapy Procedures (APCs 5054, 5221, 5223, 5231, 5731, and 5741)

On November 1, 2016, CMS approved for Medicare coverage the Category B Investigational Device Exemption (IDE) study associated with EBR System's WiSE System for cardiac resynchronization therapy (Study Title: Stimulation Of the Left Ventricular Endocardium for Cardiac Resynchronization Therapy in Non-Responders and Previously Untreatable Patients, SOLVE CRT; NCT number NCT02922036; IDE number G150244). In 2019, AMA established eight Category III CPT codes associated with the WiSE System effective January 1, 2019. The codes are CPT codes 0515T through 0522T, and describe the implant, removal and replacement, revision, interrogation, and programming of the system. For 2024, the AMA's CPT Editorial Panel revised the descriptors for existing CPT codes 0517T, 0518T, 0519T, 0520T, and established three new codes, specifically, CPT codes 0861T, 0862T, and 0863T, effective January 1, 2024.

For the 2024 update, as listed in OPPS Addendum B that was released with the CY 2024 OPPS/ASC proposed rule, we proposed to assign the codes to the SIs and APCs listed in Table 64 below, for the existing, new, and revised codes.

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TABLE 64: EXISTING, NEW, AND REVISED CATEGORY III CPT CODES RELATED TO THE WISE SYSTEM

CPT Code	2023 Description	2024 Description	Proposed CY 2024 OPPS APC	Proposed CY 2024 OPPS APC Group Title	Proposed CY 2024 OPPS Payment
0515T	Insertion; complete system	Insertion; complete system	5231	Level 1 ICD and Similar Procedures	$23,075.10
0516T	Insertion; electrode	Insertion; electrode	5222	Level 2 Pacemaker and Similar Procedures	$8,264.84
0517T	Insertion; battery and/or transmitter only	Insertion; (both) battery and transmitter	5222	Level 2 Pacemaker and Similar Procedures	$8,264.84
0518T	Removal; battery and/or transmitter	Removal; battery	5211	Level 1 Electrophysiologic Procedures	$1,146.59
0861T	N/A	(new code for 2024) Removal; (both) battery and transmitter	5211	Level 1 Electrophysiologic Procedures	$1,146.59
0519T	Removal and replacement; battery and/or transmitter	Removal and replacement; (both) battery and transmitter	5221	Level 1 Pacemaker and Similar Procedures	$3,903.23
0520T	Removal and replacement; battery and/or transmitter, including a new electrode	Removal and replacement; Battery	5221	Level 1 Pacemaker and Similar Procedures	$3,903.23
0862T	N/A	(new code for 2024) Relocation; battery	5054	Level 4 Skin Procedures	$1,770.89
0863T	N/A	(new code for 2024) Relocation; transmitter	5054	Level 4 Skin Procedures	$1,770.89
0521T	In-person interrogation evaluation	In-person interrogation evaluation	5731	Level 1 Minor Procedures	$26.53
0522T	In-person programming device evaluation	In-person programming device evaluation	5741	Level 1 Electronic Analysis of Devices	$36.79

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We received comments from the WiSE System manufacturer on our proposed assignments for the codes listed in Table 64. The commenter clarified that the

IDE clinical trial associated with the WiSE System has ended and that they expect FDA PMA approval in the second quarter of 2024. The commenter also provided the following target pricing for the components of the WiSE System:

- WiSE System: $45,000
- Electrode: $17,300
- Battery: $9,000
- Transmitter: $18,700
- Battery and Transmitter: $27,700

Of the 11 codes, the device manufacturer disagreed with the proposed APC assignments for seven codes listed in Table 64. Below are the comments associated with certain codes, their suggested APC assignments, and our responses to the comments.

Comment: For CPT code 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])), we proposed to continue to assign to APC 5231 (Level 1 ICD and Similar Procedures; proposed payment of $ 23,075.10). The device manufacturer disagreed with the assignment and suggested reassignment to APC 1581 (New Technology—Level 44 ($50,001–$60,000)) with a proposed payment of $55,000.50, based on its target price of $45,000 for the complete WiSE System.

Response: CPT code 0515T was effective January 1, 2019. We note that the 2024 OPPS payment rates are based on claims submitted between January 1, 2022, and December 31, 2022, processed through June 30, 2023. Analysis of our claims data show a geometric mean cost of about $43,974 based on 2 single claims (out of 2 total claims). The commenter reported a target price of $45,000 for the complete system, however, based on the low volume of only 2 single claims, we believe that we should maintain the code's assignment to APC 5231 before reassigning to a more appropriate APC. We believe that the continued assignment to APC 5231 will enable Medicare to track the services accordingly and establish an appropriate payment for the code. Therefore, we are finalizing our proposal to APC 5231 for CPT code 0515T.

Comment: The device manufacturer disagreed with our proposal to continue to assign CPT code 0516T to APC 5222 (Level 2 Pacemaker and Similar Procedures; proposed payment of $8,264.84) and recommended reassignment to APC 5224 (Level 4 Pacemaker and Similar Procedures; proposed payment of $18,718.23).

Response: CPT code 0516T was also effective January 1, 2019. Our claims data show a geometric mean cost of about $9,645 based on 2 single claims (out of 2 total claims). Based on our evaluation of the procedure, opinion from our clinicians, and the similarity of the procedure to CPT code 33207 (Insertion of new or replacement of permanent pacemaker with transvenous electrode(s); ventricular), which we proposed for assignment to APC 5223 (Level 3 Pacemaker and Similar Procedures; proposed payment of $10,354.26), we believe that APC 5223 is the more appropriate assignment for CPT code 0516T. Therefore, for CY 2024, we are finalizing our proposal with modification, and assigning CPT code 0516T to APC 5223.

Comment: As noted in Table 64, the code descriptor for CPT code 0517T in CY 2023 described the insertion of the battery and/or transmitter only; however, for 2024, the revised descriptor describes the insertion of both the battery and transmitter. We proposed to continue to assign CPT code 0517T to APC 5222 (Level 2 Pacemaker and Similar Procedures; proposed payment of $8,264.84). A commenter disagreed with the assignment and recommended reassignment to APC 5232 (Level 2 ICD and Similar Procedures; proposed payment of $31,975.11). We note the commenter listed APC 5231 (Level 1 ICD; proposed payment of $23,075.10) but included in parentheses the proposed payment of $31,975.11, which is the proposed payment for APC 5232 (Level 2 ICD). We believe the commenter meant to suggest APC 5232 rather than APC 5231.

Response: Based on our analysis of the data for this final rule, our claims data shows a geometric mean cost of approximately $51,240 based on 2 single claims (out of 2 total claims) for CPT code 0517T. Based on the revised descriptor which describes insertion of a battery and a transmitter, as well as input from our clinicians, we believe we should reassign the code from APC 5222 (Level 2 Pacemaker and Similar Procedures; proposed payment of $8,264.84) to APC 5223 (Level 3 Pacemaker and Similar Procedures; proposed payment of $10,354.26). Because the IDE clinical study associated with the WiSE System has just ended and the device is still pending FDA PMA approval, we do not believe that we should reassign CPT code 0517T to APC 5232 at this time. We believe that assignment to APC 5223 for CPT code 0517T is the best approach at this time. Therefore, for CY 2024, we are finalizing our proposal with modification, and reassigning CPT code 0517T to APC 5223. We will evaluate the APC assignment for CPT code 0517T in next year's rulemaking to determine whether another APC would be more appropriate.

Comment: As noted in Table 64, for CY 2023, CPT code 0518T described the removal of the ''battery and/or transmitter'' and was assigned to APC 5221 (Level 1 Pacemaker and Similar Procedures). However, for 2024, based on its revised description of removal of ''battery component only,'' we proposed to reassign the code to APC 5211 (Level 1 Electrophysiologic Procedures; proposed payment of $1,146.59) to reflect the reduced resources to perform the procedure. A commenter disagreed with the proposed assignment and suggested reassignment to APC 5222 (Level 2 Pacemaker and Similar Procedures; proposed payment of $8,264.84) consistent with the APC assignment for CPT code 33233 (Removal of permanent pacemaker pulse generator only).

Response: Based on our analysis of the data for this final rule, we have no claims data for CPT code 0518T. However, based on input from our clinicians and the code's similarity to 33241 (Removal of implantable defibrillator pulse generator only), which is proposed to be assigned to APC 5221 (Level 1 Pacemaker and Similar Procedures), we believe that we should reassign the code to APC 5221. Therefore, for CY 2024, we are finalizing our proposal with modification, and reassigning CPT code 0518T to APC 5221.

Comment: As noted in Table 64, for CY 2023, CPT code 0519T described removal and replacement of the battery and/or transmitter. However, for CY 2024, the code has been revised to describe the removal and replacement of both the battery and transmitter. For CY 2024, we proposed to continue to assign the code to APC 5221 (Level 1 Pacemaker and Similar Procedures; proposed payment of $ 3,903.23). A commenter disagreed with the assignment and suggested reassignment to APC 5232 (Level 2 ICD and Similar Procedures; proposed payment of $31,975.11). Similar to CPT code 0517T, the commenter listed APC 5231 (Level 1 ICD; proposed payment of $23,075.10) but included in parentheses a proposed payment amount of $31,975.11, which is the proposed payment for APC 5232 (Level 2 ICD). We believe the commenter meant to suggest APC 5232 rather than APC 5231.

Response: Analysis of our claims data show a geometric mean cost of about $6,127 for CPT code 0519T based on 4

single claims (out of 4 total claims). Because the revised code describes the removal and replacement of the battery and transmitter, we believe this code should be assigned to the same APC as CPT code 0517T. Therefore, for CY 2024, we are finalizing our proposal with modification, and assigning CPT code 0519T to APC 5223.

Comment: As noted in Table 64, for CY 2023, CPT code 0520T described the removal and replacement of a pulse generator, including a new electrode, and was assigned to APC 5231 (Level 1 ICD and Similar Procedures) with a payment rate of $22,818.32. However, for 2024, the code descriptor has been revised significantly and now describes the removal and replacement of the battery component only. Based on the reduced work associated with the revised descriptor, we proposed to reassign CPT code 0520T to APC 5221 (Level 1 Pacemaker and Similar Procedures; proposed payment of $3,903.23). The device manufacturer disagreed with the proposal and suggested assignment to APC 5223 (Level 3 Pacemaker and Similar Procedures; proposed payment of $10,354.26), consistent with the APC assignment for CPT code 33206 (Insertion of new or replacement of permanent pacemaker with transvenous electrode(s); atrial)).

Response: We have no claims data for CPT code 0520T, however, based on our evaluation of the procedure and recommendation from our clinicians, we agree with the commenter that the code should be reassigned to APC 5223. Therefore, for CY 2024, we are finalizing our proposal with modification, and assigning CPT code 0520T to APC 5223.

Comment: CPT code 0861T is a new code for CY 2024. We proposed to assign the code to APC 5211 (Level 1 Electrophysiologic Procedures; proposed payment rate of $ 1,146.59), based on its similarity to CPT code 0518T (Removal of only pulse generator component(s) (battery and/or transmitter) of wireless cardiac stimulator for left ventricular pacing), which is also proposed to APC 5211. The commenter disagreed with the proposal, and recommended assignment to APC 5222 (Level 2 Pacemaker and Similar Procedures; proposed payment of $8,264.84).

Response: Consistent with our final policy for CPT code 0518T, we believe that we should reassign CPT code 0861T to APC 5221. Therefore, for CY 2024, we are finalizing our proposal with modification, and assigning CPT code 0861T to APC 5221.

Comment: As listed in Table GX1, we proposed to assign CPT codes 0862T, 0863T, 0521T, and 0522T, to the APCs listed in Table GX1. The device manufacturer agreed with our APC assignments for the codes.

Response: We appreciate the commenter's feedback. Therefore, for CY 2024, we are finalizing our proposal without modification for CPT codes 0862T, 0863T, 0521T, and 0522T.

Finally, we remind the commenter that 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 market basket increase reduced by the productivity adjustment. 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. For new procedures and items, we get many requests from manufacturers to increase the reimbursement for the code associated with their procedures and items. 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. On balance, 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).

In summary, after consideration of the public comment that we received, we are finalizing the APC assignments for CPT codes 0515T through 0522T, and 0861T through 0863T to the APCs listed in Table 65 below. As we do every year, we will reevaluate the APC assignments for these codes in the next rulemaking cycle. We remind hospitals that we review, on an annual basis, the APC assignments for all items and services paid under the OPPS. The final payment rates for the codes can be found in Addendum B to this final rule with comment period. In addition, we refer readers to Addendum D1 of this final rule with comment period for the status indicator (SI) meanings for all codes reported under the OPPS. Addenda B and D1 are available via the internet on the CMS website.

TABLE 65: FINAL CY 2024 SIs AND APC ASSIGNMENTS FOR THE CARDIAC RESYNCHRONIZATION THERAPY CPT CODES 0515T THROUGH 0522T, AND CPT CODES 0861T THROUGH 0863T

CPT Code	Short Descriptor	Proposed CY 2024 SI	Proposed CY 2024 APC	Final CY 2024 SI	Final CY 2024 APC
0515T	Insj wcs lv compl sys	J1	5231	J1	5231
0516T	Insj wcs lv eltrd only	J1	5222	J1	5223
0517T	Insj wcs lv bth compnt pg	J1	5222	J1	5223
0518T	Rmvl pg wcs lv battery only	T	5211	Q2	5221
0861T	Rmvl pg wcs lv both compnt	T	5211	Q2	5221
0519T	Rmv&rplcmt pg wcs lv both	T	5221	J1	5223
0520T	Rmv&rplcmt pg wcs lv battery	T	5221	J1	5223
0862T	Rlcj pg wcs lv battery only	T	5054	T	5054
0863T	Rlcj pg wcs lv trnsmtr only	T	5054	T	5054
0521T	Interrog dev eval wcs ip	Q1	5731	Q1	5731
0522T	Prgrmg dev eval wcs ip	Q1	5741	Q1	5741

17. Catheter Placement Codes (APCs 5181 Through 5184)

For CY 2024, we proposed to continue to assign catheter placement CPT codes 36555–36597 status indicator ''J1'' and to APCs 5181 through 5184 with the proposed payment rates listed in table 66.

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TABLE 66: PROPOSED CY 2024 OPPS SI, APC, AND PAYMENT RATE FOR THE CATHETER PLACEMENT CODES

HCPCS Code	Long Descriptor	Proposed CY 2024 OPPS SI	Proposed CY 2024 OPPS APC	Proposed CY 2024 OPPS APC Title	Proposed CY 2024 OPPS Payment Rate
36555	Insertion of non-tunneled centrally inserted central venous catheter; younger than 5 years of age	J1	5183	Level 3 Vascular Procedures	$3,054.97
36556	Insertion of non-tunneled centrally inserted central venous catheter; age 5 years or older	J1	5183	Level 3 Vascular Procedures	$3,054.97
36557	Insertion of tunneled centrally inserted central venous catheter, without subcutaneous port or pump; younger than 5 years of age	J1	5184	Level 4 Vascular Procedures	$5,284.18
36558	Insertion of tunneled centrally inserted central venous catheter, without subcutaneous port or pump; age 5 years or older	J1	5183	Level 3 Vascular Procedures	$3,054.97
36560	Insertion of tunneled centrally inserted central venous access device, with subcutaneous port; younger than 5 years of age	J1	5183	Level 3 Vascular Procedures	$3,054.97
36561	Insertion of tunneled centrally inserted central venous access device, with subcutaneous port; age 5 years or older	J1	5183	Level 3 Vascular Procedures	$3,054.97
36563	Insertion of tunneled centrally inserted central venous access	J1	5184	Level 4 Vascular Procedures	$5,284.18

	device with subcutaneous pump				
36565	Insertion of tunneled centrally inserted central venous access device, requiring 2 catheters via 2 separate venous access sites; without subcutaneous port or pump (e.g., tesio type catheter)	J1	5183	Level 3 Vascular Procedures	$3,054.97
36566	Insertion of tunneled centrally inserted central venous access device, requiring 2 catheters via 2 separate venous access sites; with subcutaneous port(s)	J1	5184	Level 4 Vascular Procedures	$5,284.18
36568	Insertion of peripherally inserted central venous catheter (PICC), without subcutaneous port or pump, without imaging guidance; younger than 5 years of age	J1	5182	Level 2 Vascular Procedures	$1,534.27
36569	Insertion of peripherally inserted central venous catheter (PICC), without subcutaneous port or pump, without imaging guidance; age 5 years or older	J1	5182	Level 2 Vascular Procedures	$1,534.27
36570	Insertion of peripherally inserted central venous access device, with subcutaneous port; younger than 5 years of age	J1	5183	Level 3 Vascular Procedures	$3,054.97
36571	Insertion of peripherally inserted central venous access device, with subcutaneous port; age 5 years or older	J1	5183	Level 3 Vascular Procedures	$3,054.97

36576	Repair of central venous access device, with subcutaneous port or pump, central or peripheral insertion site	J1	5182	Level 2 Vascular Procedures	$1,534.27
36578	Replacement, catheter only, of central venous access device, with subcutaneous port or pump, central or peripheral insertion site	J1	5183	Level 3 Vascular Procedures	$3,054.97
36580	Replacement, complete, of a non-tunneled centrally inserted central venous catheter, without subcutaneous port or pump, through same venous access	J1	5182	Level 2 Vascular Procedures	$1,534.27
36581	Replacement, complete, of a tunneled centrally inserted central venous catheter, without subcutaneous port or pump, through same venous access	J1	5183	Level 3 Vascular Procedures	$3,054.97
36582	Replacement, complete, of a tunneled centrally inserted central venous access device, with subcutaneous port, through same venous access	J1	5183	Level 3 Vascular Procedures	$3,054.97
36583	Replacement, complete, of a tunneled centrally inserted central venous access device, with subcutaneous pump, through same venous access	J1	5184	Level 4 Vascular Procedures	$5,284.18
36584	Replacement, complete, of a peripherally inserted central venous catheter	J1	5182	Level 2 Vascular Procedures	$1,534.27

	(PICC), without subcutaneous port or pump, through same venous access, including all imaging guidance, image documentation, and all associated radiological supervision and interpretation required to perform the replacement				
36585	Replacement, complete, of a peripherally inserted central venous access device, with subcutaneous port, through same venous access	J1	5183	Level 3 Vascular Procedures	$3,054.97
36595	Mechanical removal of pericatheter obstructive material (e.g., fibrin sheath) from central venous device via separate venous access	J1	5183	Level 3 Vascular Procedures	$3,054.97
36596	Mechanical removal of intraluminal (intracatheter) obstructive material from central venous device through device lumen	J1	5182	Level 2 Vascular Procedures	$1,534.27
36597	Repositioning of previously placed central venous catheter under fluoroscopic guidance	J1	5182	Level 2 Vascular Procedures	$1,534.27

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Comment: We received one comment where the commenter requested that we change the status indicator for all catheter placements CPT codes in the 365XX series from status indicator ''J1'' to status indicator ''T.'' This commenter stated that there are times that patients require placement of such a catheter and then receive an infusion of a drug such as chemotherapy. Because several of those codes are assigned to status indicator ''J1,'' the drug cost, unless the drug is a pass-through drug, is not reimbursed. For one infusion, Lutathera (HCPCS code A9513), the drug cost is $55,000 and the $1,487 payment for C–APC 5182 clearly does not cover that cost. The commenter noted that while outlier payment will apply, it is inadequate to compensate for the actual expenditure for the treatment.

Response: The Outpatient Coding Editor (IOCE) will package the drug cost into the Comprehensive APC, even if we change the status indicators for the catheter placement codes from ''J1'' to ''T'' because the APCs that the catheter placement codes are assigned to are assigned to status indicator ''J1.'' Therefore, the drug costs would not be reimbursed separately if we change the status indicators for the catheter placement codes from ''J1'' to ''T.'' Because of this, the only way to receive separate payment for the individual

procedures in these situations would be for the status indicator of the APC and all services assigned to the APC to be ''T.'' We continue to believe that this APC is appropriately assigned to comprehensive status. While there may be cases that would involve more complexity and cost, those packaged costs are reflected in claims used for ratesetting and the HCPCS and APC geometric mean costs, to the degree that they are performed in that manner. Nevertheless, we appreciate the comment, and we will take the commenter's recommendation into consideration in future rulemaking.

In summary, after consideration of the comment we have received, we are finalizing our proposal without modification. Specifically, we will continue to assign catheter placement codes listed in Table 66 to status indicator ''J1'' for CY2024. We plan to review the comprehensive APC policy for CY 2025 to determine if we need to adopt any packaging changes as part of that rulemaking. The final CY 2024 OPPS payment rates for these codes can be found in Addendum B to this final rule with comment period. In addition, we refer readers to Addendum D1 of this final rule with comment period for the status indicator meanings for all codes reported under the OPPS. Addenda B and D1 are available via the internet on the CMS website.

18. Cerene Cryotherapy Endometrial Ablation Procedure (APC 5415)

For CY 2023, we assigned CPT code 58356 (Endometrial cryoablation with ultrasonic guidance, including endometrial curettage, when performed) to APC 5415 (Level 5 Gynecologic Procedures) with a payment rate of $4,635.11. For CY 2024, as listed in OPPS Addendum B that was released with the CY 2024 OPPS/ASC proposed rule, we proposed to maintain the assignment for the code to APC 5415 with a payment rate of $4,783.96.

Comment: A commenter requested that we finalize the proposed assignment to APC 5415 for CPT code 58356.

Response: We reviewed our claims data for this final rule with comment period, which is based on claims submitted between January 1, 2022, and December 31, 2022, processed through June 30, 2023, and found no claims data for CPT code 58356. However, because the code has been in existence since January 1, 2005, we reviewed our historical claims data for the last 5 years, specifically, the historical cost statistics released with the CY 2019 through CY 2023 OPPS/ASC final rules, and found some claims for the code. Specifically, our historical claims data show a geometric mean cost that ranged between $1,712 and $5,032, based on 3 and 5 single claims. Because the code has been assigned to this same APC for many years now, we believe we should the maintain the assignment to APC 5415 for CPT code 58356. We note that we review, on an annual basis, the APC assignments for all services and items paid under the OPPS.

In summary, after consideration of the public comment, we are finalizing our proposal, without modification, to assign CPT code 58356 to APC 5415 for CY 2024. The final CY 2024 payment rate for the code can be found in Addendum B to this final rule with comment period. In addition, we refer readers to Addendum D1 of this final rule with comment period for the SI meanings for all codes reported under the OPPS. Addenda B and D1 are available via the internet on the CMS website.

19. Complex Bunion Correction Procedures CPT Codes 28297 and 28740 (APC 5114)

CPT code 28297 (Correction, hallux valgus (bunionectomy), with sesamoidectomy, when performed; with first metatarsal and medial cuneiform joint arthrodesis, any method) with a geometric mean cost of around $10,664 and CPT code 28740 (Arthrodesis, midtarsal or tarsometatarsal, single joint) with a geometric mean cost of around $10,376 describe complex bunion correction procedures. For the CY 2024 OPPS proposed rule, we proposed assigning both procedures to APC 5114 (Level 4 Musculoskeletal Procedures) with a payment rate of around $6,974.

Comment: One commenter noted that CPT codes 28297 and 28740 were close to violating the 2 times rule in APC 5114 and eligible for reassignment to APC 5115 (Level 5 Musculoskeletal Procedures) with a payment rate of around $13,421 if these procedures had been identified as significant procedures for 2 times rule purposes as the lowest-cost significant procedure. The lowest cost significant procedure in APC 5114 (CPT code 27385) had a geometric mean cost of around $5,357 and two times the amount would have been $10,714, which is just $50 more than the cost of CPT 28297 and about $350 more than the cost of CPT 28740. The commenter believed that there was a good chance that these procedures may have geometric means exceeding the 2 times rule requirements once the CY 2024 claims data were updated.

Response: Our review of updated data for CY 2024 found that neither CPT code 28297 nor CPT code 28740 violates the 2 times rule in their current assignment to APC 5114 if the procedures were significant. The updated estimated 2-times limit based on CPT code 27385 was around $10,797. CPT code 28297's updated geometric mean cost was around $10,728 and CPT code 28740 updated geometric mean cost was around $10,565. Also, these procedures were towards the higher-cost end of APC 5114 but moving them to APC 5115 would group CPT codes 28297 and 28740 with procedures that are generally more complex and resource-intensive than the procedures described by CPT codes 28297 and 28740.

After consideration of the public comments we received, we are implementing our proposal without modification for CPT codes 28297 and 28740. Table 67 shows the finalized status indicator and APC assignment for all of the procedure codes. We refer readers to Addendum B of this final rule with comment period for the payment rates for all codes reportable under the OPPS. Addendum B is available via the internet on the CMS website.

TABLE 67: FINAL CY 2024 OPPS APC STATUS INDICATOR ASSIGNMENTS FOR CPT CODES 28297 AND 28740

CPT Code	Long Descriptor	Final CY 2024 OPPS SI	Final CY 2024 OPPS APC
28297	Correction, hallux valgus (bunionectomy), with sesamoidectomy, when performed; with first metatarsal and medial cuneiform joint arthrodesis, any method	J1	5114
28740	Arthrodesis, midtarsal or tarsometatarsal, single joint	J1	5114

20. Cryoablation of the Prostate (APC 5376)

CPT code 55873 (Cryosurgical ablation of the prostate (includes ultrasonic guidance and monitoring)) describes the procedure associated with cryoablation of the prostate. For CY 2023, we assigned the code to APC 5376 (Level 6 Urology and Related Services), with a payment rate of $8,557.53. For CY 2024, as listed in OPPS Addendum B that was released with the CY 2024 OPPS/ASC proposed rule, we proposed to continue the code's assignment to APC 5376 with a payment rate of $8,847.08.

Comment: A commenter requested that we finalize the proposed assignment to APC 5376 for CPT code 55873.

Response: We note that the CY 2024 OPPS payment rates are based on claims submitted between January 1, 2022, and December 31, 2022, processed through June 30, 2023. We reviewed the claims data for this final rule, and based on our review, we found the geometric mean cost of approximately $8,942 for CPT code 55873 based on 938 single claims (out of 942 total claims), is consistent with the geometric mean cost of about $9,022 for APC 5376. Based on the resource costs, we believe that CPT code 55873 appropriately fits in APC 5376 based on its clinical similarity and resource homogeneity to the codes in the APC.

In summary, after consideration of the public comment, we are finalizing our proposal, without modification, to assign CPT code 55873 to APC 5376 for CY 2024. The final CY 2024 payment rate for the code can be found in Addendum B to this final rule with comment period. In addition, we refer readers to Addendum D1 of this final rule with comment period for the SI meanings for all codes reported under the OPPS. Addenda B and D1 are available via the internet on the CMS website.

21. Drug Induced Sleep Endoscopy Evaluation CPT Code 42975 (APC 5153)

For the CY 2024 OPPS final rule, we proposed that CPT code 42975 (Drug-induced sleep endoscopy, with dynamic evaluation of velum, pharynx, tongue base, and larynx for evaluation of sleep-disordered breathing, flexible, diagnostic) with a geometric mean around $1,291 be assigned to APC 5153 (Level 3 Airway Endoscopy) with a payment rate of around $1,657.

Comment: One commenter supported our decision to assign CPT code 42975 to APC 5153.

Response: We appreciate the support of the commenter.

After consideration of the public comment we received, we are implementing our proposal without modification for CPT code 42975 to continue to assign the procedure to APC 5153 (Level 3 Airway Endoscopy). Table 68 shows the finalized status indicator and APC assignment for all of the procedure codes. We refer readers to Addendum B of this final rule with comment period for the payment rates for all codes reportable under the OPPS. Addendum B is available via the internet on the CMS website.

TABLE 68: FINAL CY 2024 OPPS APC STATUS INDICATOR ASSIGNMENTS FOR CPT CODE 42975

CPT Code	Long Descriptor	Final CY 2024 OPPS SI	Final CY 2024 OPPS APC
42975	Drug-induced sleep endoscopy, with dynamic evaluation of velum, pharynx, tongue base, and larynx for evaluation of sleep-disordered breathing, flexible, diagnostic	J1	5153

22. EchoGo Echocardiography Image Processing Service (APC 5743)

Effective July 1, 2023, based on a New Technology application received by CMS for an echocardiography image processing service, CMS established C9786 (Echocardiography image post processing for computer aided detection of heart failure with preserved ejection fraction, including interpretation and report) and assigned it to APC 5742 (Level 2 Electronic Analysis of Devices). For CY 2024, CMS proposed to continue to assign HCPCS code C9786 to APC 5742.

Comment: One commenter supported the establishment of HCPCS code C9786 to describe the service and believed that the clinical APC group to which we proposed to assign the code for C9786 was appropriate. The commenter recommended that we work with the manufacturer to ensure proper accounting of hospital resources used to furnish the service.

Response: We thank the commenter for their support. We welcome ongoing dialogue and engagement from interested parties, including manufacturers, regarding hospital resource costs and suggestions for payment changes for consideration in future rulemaking.

Comment: We received a comment from the manufacturer requesting that HCPCS code C9786 be reassigned to APC 5743 (Level 3 Imaging without Contrast), which had a proposed payment rate of $277.18. The commenter believes that assigning HCPCS code C9786 to APC 5743 would be more appropriate based on resources involved in furnishing the service. The commenter explained that in addition to a per-service cost, there are a number of other costs incurred by hospitals to furnish the service, including a cardiac sonographer, use of a Picture Archiving and Communication System (PACS) workstation, and IT related costs. The commenter explained that the combined costs incurred by hospitals to furnish C9786 are considerably greater than those for procedures assigned to APC 5742, but are similar to the costs incurred for procedures assigned to APC 5743.

Response: We thank the commenter for their recommendation. Based on our evaluation of the additional information provided and the services assigned to APC 5743, we agree that there are more resource similarities between HCPCS code C9786 and the codes assigned to APC 5743 than to the codes assigned to APC 5742. Therefore, for CY 2024 we are finalizing assigning HCPCS code C9786 to APC 5743.

After consideration of the public comments, we are finalizing the assignment of HCPCS code C9786 to APC 5743. The final CY 2024 payment rate for these codes can be found in Addendum B to this final rule with comment period. We also refer readers to Addendum D1 of this final rule with comment period for the SI meanings for all codes reported under the OPPS. Addenda B and D1 are available via the internet on the CMS website. In addition, we note that CMS recognizes that software-based technologies are rapidly evolving, like the product used for HCPCS code C9786. Consistent with our comment solicitation on payment policy for software as a service (SaaS) procedures in the CY 2023 OPPS final rule (87 FR 72035 and 72036), we are considering, for future rulemaking, whether or not specific adjustments to payment policies and rate calculations are necessary to more accurately and appropriately pay for these products and services across settings of care. CMS remains open to feedback on these issues and welcomes engagement from interested parties, including from manufacturers, providers, and beneficiaries.

23. Endoscopic Procedure—Upper GI Tract CPT Code 43252 (APC 5302)

CPT code 43252 (Esophagogastroduodenoscopy, flexible, transoral; with optical endomicroscopy) describes a service that is used to visualize the upper portions of the GI tract from the esophagus to the duodenum. For the CY 2024 OPPS proposed rule, the geometric mean cost for this procedure was around $1,611, and we proposed to assign CPT code 43252 to APC 5302 (Level 2 Upper GI Procedures) with a payment rate of around $1,854. The payment rate for APC 5302 is approximately $240 more than the geometric mean cost of CPT code 43252.

Comment: Two commenters requested that we assign CPT code 43252 to APC 5303 (Level 3 Upper GI Procedures) with a payment rate of around $3,803 for CY 2024. The procedure is assigned to APC 5303 for CY 2023 APC. Commenters assert that the payment amount for APC 5302 is too low for the procedure described by CPT code 43252. One commenter referenced an independent data analysis showing the number of claims for the service declined from around 340 services in CY 2021 to around 213 services in CY 2022. The commenter had questions about the quality of the CY 2022 data as some providers who had previously performed the procedure described by CPT code 43252 did not perform the procedure in CY 2022.

Response: As we have stated regularly over the history of the OPPS, it is the responsibility of providers and other interested parties and not CMS to resolve potential claims and reporting issues for individual CPT codes and medical services payable by Medicare. There is no clear systematic error with the claims data for CPT code 43252. Also, the geometric mean cost for the service, which is around $1,596, is substantially lower than the payment rate for APC 5302 which is around $1,863. We note as well that in CY 2021, the geometric mean cost for CPT code 43252, which was around $1,985 was roughly $1,350 less than the payment rate for APC 5303, which was around $3,350. Therefore, it is not unexpected that the procedure would be reassigned to a lower-paying APC for CY 2024.

After consideration of the public comments we received, we are implementing our proposal without modification for CPT code 43252 to continue to assign the procedure to APC 5302 (Level 2 Upper GI Procedures). Table 69 shows the finalized status indicator and APC assignment for the procedure code. We refer readers to Addendum B of this final rule with comment period for the payment rates for all codes reportable under the OPPS. Addendum B is available via the internet on the CMS website.

TABLE 69: FINAL CY 2024 OPPS APC STATUS INDICATOR ASSIGNMENTS FOR CPT CODE 43252

CPT Code	Long Descriptor	Final CY 2024 OPPS SI	Final CY 2024 OPPS APC
43252	Esophagogastroduodenoscopy, flexible, transoral; with optical endomicroscopy	J1	5302

24. Endovascular Procedures With Coronary And Peripheral Intravascular Lithotripsy (IVL) (APC 5192, 5193, 5194)

Coronary IVL is a device that, according to its manufacturer, can help surgeons perform a safe and effective angioplasty procedure when arterial plaque is calcified. These procedures also are known as percutaneous coronary intervention (PCI). Coronary IVL received device pass-through status in the OPPS on July 1, 2021, and the device pass-through status is scheduled to expire on June 30, 2024. The device is described by HCPCS code C1761 (Catheter, transluminal intravascular lithotripsy, coronary) and is currently assigned to APC 2033 (Cath, trans intra litho/coro). The procedure also is reported with add-on CPT code 0715T (Percutaneous transluminal coronary lithotripsy (list separately in addition to code for primary procedure)), which is packaged in the OPPS. In CY 2024, CPT code 0715T is being replaced by CPT code 92972 (Percutaneous transluminal coronary lithotripsy (list separately in addition to code for primary procedure)). We propose to package this code as well.

According to the manufacturer, the Coronary IVL device is used primarily with four endovascular procedures:

- C9600 (Percutaneous transcatheter placement of drug eluting intracoronary stent(s), with coronary angioplasty when performed; single major coronary artery or branch);
- 92928 (Percutaneous transcatheter placement of intracoronary stent(s), with coronary angioplasty when performed; single major coronary artery or branch);
- 92943 (Percutaneous transluminal revascularization of chronic total occlusion, coronary artery, coronary artery branch, or coronary artery bypass graft, any combination of intracoronary stent, atherectomy and angioplasty; single vessel); and
- 92920 (Percutaneous transluminal coronary angioplasty; single major coronary artery or branch).

For the OPPS CY 2024 proposed rule, we proposed to assign these procedures to either APC 5192 (Level 2 Endovascular Procedures) or APC 5193 (Level 3 Endovascular Procedures), based on the geometric mean cost of each procedure. Because both APC 5192 and APC 5193 are comprehensive APCs, claims with higher costs for the PCI procedures described are eligible for a complexity adjustment which can provide one higher APC level of payment for these procedures. We also proposed to continue to assign HCPCS code C1761 to APC 2033 until June 30, 2024, when device pass-through status ends for HCPCS code C1761. Starting July 1, 2024, HCPCS code C1761 is proposed to be packaged with its associated endovascular procedures.

Comment: Three commenters including the manufacturer of the Coronary IVL have requested that we take action to preserve the additional payment for the device described by HCPCS code C1761 that is used for PCI procedures through the end of CY 2024. The commenters suggest that we either use our equitable adjustment authority to extend pass-through status for HCPCS code C1761 through December 31, 2024, or increase the payment for the procedures most frequently used with Coronary IVL starting on July 1, 2024.

Response: We appreciate the commenters' request to ensure consistent payment throughout CY 2024 for PCI procedures (HCPCS code C9600, CPT codes 92928, 92943, and 92920) that are performed using the Coronary IVL device described by HCPCS code C1761. However, only a small share of the PCI procedures are using the Coronary IVL device. Less than 6 percent of the procedures billed with HCPCS code C9600, CPT code 92928, and CPT code 92943 use the device described by HCPCS code C1761. For CPT code 92920, the percentage of procedures using the Coronary IVL device is less than 0.5 percent. The low amount of utilization of the Coronary IVL device with these PCI procedures means that it would not be appropriate to assign these procedures to a higher-paying APC to account for the cost of the device. These code combinations would also not meet the criteria for a complexity adjustment, as discussed in section II.A.2.b of this final rule with comment period. Likewise, we do not see a justification for extending device pass-through status for HCPCS code C1761. Device pass-through did not start for the Coronary IVL device until after the most serious disruptions in medical care occurred with the COVID–19 PHE, and none of the commenters suggested that CMS did not get adequate cost data for the device. In fact, the manufacturer was even willing to have pass-through status end early for HCPCS code C1761 because they felt enough cost data regarding the device had been collected.

After consideration of the public comments we received, we are implementing our proposal without modification for HCPCS codes C1761 and C9600 and CPT codes 92920, 92928, 92943, and 92972. Table 70 shows the finalized status indicator and APC assignment for all of the procedure codes. We refer readers to Addendum B of this final rule with comment period or the payment rates for all codes reportable under the OPPS. Addendum B is available via the internet on the CMS website.

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TABLE 70: FINAL CY 2024 OPPS APC AND STATUS INDICATOR ASSIGNMENTS FOR HCPCS CODES C1761, C9600, AND CPT CODES 92920, 92928, 92943, AND 92972

CPT Code	Long Descriptor	Final CY 2024 OPPS SI Until June 30, 2024	Final CY 2024 OPPS APC Until June 30, 2024	Final CY 2024 OPPS SI On or After July 1, 2024	Final CY 2024 OPPS APC On or After July 1, 2024
C1761	Catheter, transluminal intravascular lithotripsy, coronary	H	2033	N	N/A
C9600	Percutaneous transcatheter placement of drug eluting intracoronary stent(s), with coronary angioplasty when performed; single major coronary artery or branch	J1	5193	J1	5193
92920	Percutaneous transluminal coronary angioplasty; single major coronary artery or branch	J1	5192	J1	5192
92928	Percutaneous transcatheter placement of intracoronary stent(s), with coronary angioplasty when performed; single major coronary artery or branch	J1	5193	J1	5193
92943	Percutaneous transluminal revascularization of chronic total occlusion, coronary artery, coronary artery branch, or coronary artery bypass graft, any combination of intracoronary stent, atherectomy and angioplasty; single vessel	J1	5193	J1	5193
92972	Percutaneous transluminal coronary lithotripsy (List separately in addition to code for primary procedure)	N	N/A	N	N/A

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25. Extracorporeal Shock Wave Lithotripsy CPT Code 50590 (APC 5374)

Extracorporeal shock wave lithotripsy is a procedure used to break up stone in the urinary tract using directed shock wave therapy. Shock waves are generated by a lithotripter which is a machine and capital equipment for the provider. The procedure is described by CPT code 50590 (Lithotripsy, extracorporeal shock wave). For the CY 2024 OPPS proposed rule, CPT code 50590 had a geometric mean of around $3,450, and we proposed to assign the

service to APC 5374 (Level 4 Urology and Related Services).

Comment: The HOP Panel and multiple commenters requested that CPT code 50590 be reassigned to APC 5375 (Level 5 Urology and Related Services) with a payment rate of around $5,016 to account for some of the capital cost of the procedure. The capital costs identified were primarily the purchase and maintenance of the lithotripter which, according to one commenter, cost $600,000 to purchase and another $60,000 a year to maintain. The commenters also stated that the procedure described by CPT code 50590 has clinical and resource similarity with procedures currently assigned to APC 5375.

Response: We disagree with the commenters. Payments for services are for costs for providing individual procedures, but capital costs, depreciation, and other similar costs are largely excluded from our determination of the cost of a procedure. We note that the OPPS is a budget neutral system and, as such, the OPPS does not pay the full hospital cost of services, including for services that require the purchase and maintenance of high-cost capital equipment. We also compared the cost of CPT code 50590 to the cost of procedures currently assigned to APC 5375. While the cost of the procedure described by CPT code 50590 is around the middle of the cost range for APC 5374, it would be one of the lowest cost procedures in APC 5375. The number of procedures for CPT code 50590 would mean it would be a significant procedure in APC 5375, but its cost is around $700 lower than the current lowest-cost significant procedure for that APC. In addition, CPT code 50590 would be overpaid by around $1,500 if it was reassigned to APC 5375. Accordingly, we are continuing to assign CPT code 50590 to APC 5374.

After consideration of the public comments we received, we are implementing our proposal without modification for CPT code 50590 to continue to assign the procedure to APC 5374 (Level 4 Urology and Related Services). Table 71 shows the finalized status indicator and APC assignment for all of the procedure codes. We refer readers to Addendum B of this final rule with comment period for the payment rates for all codes reportable under the OPPS. Addendum B is available via the internet on the CMS website.

TABLE 71: FINAL CY 2024 OPPS APC STATUS INDICATOR ASSIGNMENTS FOR CPT CODE 50590

CPT Code	Long Descriptor	Final CY 2024 OPPS SI	Final CY 2024 OPPS APC
50590	Lithotripsy, extracorporeal shock wave	J1	5374

26. Eye-Movement Analysis Without Spatial Calibration (APC 5734)

The CPT Editorial Panel established CPT code 0615T (Eye-movement analysis without spatial calibration, with interpretation and report), effective July 1, 2020, to describe eye-movement analysis without spatial calibration that involves the use of the EyeBOX system as an aid in the diagnosis of concussion, also known as mild traumatic brain injury (mTBI). The EyeBOX is intended to measure and analyze eye movements as an aid in the diagnosis of concussion within one week of head injury in patients 5 through 67 years of age in conjunction with a standard neurological assessment of concussion. A negative EyeBOX classification may correspond to eye movement that is consistent with a lack of concussion. A positive EyeBOX classification corresponds to eye movement that may be present in both patients with or without a concussion.

For CY 2023, we assigned CPT code 0615T to APC 5734 (Level 4 Minor Procedures) with a payment rate of $116.11. For CY 2024, we proposed to continue to assign the code to APC 5734 with a payment rate of $123.302.

Comment: A device manufacturer disagreed with the proposed APC assignment and requested a revision to APC 5722 (Level 2 Diagnostic Tests and Related Services) with a payment rate of $ 304.35. The device manufacturer indicated that the proposed payment is insufficient since the cost to provide the service is about $250. The commenter noted that the proposed reimbursement of $123.302 does not include the cost of providing the EyeBox service, along with the other services provided on the same day (clinic visit and other services). The device manufacturer suggested reassigning CPT code 0615T to APC 5722 (Level 2 Diagnostic Tests and Related Services) to ensure appropriate payment for the service associated with the EyeBOX test.

Response: For 2024, the OPPS payment rates are based on claims submitted between January 1, 2022, and December 31, 2022, processed through June 30, 2023. Even with the latest claims data for this final rule with comment period, we still have no claims data for CPT code 0615T. We discussed in the CY 2023 OPPS/ASC final rule with comment period that based on the claims used for the CY 2023 OPPS update, we saw no claims associated with this code (87 FR 71858). Thus, this is the second year in which we have no claims data for the code. We believe that EyeBOX may not be utilized by Medicare patients, and this may be the reason we have no claims data for the code. Based on the lack of claims data, we believe that we should maintain the assignment to APC 5734 for CPT code 0615T. Therefore, we are not revising the APC assignment for CY 2024 for CPT code 0615T. We remind the commenter that we review, on an annual basis, the APC assignments for all services and items paid under the OPPS.

In summary, after consideration of the public comment we received, we are finalizing our proposal, without modification, to continue assignment to APC 5734 for CPT code 0615T for CY 2024. We refer readers to Addendum B of this final rule with comment period for the payment rates for all codes reported under the OPPS. In addition, we refer readers to Addendum A of this final rule with comment period for the status indicator meanings for all codes reported under the OPPS. Addenda A and Addendum B are available via the internet on the CMS website.

27. Femoral Popliteal Revascularization Procedure (APC 5192)

For CY 2023, we assigned CPT code 37224 (Revascularization, endovascular, open or percutaneous, femoral, popliteal artery(s), unilateral; with transluminal angioplasty) to APC 5192 (Level 2 Endovascular Procedures), with a payment rate of $5,215.40. For CY 2024, as listed in OPPS Addendum B that was released with the CY 2024 OPPS/ASC proposed rule, we proposed to maintain the assignment to APC 5192 with a payment rate of $5,500.17.

Comment: A commenter requested an APC reassignment for CPT code 37224 from APC 5192 to APC 5193 (Level 3 Endovascular Procedures), with a payment rate of $10,602.57, based on resource cost and clinical comparability to the procedures in the APC 5193.

Response: The CY 2024 OPPS payment rates are based on claims submitted between January 1, 2022, and December 31, 2022, processed through June 30, 2023. We analyzed the claims data for this final rule, and based on our review, we found the geometric mean cost of approximately $8,211 for CPT code 37224 based on 6,690 single claims (out of 6,730 total claims), is consistent with the geometric mean cost of about $5,598 for APC 5192, rather than the geometric mean cost of approximately $10,774 for APC 5193. Based on the claims data, we believe that CPT code 37224 fits more appropriately in APC 5192 rather than in APC 5193 based on resource cost and clinical similarity and to the procedures in APC 5192. We note that 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.

In summary, after consideration of the public comment, we are finalizing our proposal, without modification, to assign CPT code 37224 to APC 5192 for CY 2024. The final CY 2024 payment rate for the code can be found in Addendum B to this final rule with comment period. In addition, we refer readers to Addendum D1 of this final rule with comment period for the SI meanings for all codes reported under the OPPS. Addenda B and D1 are available via the internet on the CMS website.

28. Fluorescence In Situ Hybridization (FISH) Laboratory Service (APC 5672)

For CY 2024, we proposed to reassign CPT code 88366 ((In situ hybridization (eg, FISH), per specimen; each multiplex procedure) from APC 5673 (Level 3 Pathology) to APC 5672 (Level 2 Pathology) with a proposed payment rate of $165.41.

Comment: We received two comments explaining that CMS's proposal to reassign CPT code 88366 to APC 5672 would not capture the resource costs of the service. The commenters stated that, while not reflected in the OPPS claims data, the direct supply and equipment practice expense costs associated with the service reported under CPT code 88366 are nearly $30 higher than the proposed CY 2024 payment rate for APC 5672. The commenters requested that we continue to assign CPT code 88366 to APC 5673, as CMS has in previous years.

Response: We appreciate the commenters' feedback on our proposal. However, we have no reason to believe that the claims data used to calculate the cost for CPT code 88366 does not appropriately reflect the hospitals' cost for providing this service, as asserted by the commenter. The commenter did not provide an explanation as to why the OPPS claims data did not reflect the cost of the service. We examined our claims data for the last several years, given the concern raised by the commenter regarding the accuracy of the claims data. In our review of the claims data for CPT code 88366, we found a steadily moderate volume of claims, and geometric mean costs that have remained stable, and consistently lower than the geometric mean costs for APC 5673 while remaining close to the geometric mean cost for APC 5672. For example, for the CY 2021 and CY 2022 final rules, the single frequency claims for CPT code 88366 were approximately 350 per year and the geometric mean costs for the code were just slightly below the geometric mean cost of APC 5672. Similarly, when we reviewed the claims data for the CY 2024 proposed rule, the claims frequency remained consistent at 348 single frequency claims and the geometric mean cost for CPT code 88366 was $113.14, approximately $50 lower than the geometric mean for APC 5672, which was $167.30. Therefore, based on our review of the available claims data, we believe that assigning CPT code 88366 to APC 5672 would be clinically and resource appropriate.

After consideration of the public comments, we are finalizing our proposal without modification to assign CPT code 88366 to APC 5672 for CY 2024. The final CY 2024 payment rate for the code can be found in Addendum B to this final rule with comment period. We also refer readers to Addendum D1 of this final rule with comment period for the SI meanings for all codes reported under the OPPS. Addenda B and D1 are available via the internet on the CMS website.

29. Fractional Flow Reserve Derived From Computed Tomography (FFRCT)/ HeartFlow (APC 5724)

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 service is indicated 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 patients should undergo further invasive testing (that is, a coronary angiogram).

HeartFlow is currently described by CPT code 0503T (Noninvasive estimated coronary fractional flow reserve (ffr) derived from coronary computed tomography angiography data using computation fluid dynamics physiologic simulation software analysis of functional data to assess the severity of coronary artery disease; analysis of fluid dynamics and simulated maximal coronary hyperemia, and generation of estimated ffr model). On January 1, 2024, CPT code 0503T will be replaced by CPT code 75580 (Noninvasive estimate of coronary fractional flow reserve (FFR) derived from augmentative software analysis of the data set from a coronary computed tomography angiography, with interpretation and report by a physician or other qualified health care professional). HeartFlow is currently assigned to APC 5724 (Level 4 Diagnostic Tests and Related Services), and we have proposed for CY 2024 to continue to assign HeartFlow (CPT code 75580) to APC 5724 with a payment rate of around $1,024.

Comment: One commenter expressed concerns that HeartFlow is underpaid in its current and proposed APC assignment of APC 5724, which the commenter feels may limit access to the procedure.

Response: The geometric mean cost for the HeartFlow procedure in CY 2024 is around $860 which is substantially lower than the payment rate for APC 5724 which is around $1,024. The HeartFlow procedure is receiving a payment that is over $160 the estimated cost of the service, which means most providers are receiving sufficient payment for the service.

Comment: Multiple commenters supported our proposal to continue to assign HeartFlow to APC 5724 for CY 2024.

Response: We appreciate the support of the commenters of our policy.

After consideration of the public comments we received, we are finalizing our proposal without modification. Table 72 shows the finalized status indicator and APC assignment for CPT code 75580 for CY 2024. We refer readers to Addendum B of this final rule with comment period for the payment rates for all codes reportable under the OPPS. Addendum B is available via the internet on the CMS website.

TABLE 72: FINAL CY 2024 OPPS APC AND STATUS INDICATOR ASSIGNMENTS FOR CPT CODE 75580

CPT Code	Long Descriptor	Final CY 2024 OPPS SI	Final CY 2024 OPPS APC
75580	Noninvasive estimate of coronary fractional flow reserve (FFR) derived from augmentative software analysis of the data set from a coronary computed tomography angiography, with interpretation and report by a physician or other qualified health care professional	S	5724

30. Gastric Electrophysiology Mapping with Simultaneously Validated Patient System Profiling (GEMS) Service (APC 5723)

Effective July 1, 2023, based on a New Technology application received by CMS for the GEMS service, CMS established HCPCS code C9787 (Gastric electrophysiology mapping with simultaneous patient symptom profiling) and assigned it to APC 5723 (Level 3 Diagnostic Tests and Related Services). For CY 2024, CMS proposed to continue to assign HCPCS code C9787 to APC 5723 with a proposed payment rate of $512.71 for CY 2024.

Comment: We received several comments, including a comment from the manufacturer, requesting that we reassign HCPCS code C9787 to New Technology APC 1520 (New Technology—Level 20 ($1801–$1900)) with a payment rate of $1,850 given the lack of resource coherence with APC 5723. The commenters provided invoice costs and stated that the proposed APC assignment would be insufficient to cover the cost of furnishing the service and, therefore, may limit patient access. Per the comments received, hospitals would incur a minimum cost of $1,489 for the single-use device and supply costs associated with the Gastric Alimetry System, in addition to capital equipment costs of $10,000 for the Gastric Alimetry Reader as well as other capital costs. Given these costs, one commenter stated that even reassigning HCPCS code C9787 to the highest level in the same APC series as proposed, APC 5724 (Level 4 Diagnostic Tests and Related Services), would be insufficient to cover the costs of the service. While one commenter stated that the closest clinical APC with clinical and resource coherence for the GEMS service is APC 5302 (Level 2 Upper GI Procedures) with a proposed payment rate of $1,833.10 for CY 2024, the commenter still believed that assignment to a New Technology APC would be most appropriate because the service is new and the technology was first cleared by the FDA in June 2022. The commenter further stated that without an assignment to a New Technology APC, there is a significant risk that CMS will never generate the necessary claims data to assign the service to an appropriate clinical APC because hospitals will not offer the service when payment is less than a third of the cost to provide it.

Response: We thank the commenters for their input.

We disagree with the APC assignments recommended by commenters based on the purported costs of the service. Based on our review of the technology used as part of the service, clinical similarity of the service to existing procedures, input from CMS medical advisors, and review of all other information available to us, after further evaluation, we have found close resource and clinical similarities between HCPCS code C9787 and certain procedures currently assigned to APC 5723, including CPT code 0779T (Gastrointestinal myoelectrical activity study, stomach through colon, with interpretation and report). For example, both services are non-invasive diagnostic aids for gastrointestinal disorders that collect electrical signals through adhesive patches. From a resource perspective, we believe the costs associated with CPT code 0779T would be similar to those for HCPCS code C9787 based on similarities between the technologies and invoice prices. While the comments submitted focused on the purported resource costs of HCPCS code C9787, we did not find that the information provided was sufficient to differentiate between the service described by CPT code 0779T and that of HCPCS code C9787, and ultimately demonstrate that an assignment to APC 5723 is inappropriate. Because we believe that HCPCS code C9787 has similar clinical and resource characteristics as CPT code 0779T, we are finalizing our proposal to continue to assign C9787 to APC 5723 for CY 2024.

After consideration of the public comments, we are finalizing our proposal to continue to assign HCPCS code C9787 to APC 5723. The final CY 2024 payment rate for the code can be found in Addendum B to this final rule with comment period. We also refer readers to Addendum D1 of this final rule with comment period for the SI meanings for all codes reported under the OPPS. Addenda B and D1 are available via the internet on the CMS website.

31. High Intensity-Focused Ultrasound (HIFU) of the Prostate (APC 5376)

CPT code 55880 (Ablation of malignant prostate tissue, transrectal, with high intensity-focused ultrasound (hifu), including ultrasound guidance) was effective January 1, 2021. For CY 2023, we assigned the code to APC 5376 (Level 6 Urology and Related Services),

with a payment rate of $8,557.53. For CY 2024, as listed in OPPS Addendum B that was released with the CY 2024 OPPS/ASC proposed rule, we proposed to maintain the assignment to APC 5376 with a payment rate of $8,847.08.

Comment: A commenter requested that we finalize the proposed assignment to APC 5376 for CPT code 55880.

Response: Our analysis of the claims data for this final rule demonstrates that the geometric mean cost for CPT code 55880 is approximately $6,613, which is consistent with APC 5376, whose geometric mean cost ranges between $6,613 and $9,827. We believe the code fits appropriately in APC 5376 based on clinical similarity and resource homogeneity with the procedures in the APC.

In summary, after consideration of the public comment, we are finalizing our proposal without modification to assign CPT code 55880 to APC 5376 for CY 2024. The final CY 2024 payment rate for the code can be found in Addendum B to this final rule with comment period. In addition, we refer readers to Addendum D1 of this final rule with comment period for the SI meanings for all codes reported under the OPPS. Addenda B and D1 are available via the internet on the CMS website.

32. Hospital Outpatient Clinic Visit for Assessment and Management of a Patient (G0463)

In 2014, CMS established HCPCS code G0463 to describe the service associated with a hospital outpatient clinic visit for assessment and management of a patient. In the CY 2014 OPPS/ASC final rule with comment period (78 FR 75042), we stated that the code is applicable for hospital use only representing any clinic visit under the OPPS. We further stated that HCPCS code G0463 replaces evaluation and management (E&M) CPT codes 99201–99205 (new patient) and 99211–99215 (established patient), thereby eliminating the distinction between new and established clinic visits.

Comment: We received two comments requesting CMS revise the definition of HCPCS code G0463 (Hospital Outpatient Clinic Visit for Assessment and Management of a Patient), and issue guidance for the correct use of this code, or alternatively create a new HCPCS code that describes a hospital outpatient department assessment. Both commenters assert that commercial payers are processing institutional claims from hospitals which include HCPCS code G0463 and have implemented billing policies which inappropriately conflate HCPCS code G0463 as a professional Evaluation and Management (E/M) code. The commenters state that the misuse of HCPCS code G0463 does not support orderly, consistent, and standardized hospital outpatient coding and billing for outpatient visits, and it is CMS's responsibility to ensure that the code is used correctly.

Response: HCPCS code G0463 was established for use under Medicare's hospital OPPS. We reiterate that HCPCS code G0463 is used to describe hospital outpatient clinic services, not professional services. As part of the Health Insurance Portability and Accountability Act (HIPAA) code set, third-party payers may use any HCPCS code, including HCPCS codes established by CMS, to implement their policies, however, CMS does not establish third-party payer payment policies. Because the request to modify the descriptor is to implement third-party payer payment policies, we disagree that CMS should be responsible for providing instructions for how the code should be reported on non-Medicare claims. Third-party payers routinely provide coding guidance for how providers should report services and items for payment under their specific policies. If the commenters have concerns with the instructions provided by the third-party payers, we recommend the commenters reach out to the third-party payer that provided the guidance. We note that under the OPPS, HCPCS code G0463 is used to report clinic visits and enable Medicare to pay appropriately for those visits. For more information on the history of HCPCS code G0463, refer to the CY 2014 OPPS/ASC final rule with comment period.

33. Imaging of Retina for Detection or Monitoring of Disease (CPT Code 92229) (APC 5733)

CPT code 92229 (Imaging of retina for detection or monitoring of disease; point-of-care autonomous analysis and report, unilateral or bilateral) is performed to screen patients with diabetes for signs of diabetic retinopathy and other eye diseases. The code was established in January 2021 and assigned to APC 5733 (Level 3 Minor Procedures). The code was assigned to Level 3 Minor Procedures because the service had clinical and resource similarity to long-established CPT code 92227 (Imaging of retina for detection or monitoring of disease; with remote clinical staff review and report, unilateral or bilateral) which also is assigned to Level 3 Minor Procedures.

In CY 2022, there were 174 claims for CPT code 92229 and the geometric mean for the service was $34.53. The cost of the procedure was substantially closer to the payment rate for APC 5732 (Level 2 Minor Procedures) with a payment rate of $34.53 than to the payment rate for APC 5733 of $58.79. Based on these data, we proposed assigning CPT code 92229 to APC 5732 for CY 2024.

Comment: Multiple commenters requested that we continue to assign CPT code 92229 to APC 5733 for CY 2024. The commenters asserted that there had not been enough claims data to accurately determine the cost of the procedure. Also, the commenters noted that the procedure described by CPT code 92229 had clinical and resource similarities to other procedures that had been assigned to either Level 3 Minor Procedures (APC 5733) or Level 4 Minor Procedures (APC 5734). Finally, the commenters also expressed concerns that assigning CPT code 92229 to APC 5732 would reduce access to retinal screenings for people with diabetes or at risk for eye diseases, especially for patients who are either poor or members of minority populations.

Response: We note that CMS recognizes that software-based technologies are rapidly evolving, like the procedure described by CPT code 92229. In line with our comment solicitation on payment policy for software as a service (SaaS) procedures in the CY 2023 OPPS final rule (87 FR 72035 and 72036), CMS is considering, for future rulemaking, whether or not specific adjustments to payment policies and rate calculations are necessary in order to more accurately and appropriately pay for these products and services across settings of care. CMS remains open to feedback on these issues and welcomes engagement from interested parties, including from manufacturers, providers, and beneficiaries. We agree with the commenters that for CPT code 92229 we should wait for more claims data to be available before adjusting the current payment rates for these services.

After consideration of the public comments we received, we are implementing our proposal with modification by maintaining the current assignment for CPT code 92229 in APC 5733 (Level 3 Minor Procedures). Table 73 shows the finalized status indicator and APC assignment for CPT code 92229 for CY 2024. We refer readers to Addendum B of this final rule with comment period for the payment rates for all codes reportable under the OPPS. Addendum B is available via the internet on the CMS website.

TABLE 73: FINAL CY 2024 OPPS APC AND STATUS INDICATOR ASSIGNMENTS FOR CPT CODE 92229

CPT Code	Long Descriptor	Final CY 2024 OPPS SI	Final CY 2024 OPPS APC
92229	Imaging of retina for detection or monitoring of disease; point-of-care autonomous analysis and report, unilateral or bilateral	S	5733

34. Imagio® Breast Imaging Service (APC 5522)

Effective October 1, 2023, based on a New Technology application received by CMS for the Imagio® Breast Imaging System, CMS established HCPCS code C9788 (Opto-acoustic imaging, breast (including axilla when performed), unilateral, with image documentation, analysis and report, obtained with ultrasound examination) and assigned it to APC 5521 (Level 1 Imaging without Contrast). For CY 2024, CMS proposed to continue to assign HCPCS code C9788 to APC 5521. Additionally, the AMA established a new Category III code to describe the same service, which will be effective January 1, 2024. For CY 2024, CMS also proposed to assign CPT placeholder code X183T (Opto-acoustic imaging, breast, unilateral, including axilla when performed, real-time with image documentation, augmentative analysis and report (List separately in addition to code for primary procedure)) to APC 5521, the same APC to which HCPCS code C9788 is assigned. Since the release of the proposed rule, CPT placeholder code X183T has been finalized as CPT code 0857T. We note that because both HCPCS code C9788 and CPT code 0857T describe the same service, effective January 1, 2024, CMS will delete HCPCS code C9788 and only CPT code 0857T will be used to bill for the service. For clarity, we will refer only to CPT code 0857T throughout this discussion regarding the final payment policy for the service for CY 2024.

Comment: We received a comment from the manufacturer stating that the initial assignment to APC 5521 is inappropriately low to cover hospital costs to furnish the service. Based on resource costs, the commenter requested that CMS reassign CPT code 0857T from APC 5521 to APC 5523 (Level 3 Imaging without Contrast) with a proposed CY 2024 payment rate of $236.31. Specifically, the commenter provided a breakdown of the per-use device cost by dividing the price of the capital equipment, the Imagio® Breast Imaging System, by its useful life of 5 years and further dividing it by an estimated total use per year. The commenter noted that the cost breakdown was provided based on figures that had been updated since the time of their New Technology APC application in December 2022. Based on the calculations of the per-use device cost, as well as the procedure costs for equipment, labor, and supply, the commenter stated that the proposed payment rate for APC 5523 was a more appropriate APC assignment for the service.

Response: We thank the commenter for their comment. We note that, in a budget neutral environment, payments may not fully cover hospitals' costs in a particular circumstance, including those for the purchase and maintenance of capital equipment, like that of the Imagio® Breast Imaging System. 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). Therefore, 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 for new services that lack hospital claims data based on realistic Medicare utilization projections for all such services delivered in cost-efficient hospital outpatient settings.

With that said, based on the comment received, including the cost information provided, and further review of the service, we agree that the proposed APC assignment for CPT code 0857T to APC 5521 is not appropriate. However, we also do not believe that Medicare should pay for the entire cost of capital equipment as provided by the manufacturer when hospitals will furnish the service using the same equipment for both Medicare and non-Medicare beneficiaries. Therefore, we believe that an APC assignment to APC 5522 (Level 2 Imaging without Contrast) with a proposed payment rate of $106.04 would be more resource appropriate.

Comment: The commenter requested CMS's feedback on what cost data or cost analysis are accepted by CMS when products are new to the market. Specifically, when there are few claims submitted for a new device, the commenter asked whether CMS would be open to accepting invoices provided by the company or other documentation to ensure an appropriate initial APC assignment rather than having to go through multiple rounds of reassignment requests through multiple rulemaking cycles.

Response: We appreciate the comment. We generally assign new CPT codes to an APC based on input from a variety of sources, including, but not limited to, review of the resource costs and clinical similarity of the service to existing procedures; input from CMS medical advisors; information from interested specialty societies; and review of all other information available to us. We also believe continued engagement with interested parties through notice and comment rulemaking is a fundamental piece of the OPPS and allows for CMS to gather additional information. Regarding invoice pricing, CMS considers invoices provided by commenters or manufacturers, as well as other available cost information when assigning services to clinical APCs. However, invoice pricing is not the only piece of information that we consider, and therefore, we may appropriately assign a service to a clinical APC based on clinical and resource similarities, with a payment rate that nevertheless may not match the initial invoice costs provided exactly.

After consideration of the public comment, we are finalizing the assignment of CPT code 0857T to APC 5522. The final CY 2024 payment rate for the code can be found in Addendum B to this final rule with comment period. We also refer readers to

Addendum D1 of this final rule with comment period for the SI meanings for all codes reported under the OPPS. Addenda B and D1 are available via the internet on the CMS website.

35. InSpace Subacromial Tissue Spacer Procedure (APC 5115)

For 2024, we proposed to continue to assign HCPCS code C9781 Arthroscopy, shoulder, surgical; with implantation of subacromial spacer (*e.g.,* balloon), includes debridement (*e.g.,* limited or extensive), subacromial decompression acromioplasty, and biceps tenodesis when performed) to APC 5115 (Level 5 Musculoskeletal Procedures) with a proposed payment rate of $13,269.40.

Comment: We received several comments that endorsed the proposed APC assignment. Commenters expressed strong support for CMS's proposed increase to the payment rates associated with the InSpace balloon placement procedure described by HCPCS code C9781. They stated that the payment rates ensure that both patients and healthcare providers are able to fully leverage the benefits this technology offers.

Response: We appreciate the commenters' support of our proposal. Based on our review of claims data available for this final rule with comment period, we believe an assignment to APC 5115 for CPT code C9781 is appropriate for CY 2024.

In summary, after consideration of the public comments, we are finalizing our proposal without modification and assigning CPT code C9781 to APC 5115 for CY 2024. The final CY 2024 OPPS payment rate for the code can be found in Addendum B to this final rule with comment period.

36. Integrated Neurostimulation Services for Bladder Dysfunction (APCs 5461 and 5464)

For CY 2024, the CPT Editorial Panel established four new Category III CPT codes, specifically, CPT codes 0816T, 0817T, 0818T and 0819T to describe integrated neurostimulation services for bladder dysfunction, effective January 1, 2024. CPT code 0816T is associated with the eCoin System. Because the final CY 2024 CPT code numbers were not available when we published the proposed rule, the codes were listed as placeholder codes X129T, X130T, X131T and X132T in the OPPS Addendum B of the CY 2024 OPPS/ASC proposed rule.

- 0816T: Open insertion or replacement of integrated neurostimulation system for bladder dysfunction including electrode(s) (*e.g.,* array or leadless), and pulse generator or receiver, including analysis, programming, and imaging guidance, when performed, posterior tibial nerve; subcutaneous
- 0817T: Open insertion or replacement of integrated neurostimulation system for bladder dysfunction including electrode(s) (*e.g.,* array or leadless), and pulse generator or receiver, including analysis, programming, and imaging guidance, when performed, posterior tibial nerve; subfascial
- 0818T: Revision or removal of integrated neurostimulation system for bladder dysfunction, including analysis, programming, and imaging, when performed, posterior tibial nerve; subcutaneous
- 0819T: Revision or removal of integrated neurostimulation system for bladder dysfunction, including analysis, programming, and imaging, when performed, posterior tibial nerve; subfascial

In the 2024 OPPS/ASC proposed rule, we proposed to assign CPT codes 0816T and 0817T to APC 5464 (Level 4 Neurostimulator and Related Procedures) with a proposed payment rate of $21,376.53 based on clinical and resource similarity to CPT code 64590 (Insertion or replacement of peripheral or gastric neurostimulator pulse generator or receiver, direct or inductive coupling). In addition, we proposed to assign CPT codes 0818T and 0819T to APC 5461 (Level 1 Neurostimulator and Related Procedures) with a proposed payment rate of $3,364.67 based on clinical and resource similarity to CPT code 64595 (Revision or removal of peripheral or gastric neurostimulator pulse generator or receiver).

Comment: Most commenters endorsed the assignment of CPT code 0816T to APC 5464. They were appreciative that CMS recognizes through this APC assignment the importance of advancing healthcare options for Medicare beneficiaries and the need for continued accessibility of new technologies, like the eCoin system procedure, into sites of service that best serve the complexities of treating some Medicare beneficiaries. One commenter stated that they believe the decision by CMS appropriately aligns the proposed payment level with the intended purpose and clinical complexity of the eCoin system described by CPT code 0816T. In doing so, the commenter stated, CMS continues to empower appropriate medical decision-making by providers for Medicare beneficiaries that will best align with each patient's unique healthcare needs. Another commenter expressed that they were very pleased with our decision to assign implantable tibial generator codes 0816T and 0817T to Level 4 APC 5464 and revision/removal generator codes 0818T and 0819T to Level 1 APC 5461. This commenter stated that this decision creates resource and clinical parity with CPT code 64590 (Insertion or replacement of peripheral or gastric neurostimulator pulse generator or receiver, direct or inductive coupling) which describes sacral neuromodulation (SNM) generator implant and CPT code 64595 (Revision or removal of peripheral or gastric neurostimulator pulse generator or receiver) which describes revision/removal procedures which have the same Level 4 APC and Level 1 APC categories, respectively. This supports the fact that implantable tibial procedures require similar resources and support as SNM including pre-op time, recovery, fluoroscopy, patient follow-up, monitoring and anesthesia.

Response: We appreciate the commenters' feedback on these new Category III CPT codes. We agree with commenters' recommendations to finalize the proposed APC assignments.

In summary, after reviewing the public comments for the proposal, we are finalizing our proposal without modification to assign CPT codes 0816T and 0817T to APC 5464 and to assign CPT codes 0818T and 0819T to APC 5461. The final CY 2024 payment rates for these codes can be found in Addendum B to this final rule with comment period. In addition, we refer readers to Addendum D1 of this final rule with comment period for the status indicator meanings for all codes reported under the OPPS. Addenda B and D1 are available via the internet on the CMS website.

For additional discussion regarding the commenters' request to increase the device offset of CPT codes 0816T and 0817T refer to section IV.B. of this final rule with comment period.

37. LimFlow TADV Procedure CPT Code 0620T (APC 1578)

The LimFlow TADV procedure which is described by CPT code 0620T (Endovascular venous arterialization, tibial or peroneal vein, 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) is a new endovascular procedure that is used to treat patients with chronic limb-

threatening ischemia. According to the developer, these patients are no longer eligible for conventional endovascular or open bypass surgery to treat their artery blockage, and without this procedure, they are likely to face limb amputation.

According to the developer, the LimFlow TADV procedure received full FDA PMA approval on September 11, 2023. Previously, the procedure could be performed through a Category B IDE study. CPT code 0620T, which describes the LimFlow TADV procedure was established in January of 2021 and was assigned to APC 5194 (Level 4 Endovascular Procedures) with a payment rate of around $17,400, which is the highest-paying APC for endovascular procedures. For the CY 2024 proposed rule, we proposed to continue to assign CPT code 0266T to APC 5194.

Comment: The HOP Panel and two commenters, including the developer of LimFlow TADV procedure, requested that CPT code 0620T be reassigned to a New Technology APC that better reflects the cost of the procedure. Commenters were concerned that if CPT code 0620T continued to be assigned to APC 5194, the low payment for the procedure would discourage providers from performing the procedure and deny access to LimFlow TADV to vulnerable and underserved populations.

Response: We agree with the HOP Panel and commenters that CPT code 0620T should be reassigned to a New Technology APC that better reflect the costs of the procedure. Because there are only 15 claims for the procedure for CY 2021 and CY 2022, the LimFlow TADV procedure is subject to our new technology procedure low-volume policy. An analysis of the median, arithmetic mean, and geometric mean of CPT code 0620T found that the median was $25,801.85, the arithmetic mean was $28,628.62, and the geometric mean was $26,716.31. Based on our policy, we estimate the cost of the LimFlow TADV procedure to be $28,628.62 as the arithmetic mean has the highest value of the three cost statistics. Therefore, we plan to reassign CPT code 0620T to New Technology APC 1578 (New Technology—Level 41 ($25,001–$30,000)) with a payment rate of around $27,500.

After consideration of the public comments we received, we are implementing our proposal with modification for CPT code 0620T as we will update its APC assignment to APC 1578 (New Technology—Level 41 ($25,001–$30,000)). Table 74 shows the finalized status indicator and APC assignment for all of the procedure codes. We refer readers to Addendum B of this final rule with comment period for the payment rates for all codes reportable under the OPPS. Addendum B is available via the internet on the CMS website.

TABLE 74: FINAL CY 2024 OPPS APC STATUS INDICATOR ASSIGNMENTS FOR CPT CODE 0620T

CPT Code	Long Descriptor	Final CY 2024 OPPS SI	Final CY 2024 OPPS APC
0620T	Endovascular venous arterialization, tibial or peroneal vein, 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	S	1578

38. Lixelle Apheresis

Lixelle β2-microglobulin Apheresis Column is indicated for use in the treatment of dialysis-related amyloidosis (DRA), a disease that affects people with end-stage renal disease (ESRD). DRA is a metabolic disorder from the failure of the kidney to filter and remove β2-microglobulin, typically from chronic hemodialysis (typically 5 years or longer). The Lixelle device is used in an apheresis procedure that selectively removes β2-microglobulin from circulating blood and used pursuant to a physician prescription in conjunction with hemodialysis. It is intended to be used at each hemodialysis session (that is, frequency of treatment is expected to be 3 times per week). In March 2015, FDA approved LIXELLE® as a Class III Humanitarian Use Device (HUD) with an approved Humanitarian Device Exemption (HDE). There are currently no specific HCPCS or CPT code that represent the Lixelle service.

Comment: A commenter urged CMS to provide reimbursement for Lixelle to benefit patients with DRA. Another commenter requested separate payment under the Medicare ESRD PPS. This same commenter stated that if separate payment does not apply under the ESRD PPS, the service should be paid separately under the OPPS when furnished in the HOPD facility. Specifically, the commenter requested that CMS provide separate payment under the OPPS, and offered the following options:

(1) establish a new HCPCS C code or G code for the Lixelle apheresis procedure and assign the code to APC 5242 (Level 2 Blood Product Exchange and Related Services); or

(2) pay separately for the apheresis procedure used with the Lixelle device through CPT code 36516 (Therapeutic apheresis with extracorporeal immunoadsorption, selective adsorption or selective filtration and plasma

reinfusion), proposed to be assigned to APC 5243 (Level 3 Blood Product Exchange and Related Services) for CY 2024, and require the use of a modifier or add-on code when the Lixelle apheresis procedure is billed to reduce the payment for the procedure to the payment rate for APC 5242 (Level 2 Blood Product Exchange and Related Services); or

(3) allow separate payment for the dialysis performed as part of Lixelle apheresis procedure through HCPCS code G0257 (Unscheduled or emergency dialysis treatment for an ESRD patient in a hospital outpatient department that is not certified as an ESRD facility), which is assigned to APC 5401 (Dialysis) for CY 2024, and require the use of a modifier or add-on code to provide additional payment beyond that provided for APC 5401

Response: We appreciate the recommendations and will consider them for future rulemaking. We note this complex, ongoing issue is still under consideration and a thorough evaluation is necessary to ensure the appropriate Medicare benefit category and payment for the service.

39. Meibomian Gland Repair (MGR) (APC 5733)

For 2020, the AMA's Editorial Panel established CPT code 0563T (Evacuation of meibomian glands, using heat delivered through wearable, open-eye eyelid treatment devices and manual gland expression, bilateral), effective January 1, 2020, to describe the treatment associated meibomian gland dysfunction (MGD) and dry eye disease (DED). For CY 2023, we assigned the code to APC 5733 (Level 3 Minor Procedures) with a payment rate of $57.48. For CY 2024, we proposed to continue with the assignment to APC 5733 with a payment of $58.13.

Comment: A commenter disagreed with proposed assignment to APC 5733 and stated that the proposed payment for CPT code 0563T does not reflect the time, intensity, clinical resources, and technology required to provide the service. The commenter indicated that the time and resources required to perform the service is significantly greater than the proposed reimbursement for APC 5733. The commenter further stated that based on the clinical complexity of the service, CPT code 0563T would be more appropriately placed in APC 5502 (Level 2 Extraocular, Repair, and Plastic Eye Procedures) with a payment of $991.30, based on its clinical similarity to the procedures in the APC, and urged CMS to revise the assignment to APC 5502.

Response: We reviewed our claims data for this final rule with comment period. We note that the CY 2024 OPPS payment rates are based on claims submitted between January 1, 2022, and December 31, 2022, processed through June 30, 2023. Based on our evaluation of the claims data for this final rule with comment period, we found no claims data for the code. Due to the lack of claims data, we believe that we should continue to assign the code to APC 5733. Once we have adequate claims data, we will review and determine whether a change in the APC assignment is necessary.

In summary, after consideration of the public comment, we are finalizing our proposal without modification, and assigning CPT code 0563T to APC 5733 for CY 2024. As we do every year, we will reevaluate the APC assignment for the code in the next rulemaking cycle. We note that we review, on an annual basis, the APC assignments for all items and services paid under the OPPS. The final CY 2024 OPPS payment rate for all the codes payable under the OPPS can be found in Addendum B to this final rule with comment period. In addition, we refer readers to Addendum D1 of this final rule with comment period for the SI meanings for all codes reported under the OPPS. Addendum D1 is available via the internet on the CMS website.

40. MindMotion® GO Neurorehabilitative Remote Therapy Service (APC 5741)

Effective July 1, 2022, the CPT Editorial Panel created CPT codes 0733T (Remote real-time, motion capture-based neurorehabilitative therapy ordered by a physician or other qualified health care professional; supply and technical support, per 30 days) and 0734T (Remote real-time, motion capture-based neurorehabilitative therapy ordered by a physician or other qualified health care professional; treatment management services by a physician or other qualified healthcare professional, per calendar month) to describe the clinician services associated with patient use of MindMotion® GO, a rehabilitative at home therapy program, remotely monitored by a therapist, for patients who have suffered certain neurological conditions. For CY 2024, CMS proposed to continue to assign CPT code 0733T to APC 5741 (Level 1 Electronic Analysis of Devices) with a proposed payment rate of $36.79. CMS also proposed to continue to assign status indicator ''B'' to CPT code 0734T for CY 2024.

Comment: We received a comment from the manufacturer requesting that we assign CPT code 0733T to a more clinically and resource appropriate APC for CY 2024. The commenter stated that the proposed APC assignment to APC 5741 for CPT code 0733T was not resource appropriate because it did not cover the cost of several items and capital equipment, including a mini-PC to run the treatment software, 3D motion-tracking camera to track patient movement, camera to enable certain hand rehabilitative exercises, and a pressure-sensitive peripheral to measure hand grip for different hand rehab exercises. The commenter did not provide invoice costs or estimated costs for these components. Additionally, the commenter stated that they believed APC 5741 is not clinically appropriate for CPT code 0733T because the APC contains several monitoring services, and, per the commenter, CPT code 0733T performs remote monitoring subsequent to its ability to provide treatment. Finally, the commenter pointed to CPT code 0693T (Comprehensive full body computer-based markerless 3D kinematic and kinetic motion analysis and report), which describes the service involving the DARI Motion Procedure and has a proposed APC assignment to New Technology APC 1505 (New Technology—Level 5 ($301–$400)) for CY 2024, as a clinically similar service.

Response: We thank the commenter for their input regarding the proposed CY 2024 APC assignment for CPT 0733T. First, because the code was first made effective on July 1, 2022, and is relatively new, we do not have any claims data at this time. However, we note that as is our policy for new codes for which we lack pricing information, we assign the service to an existing APC based on input from a variety of sources, including, but not limited to, review of the clinical similarity of the service to existing procedures, input from CMS medical advisors, and review of all other information available to us. Based on our understanding of the service and input from our medical advisors, we do not agree that CPT code 0733T is dissimilar to other services in APC 5741 such that it should be assigned to a different APC. We believe that CPT code 0733T is more similar to services in APC 5741 than services in other APCs, including CPT code 0693T, which is currently assigned to New Technology APC. We note that the long descriptor for CPT code 0733T describes a remote service similar to other codes with remote components in APC 5741, including CPT code 98976. Based on the

nature of the procedure and the information available to us, we continue to believe that CPT code 0733T is appropriate for assignment to APC 5741 for CY 2024.

Comment: The manufacturer also commented to support the reassignment of the status indicator for CPT code 0734T from status indicator ''B'' to status indicator ''S,'' based on a public presentation at the Advisory Panel on Outpatient Payment (HOP Panel) on August 22, 2023, recommending that the status indicator assignment of CPT code 0734T and other remote monitoring codes change from ''B'' to ''S'' and be assigned to APC 5741.

Response: We first note that CMS did not propose to change the status indicator of CPT code 0734T from ''B'' to ''S'' for CY 2024. CPT code 0734T describes a professional service, specifically treatment management services by a physician or other qualified healthcare professional. Therefore, CPT code 0734T is not payable under the OPPS and would not be appropriate for separate payment as indicated by status indicator ''S.'' For CY 2024, we believe it is appropriate to finalize the status indicator for CPT 0734T as proposed.

After consideration of the public comment, we are finalizing our proposal to continue to assign CPT code 0733T to APC 5741 as proposed. We are also finalizing our proposal to continue to assign status indicator ''B'' to CPT code 0734T. The final CY 2024 payment rate for CPT code 0733T can be found in Addendum B to this final rule with comment period. We also refer readers to Addendum D1 of this final rule with comment period for the SI meanings for all codes reported under the OPPS. Addenda B and D1 are available via the internet on the CMS website.

41. Minimally Invasive Glaucoma Surgery (MIGS) (APC 5493)

CPT code 0671T (Insertion of anterior segment aqueous drainage device into the trabecular meshwork, without external reservoir, and without concomitant cataract removal, one or more) was effective January 1, 2022. For CY 2023, we assigned CPT code 0671T to APC 5491 (Level 1 Intraocular Procedures) with a payment rate of $2,159.44. For CY 2024, as listed in OPPS Addendum B that was released with the CY 2024 OPPS/ASC proposed rule, we proposed to reassign the code to APC 5492 (Level 2 Intraocular Procedures), with a payment rate of $3,970.62. We received some comments related to the proposal.

Comment: Several commenters agreed with our proposal and requested that we finalize the assignment to APC 5492. However, other commenters disagreed with the assignment to APC 5492, and instead suggested assignment to APC 5493 (Level 3 Intraocular Procedures), with a payment rate of $5,110.58. These commenters reported that CPT code 0671T is one of three MIG codes that the CPT Editorial Panel established effective January 1, 2022, and noted that the other two MIG codes (66989 and 66991) are proposed for assignment to APC 5493. Because of its similarity to CPT codes 66989 and 66991, the commenters suggested reassignment to APC 5493 for CPT code 0671T.

Response: We reviewed our claims data for this final rule with comment period. The CY 2024 OPPS payment rates are based on claims submitted between January 1, 2022, and December 31, 2022, processed through June 30, 2023. We note that CY 2024 is the first year that we have claims data for the code. Based on our analysis of the claims data for this final rule, the resource costs related to CPT code 0671T seems more appropriately in APC 5493 rather than APC 5492. Specifically, our claims data shows a geometric mean cost of about $5,610 for CPT code 0671T based on 79 single claims (out of 79 total claims), which is consistent with the geometric mean cost of approximately $5,118 for APC 5493, rather than the geometric mean cost of approximately $3,982 for APC 5492. Based on the resource costs to furnish the service associated with CPT code 0671T, which are consistent with APC 5493, we believe that reassignment to APC 5493 is appropriate. Therefore, we are revising the assignment for CPT code 0671T, to APC 5493 for CY 2024.

With regard to the other two MIG codes mentioned by the commenter, specifically, CPT codes 66989 and 66991, refer to section III.C. of this final rule with comment period for the discussion related to the payment for the codes.

In summary, after consideration of the public comments, we are finalizing the APC assignment for CPT code 0671T with modification. Specifically, we are revising the APC assignment for CPT code 0671T to APC 5493 for CY 2024. The final CY 2024 OPPS payment rate for this code can be found in Addendum B to this final rule with comment period. In addition, we refer readers to Addendum D1 of this final rule with comment period for the SI meanings for all codes reported under the OPPS. Addendum D1 is available via the internet on the CMS website.

42. 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 to utilize prospective payment packages, we consolidated these individual APCs so that they became a general Musculoskeletal APC series (80 FR 70397 and 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 requested changes 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 and 58921).

For CY 2024, based on the claims data available for the CY 2024 OPPS/ASC proposed rule, we continued to believe that the six-level APC structure for the Musculoskeletal Procedures APC series is appropriate and we proposed to maintain it for the CY 2024 OPPS update.

Comment: One commenter requested that CMS reassign CPT code 23472 (Arthroplasty, glenohumeral joint; total shoulder) from APC 5115to APC 5116 (Level 6 Musculoskeletal Procedures). According to the commenter, the requested assignment would more closely track hospital resources used in performing these procedures and appropriately align with other clinically similar procedures. The commenter stated that with regard to cost, according

to CMS's 2 Times Listing document released with the proposed rule, the geometric mean cost (GMC) of claims reporting total shoulder CPT 23472 is $17,423.52, which represents the highest cost ''significant'' procedure within APC 5115. In fact, the GMC of CPT code 23472 exceeds the GMC of four ''significant'' procedures that CMS proposes to assign to APC 5116:

- CPT 22867 (Insertion of interlaminar/interspinous process stabilization/distraction device, without fusion, including image guidance when performed, with open decompression, lumbar; single level)—GMC of $14,803.74
- CPT 27279 (Arthrodesis, sacroiliac joint, percutaneous or minimally invasive (indirect visualization), with image guidance, includes obtaining bone graft when performed, and placement of transfixing device)—GMC of $15,788.69
- CPT 22856 (Total disc arthroplasty (artificial disc), anterior approach, including discectomy with end plate preparation (includes osteophytectomy for nerve root or spinal cord decompression and microdissection); single interspace, cervical)—GMC of $16,078.32
- CPT 22612 (Arthrodesis, posterior or posterolateral technique, single interspace; lumbar (with lateral transverse technique, when performed))—GMC of $16,870.82

This commenter stated that the GMC of CPT code 23472 is about $500.00 closer to the GMC of APC 5116 ($20,928.08) than APC 5115 ($13,420.64), reinforcing that APC 5116 is a more appropriate assignment for CPT 23472 and furthermore, this payment misalignment—resulting in a $4,000 opportunity cost to hospitals performing this procedure on average—threatens the availability of this procedure on an outpatient basis.

The commenter also provided clinical information, stating that shoulder replacement and reverse shoulder replacement procedures represented by CPT code 23472 are very complex, involving three bones and limited access space due to the muscles, ligaments, and tendons surrounding the joint. These procedures are clinically comparable to other procedures assigned to APC 5116, such as total elbow arthroplasty (TEA) CPT code 24363. TEA and TSA procedures involve similar complexity and are typically performed by specialized, fellowship- or subspecialty-trained shoulder and elbow orthopaedic surgeons.

Response: We appreciate the commenter's recommendation. Based on our analysis of the latest CY 2022 claims data available for CY 2024 OPPS ratesetting, the geometric mean cost associated with CPT code 23472 is $17,370.78 based on 51,120 single claims (out of 51,506 total claims), which is consistent with the geometric mean cost of $18,250.77 for APC 5116. We also note that the APC 5115 has a range of HCPCS geometric mean costs for cost significant codes from $10,641.75 to $16,292.97with the geometric mean cost of CPT code 23472 being at the higher end of the cost range. The geometric mean cost for APC 5115 is $12,889.60.

Based on the data, we believe that APC 5116 is the more appropriate assignment rather than APC 5115 for CPT code 23472. Therefore, we agree with the commenter and are reassigning CPT code 23472 from APC 5115 to APC 5116 for CY 2024. The final CY 2024 OPPS payment rates for the codes can be found in Addendum B to this final rule with comment period.

After consideration of the public comments, we are finalizing our proposal to maintain the six-level Musculoskeletal Procedures APC structure. We are also finalizing an assignment of CPT code 23472 to APC 5116, rather than APC 5115, for the CY 2024 OPPS.

43. Noncontact Near-infrared (NIR) Spectroscopy (APC 5732)

In July 2021, the AMA's CPT Editorial Panel established three new codes to describe the service related to noncontact near-infrared spectroscopy. For CY 2024, the CPT Editorial Panel made several changes to the codes to accurately describe the services currently performed in the medical setting for noncontact near-infrared spectroscopy. Specifically, the CPT Editorial Panel took the following actions for CY 2024:

- deleted CPT code 0641T and 0642T, effective December 31, 2023;
- revised the descriptor for existing CPT code 0640T to include the services previously described in CPT codes 0641T and 0642T; and
- established two new codes, specifically, CPT code 0859T, which was listed as placeholder code X1914T in the CY 2024 OPPS/ASC proposed rule, and CPT code 0860T, which was listed as placeholder code X171T, effective January 1, 2024.

The complete long descriptors for the codes are listed below in Table 75, along with the CY 2023 and proposed CY 2024 OPPS status indicator and APC assignments (where applicable).

TABLE 75: CY 2023 AND PROPOSED CY 2024 OPPS SI AND APC FOR THE NIR SPECTROSCOPY CPT CODES 0640T – 0642T, AND CPT CODES 0859T-0860T

CPT Code	Place-holder Code	Long Descriptor	CY 2023 OPPS SI	CY 2023 OPPS APC	Proposed 2024 OPPS SI	Proposed 2024 OPPS APC
0640T		Noncontact near-infrared spectroscopy (eg, for measurement of deoxyhemoglobin, oxyhemoglobin, and ratio of tissue oxygenation), other than for screening for peripheral arterial disease, image acquisition, interpretation, and report; first anatomic site	M		T	5732
0859T	X194T	Noncontact near-infrared spectroscopy (eg, for measurement of deoxyhemoglobin, oxyhemoglobin, and ratio of tissue oxygenation), other than for screening for peripheral arterial disease, image acquisition, interpretation, and report; each additional anatomic site (List separately in addition to code for primary procedure)			N	
0641T		Noncontact near-infrared spectroscopy studies of flap or wound (eg, for measurement of deoxyhemoglobin, oxyhemoglobin, and ratio of tissue oxygenation [StO_2]); image acquisition only, each flap or wound	T	5732	D	
0642T		Noncontact near-infrared spectroscopy studies of flap or wound (eg, for measurement of deoxyhemoglobin, oxyhemoglobin, and ratio of tissue oxygenation [StO_2]); interpretation and report only, each flap or wound	M		D	
0860T	X171T	Noncontact near-infrared spectroscopy (eg, for measurement of deoxyhemoglobin, oxyhemoglobin, and ratio of tissue oxygenation), for screening for peripheral arterial disease, including provocative maneuvers, image acquisition, interpretation, and report, one or both lower extremities			E1	

Based on the code changes, we proposed to take the following actions for CY 2024:

- CPT code 0640T: With the revised descriptor to include the descriptions that were listed in CPT codes 0641T and 0642T, we proposed to revise the status indicator for CPT code 0640T from ''M'' (professional-only service) to ''T'' and assigned the code to APC 5732 (Level 2 Minor Procedures), with a payment $ 37.05. Under the OPPS, the predecessor code for CPT code 0640T is CPT code 0641T.
- CPT code 0641T: We proposed to assign the code to status indicator ''D'' to indicate that the code would be deleted at the end of the year, and crosswalked the separate payment status indicator of ''T'' and assignment of APC 5732 to CPT code 0640T.

• CPT code 0642T: We proposed to assign the code to status indicator ''D'' to indicate that the code would be deleted at the end of the year. Because the code was assigned to status indicator ''M'' (professional-only service), we did not crosswalk this code to any payable indicators or APC.

• CPT code 0859T: Because the code describes an add-on service to CPT code 0640T, and must always be reported on the same day with CPT code 0640T, we proposed to assign the code to status indicator ''N'' to indicate that the code is packaged and payment is included in the primary service. Under the OPPS, most add-on codes are packaged, as specified in 42 CFR 419.2(b)(18).

• CPT code 0860T: We proposed to assign this code to status indicator ''E1'' to indicate that the code is not covered or payable by Medicare for CY 2024.

We received several comments related to our proposals. Below are the comments and our responses.

Comment: Many commenters requested separate payment for CPT code 0860T and indicated that Medicare beneficiaries would benefit from essential screening for peripheral arterial disease (PAD). Some commenters clarified that one-third of patients over age 65 with diabetes or a history of smoking have PAD, and with the increased risk of death and other cardiovascular complications, including heart attack and stroke, the commenters believe that it is essential to diagnose and treat PAD as early as possible. The commenters urged CMS to make available PAD screening options to the Medicare population and requested separate payment for the service.

Response: CPT code 0860T describes a screening for peripheral arterial disease (PAD). Currently, Medicare has not established coverage for screening for PAD. Specifically, this screening code does not qualify for Medicare coverage since there is no national coverage determination (NCD) for PAD screening. Consequently, we proposed to assign the code to status indicator ''E1'' to indicate that the code is not payable by Medicare when submitted on outpatient claims (any outpatient bill type) because the service associated with the code is either not covered by any Medicare outpatient benefit category, statutorily excluded by Medicare, or not reasonable and necessary.

We note that on August 7, 2013, CMS published a **Federal Register** notice (78 FR 48164 through 48169), updating the process used for opening, deciding or reconsidering national coverage determinations (NCDs). If the commenter would like to request Medicare coverage for PAD screening, we strongly recommend submitting an application to CMS. New screening and preventive tests coverage are added through the National Coverage Determination (NCD) process. Information on the Medicare coverage determination process, the application process, as well how to request a new NCD, or revision to an existing NCD, can be found on the CMS website, specifically, at *https://www.cms.gov/medicare/coverage/determination-process/request.*

Comment: Several commenters requested separate payment for CPT code 0640T, and suggested reassignment to status indicator ''S'' (Procedure or Service, Not Discounted When Multiple. Paid under OPPS; separate APC payment.), and APC 5722 (Level 2 Diagnostic Tests; proposed payment of $304.35). The commenters reported that the NIR technology described by CPT code 0640T is similar to the technology described with CPT code 0598T, which is assigned to status indicator ''S'' and APC 5722. Specifically, CPT code 0598T describes a hand-held device that detects bacteria in a wound through fluorescence color, while CPT code 0640T and CPT code 0859T describes a hand-held device that detect a wound's blood oxygen level at the point of care. Because of its similarity to CPT code 0598T, the commenters recommended reassignment to APC 5722 for CPT code 0640T.

Response: Prior to the descriptor revision for CPT code 0640T, the technical service associated with noncontact near-infrared spectroscopy was described by CPT code 0641T, which was assigned to APC 5732 for CY 2023. Under the OPPS, the predecessor code for CPT code 0640T is CPT code 0641T. We note that the CY 2024 OPPS payment rates are based on claims submitted between January 1, 2022, and December 31, 2022, processed through June 30, 2023. Based on our analysis of the claims data for this final rule with comment period, we found a geometric mean cost of about $14 for predecessor CPT code 0641T based on 46 single claims (out of 266 total claims). In contrast, we found a geometric mean cost of approximately $239 for CPT code 0598T based on 529 single claims (out of 1,317 total claims). Based on the data, the resource cost associated with noncontact real-time fluorescence imaging (CPT code 0598T), is significantly higher compared to noncontact near-infrared (NIR) spectroscopy (CPT code 0640T/0641T). While both technologies may have the same indication, we disagree that the resource cost for noncontact near-infrared (NIR) spectroscopy is similar to noncontact real-time fluorescence imaging. Therefore, we do not agree that both technologies should be placed in the same APC. We believe that the code describing noncontact near-infrared (NIR) spectroscopy, specifically, CPT code 0640T, is appropriately placed in APC 5732.

Comment: Many commenters requested separate payment for CPT code 0859T, and suggested assignment to status indicator ''S'' and APC 5722.

Response: Under the OPPS, CPT code 0859T is assigned to status indicator ''N'' to indicate that the payment is packaged in the primary code. The phrase ''list separately in addition to code for primary procedure'' is included in the long descriptor for CPT code 0859T to indicate that that the code is considered an ''add-on'' to another primary code and cannot be reported independently. Add-on codes must always be reported with another primary code on the same day. The AMA states in the CPT 2024 Professional Edition (page xviii) that ''add-on codes are always performed in addition to the primary service or procedure and must never be reported as a stand-alone code.'' In most cases, add-on codes are typically ancillary and supportive to a primary diagnostic or therapeutic modality and are an integral part of the primary service they support. As specified under regulation 42 CFR 419.2(b)(18), add-on codes are packaged under the OPPS, and payment for the codes are bundled with the primary codes. Consequently, CPT code 0859T is not paid separately under the OPPS, but instead, the payment is packaged into the primary code. In this instance, the primary code for CPT code 0859T is CPT code 0640T.

In summary, after consideration of the public comments, we are finalizing the status indicators and APC assignment, without modification, for CPT codes 0640T, 0641T, 0642T, 0859T, and 0860T. Table 76 below list the final CY 2024 OPPS SI and APC assignment for the codes. As we do every year, we will reevaluate the APC assignment for the codes in the next rulemaking cycle. We note that we review, on an annual basis, the APC assignments for all items and services paid under the OPPS. The final CY 2024 OPPS payment rate for all the codes payable under the OPPS can be found in Addendum B to this final rule with comment period. In addition, we refer readers to Addendum D1 of this final rule with comment period for the SI meanings for all codes reported under the OPPS. Addendum D1 is available via the internet on the CMS website.

TABLE 76: FINAL CY 2024 OPPS SI AND APC FOR THE NIR SPECTROSCOPY CPT CODES 0640T-0642T, AND CPT CODES 0859T-0860T

CPT Code	Long Descriptor	Final CY 2024 OPPS SI	Final CY 2024 OPPS APC
0640T	Noncontact near-infrared spectroscopy (eg, for measurement of deoxyhemoglobin, oxyhemoglobin, and ratio of tissue oxygenation), other than for screening for peripheral arterial disease, image acquisition, interpretation, and report; first anatomic site	T	5732
0859T	Noncontact near-infrared spectroscopy (eg, for measurement of deoxyhemoglobin, oxyhemoglobin, and ratio of tissue oxygenation), other than for screening for peripheral arterial disease, image acquisition, interpretation, and report; each additional anatomic site (List separately in addition to code for primary procedure)	N	
0641T	Noncontact near-infrared spectroscopy studies of flap or wound (eg, for measurement of deoxyhemoglobin, oxyhemoglobin, and ratio of tissue oxygenation [StO_2]); image acquisition only, each flap or wound	D	
0642T	Noncontact near-infrared spectroscopy studies of flap or wound (eg, for measurement of deoxyhemoglobin, oxyhemoglobin, and ratio of tissue oxygenation [StO_2]); interpretation and report only, each flap or wound	D	
0860T	Noncontact near-infrared spectroscopy (eg, for measurement of deoxyhemoglobin, oxyhemoglobin, and ratio of tissue oxygenation), for screening for peripheral arterial disease, including provocative maneuvers, image acquisition, interpretation, and report, one or both lower extremities	E1	

44. Optilume Benign Prostatic Hyperplasia (BPH) Procedure (APC 5376)

On February 5, 2020, CMS approved for Medicare coverage the Category B Investigational Device Exemption (IDE) study associated with Urotronic's BPH Catheter System (Study Title: A Clinical Study to Evaluate the Safety and Efficacy of the Optilume™ BPH Catheter System in Men With Symptomatic BPH (PINNACLE); NCT number NCT04131907; IDE number G190217). In July 2020, AMA's CPT Editorial Panel established CPT code 0619T (Cystourethroscopy with transurethral anterior prostate commissurotomy and drug delivery, including transrectal ultrasound and fluoroscopy, when performed), effective July 1, 2020, to describe the surgery related to the BPH Catheter System.

For 2023, we assigned CPT code 0619T to APC 5375 (Level 5 Urology and Related Procedures) with a payment rate of $4,702.18. For 2024, as listed in OPPS Addendum B that was released with the CY 2024 OPPS/ASC proposed rule, we proposed to maintain the assignment to APC 5375 with a payment of $4,959.89.

Comment: A commenter made some requests related to CPT code 0619T. First, the commenter explained that the surgery associated with the code involves a $5,700 Optilume BPH Catheter System Kit that contains two balloon catheters, one that is drug-coated, and another that is non-drug coated. The commenter indicated that the estimate for the total surgery cost, which includes the cost of the device, is approximately $12,109. Based on their estimate for the total surgery cost, the commenter requested a reassignment from APC 5375 to APC 5377 (Level 7 Urology and Related Procedures, proposed payment of $12,568.91), which would include the cost of both the procedure and the device kit. Secondly, as an alternative, if CMS is unable to reassign the code to APC 5377, the commenter requested the approval of their New Technology Procedure/Service application, and the establishment of a new HCPCS C-code to describe the procedure whose payment is assigned to New Technology APC 1575 with a payment of $12,500.50. In addition, the commenter clarified that the 2 claims for CPT code 0619T do not apply to the Optilume BPH procedure since the device received FDA Premarket Approval (PMA) just recently in June 2023.

Response: First, with regards to the New Technology APC application submitted to CMS, in general, New Technology APC application determinations are not made via rulemaking. We note that in this specific case, the application is pending review and still under consideration. Therefore, we are unable to respond to the APC request for the New Technology APC application in this final rule with comment period.

Secondly, we note that the CY 2024 OPPS payment rates are based on claims

submitted between January 1, 2022, and December 31, 2022, processed through June 30, 2023. We reviewed the claims data for this final rule, and based on our review, we found the geometric mean cost of approximately $6,218 for CPT code 0619T based on 3 single claims (out of 3 total claims). Although one commenter suggested that the 2 claims we have for the CY 2024 ratesetting are not valid because the device received FDA PMA approval in June 2023 and could not represent the Optilume BPH device, we note that Medicare approved coverage of the Category B IDE study that involves the use of this device in February 2020. Although the Optilume BPH device received FDA approval in June 2023, because the Category B IDE study was approved much earlier in February 2020, HOPD facilities may have reported the device on Medicare claims by using an unlisted device code (for example, C1889) or device revenue code (for example, 027X).

Based on the comments received, evaluation of the procedure, and our assessment of the request, we believe that CPT code 0619T is most similar to CPT code 0421T (Transurethral waterjet ablation of prostate, including control of post-operative bleeding, including ultrasound guidance, complete (vasectomy, meatotomy, cystourethroscopy, urethral calibration and/or dilation, and internal urethrotomy are included when performed)), which is assigned to APC 5376 with a proposed payment rate of $8,847.08. We note that APC 5376 contains several BPH-related procedures, which include the following:

- 0421T: Transurethral waterjet ablation of prostate, including control of post-operative bleeding, including ultrasound guidance, complete (vasectomy, meatotomy, cystourethroscopy, urethral calibration and/or dilation, and internal urethrotomy are included when performed)
- 55873: Cryosurgical ablation of the prostate (includes ultrasonic guidance and monitoring
- 55880: Ablation of malignant prostate tissue, transrectal, with high intensity-focused ultrasound (hifu), including ultrasound guidance), and
- C9740: Cystourethroscopy, with insertion of transprostatic implant; 4 or more implants

Based on the similarity to CPT code 0421T and the other BPH-related procedures in APC 5376, we believe that assigning CPT code 0619T to APC 5376 is the best approach at this time. We reiterate that we review our claims data on an annual basis to establish the OPPS payment rates. Once we have data, we will evaluate and, if necessary, reassign the code to an appropriate APC based on the latest claims data.

Finally, we remind the commenter that 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 market basket increase reduced by the productivity adjustment. 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. For new procedures and items, we get many requests from manufacturers to increase the reimbursement for the code associated with their procedures and items. 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. On balance, 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).

In summary, after consideration of the public comment that we received, we are finalizing our proposal, with modification. Specifically, we are finalizing our proposal and assigning CPT code 0619T to APC 5376 for CY 2024. The final payment rate for the code can be found in Addendum B to this final rule with comment period. In addition, we refer readers to Addendum D1 of this final rule with comment period for the status indicator (SI) meanings for all codes reported under the OPPS. Addenda B and D1 are available via the internet on the CMS website.

45. Optilume Urethral Stricture Procedure (APC 5375)

Effective January 1, 2018, the AMA's CPT Editorial Panel established Category III CPT code 0499T (Cystourethroscopy, with mechanical dilation and urethral therapeutic drug delivery for urethral stricture or stenosis, including fluoroscopy, when performed) to describe the procedure related to the Optilume Urethral Stricture Device System. For 2024, AMA is deleting the Category III CPT code on December 31, 2023, and replacing it with a Category I CPT code, specifically, CPT code 52284 (Cystourethroscopy, with mechanical urethral dilation and urethral therapeutic drug delivery by drug-coated balloon catheter for urethral stricture or stenosis, male, including fluoroscopy, when performed), effective January 1, 2024. We note that CPT code 52284 was listed as placeholder code 5X000 in OPPS Addendum B and Addendum O that was released with the CY 2024 OPPS/ASC proposed rule with comment period. Because we had not received the final CPT code numbers from AMA for the new codes that would be effective January 1, 2024, in time for the publication of the proposed rule, we listed the new CPT codes with their respective placeholder codes in OPPS Addendum B and Addendum O.

For CY 2023, we assigned CPT code 0499T to APC 5374 (Level 4 Urology and Related Services) with a payment rate of $4,702.18. Because CPT code 0499T was scheduled for deletion on December 31, 2023, and replaced with CPT code 52284 effective January 1, 2024, we proposed some changes to the codes for CY 2024. Specifically, for CY 2024, as listed in the OPPS Addendum B that was released with the CY 2024 OPPS/ASC proposed rule, we proposed to:

- Assign CPT code 0499T to status indicator ''D'' to indicate that the code would be deleted at the end of the year; and
- Crosswalk the replacement code, specifically, CPT 52284, to APC 5374 with a payment rate of $3,337.81

We note that at the August 21, 2023, HOP Panel Meeting, a presentation was made requesting the reassignment to APC 5375 for CPT code 52284 (placeholder code 5X000). Based on the information presented at the meeting, the Panel made no recommendation on the APC assignment for the code.

Comment: Several commenters requested the reassignment for CPT code 52284 from APC 5374 to APC 5375 (Level 5 Urology and Related Services), with a payment rate of $4,959.89. They indicated that the procedure involves

the use of a single-use device whose cost is $2,395, and they believe that the payment amount of approximately $3,338 for APC 5374 is insufficient to cover the total cost of the procedure. These commenters suggested the reassignment of CPT code 52284 to APC 5375. One commenter clarified that the Optilume Urethral Stricture device was commercially available in January 2022, however, prior to this date, the device was provided free of charge for clinical trials. This same commenter noted that the claims data in the CY 2024 OPPS/ASC proposed rule shows an increase in claims volume for predecessor CPT code 0499T, as well as an increase in the geometric mean cost, that they believe warrants a change in the assignment from APC 5374 to APC 5375.

Response: The CY 2024 OPPS payment rates are based on claims submitted between January 1, 2022, and December 31, 2022, processed through June 30, 2023. We reviewed the claims data for this final rule, and based on our analysis, we found the geometric mean cost of approximately $4,489 for (predecessor code) CPT 0499T based on 77 single claims (out of 79 total claims), which is consistent with the geometric mean cost of about $5,067 for APC 5375, rather than the geometric mean cost of approximately $3,414 for APC 5374. Based on our evaluation, we believe that the resource costs of furnishing the service associated with CPT code 52284 are higher than the resource costs associated with APC 5374. Consequently, we believe that CPT code 52284 fits accurately in APC 5375 based on its clinical and resource homogeneity to the procedures in the APC.

In summary, after consideration of the public comments, we are finalizing the APC assignment for CPT code 52284 with modification. Specifically, we are revising the APC assignment for CPT code 52284 to APC 5375 for CY 2024. The final CY 2024 OPPS payment rate for this code can be found in Addendum B to this final rule with comment period. In addition, we refer readers to Addendum D1 of this final rule with comment period for the SI meanings for all codes reported under the OPPS. Addendum D1 is available via the internet on the CMS website.

46. Payment for Procedures Using an Amniotic Membrane (APCs 5502 and 5503)

CPT code 65426 (Excision or transposition of pterygium; with graft) describes a surgical ocular procedure that requires the use of graft tissue. This procedure can be performed either with the patient's own tissue (a graft from the patient's eye) or with an amniotic membrane tissue product that is purchased by the provider. CPT code 65778 (Placement of amniotic membrane on the ocular surface; without sutures) describes the placement of an amniotic membrane on the ocular surface. For the CY 2024 OPPS proposed rule, we proposed to assign CPT code 65426 to APC 5503 (Level 3 Extraocular, Repair, and Plastic Eye Procedures) and we proposed to assign CPT code 65778 to APC 5502 (Level 2 Extraocular, Repair, and Plastic Eye Procedures).

Comment: One commenter, a manufacturer of the amniotic membrane used in both CPT codes 65426 and 65778, requested that payment for CPT code 65426 be increased from APC 5503 with a payment rate of around $2,300 to APC 5504 (Level 4 Extraocular, Repair, and Plastic Eye Procedures) with a payment rate of around $3,800. Likewise, the commenter requested that the payment for CPT code 65778 be increased from APC 5502 with a payment rate of around $1,000 to APC 5503 with a payment rate of around $2,300. The commenter requested the payment increases because the offset amounts for the amniotic membrane devices used in these procedures was substantially lower than the expected cost of the device. The commenter believes the cause of the low device percentage for these services is that many hospitals are not reporting the cost of the amniotic device, and an increased payment would ensure that providers receive a payment that recognizes the cost of the amniotic device.

Response: We disagree with the request of the commenter. Reporting service charges and appropriately coding expenditures on claims is the responsibility of the provider, and we do not adjust service payments to remedy potential coding errors. The commenter believes there is some type of systemic coding error that is leading to the low device offsets for CPT codes 65426 and 65778. We encourage the commenter to engage in provider education to encourage more thorough reporting of the device costs of these procedures. The commenter may also choose to work with the MACs to develop approaches to ensure the cost of the amniotic membrane device is included more regularly with these procedures.

After consideration of the public comments we received, we are implementing our proposal without modification for CPT codes 65426 and 65778. Table 77 shows the finalized status indicator and APC assignment for all of the procedure codes. We refer readers to Addendum B of this final rule with comment period for the payment rates for all codes reportable under the OPPS. Addendum B is available via the internet on the CMS website.

TABLE 77: FINAL CY 2024 OPPS APC STATUS INDICATOR ASSIGNMENTS FOR CPT CODES 65426 AND 65778

CPT Code	Long Descriptor	Final CY 2024 OPPS SI	Final CY 2024 OPPS APC
65426	Excision or transposition of pterygium; with graft	J1	5503
65778	Placement of amniotic membrane on the ocular surface; without sutures	Q2	5502

47. Peroral Endoscopic Myotomy (POEM) CPT Code 43497 (APC 5331)

According to interested parties, the POEM (Peroral Endoscopic Myotomy) procedure is a newer technique for the management of achalasia and is similar to laparoscopic Heller Myotomy performed by both advanced gastroenterologists and endoscopic surgeons. Achalasia is a disease that occurs due to the inability of the lower esophageal sphincter to relax and is also associated with loss of peristalsis in the esophagus. This procedure is described by CPT code 43497 (Lower esophageal myotomy, transoral (*i.e.,* peroral endoscopic myotomy [poem])), which has a geometric mean cost for CY 2024 of around $6,736. For the CY 2024 OPPS proposed rule, we proposed to assign the procedure to APC 5303 (Level 3 Upper GI Procedures) with a payment rate of around $3,803. APC 5303 is the highest-paying APC in the Upper GI Procedures APC series. CPT code 43497 is a significant procedure that contributes to the establishment of the overall payment rate for APC 5303.

Comment: Two commenters requested that we assign CPT code 43497 to APC 5331 (Complex GI Procedures) to resolve a 2 times rule violation with the procedure. The commenters noted that the geometric mean cost of CPT code 43497, which is around $6,736 is more than twice the cost of the lowest-cost significant procedure (CPT code 43260), which is around $6,454. Also, the geometric mean cost of CPT code 43497 is nearly $3,000 more than the payment rate for APC 5303.

Response: We agree with the request of the commenters that CPT code 43497 should be reassigned from APC 5303 to APC 5331 not only because of the 2 times rule violation and the substantial difference between the cost of CPT code 43497 and the payment rate for APC 5303, but in addition, we determined that the procedure described by CPT code 43497 has clinical and resource similarities with the other procedures of similar cost that are assigned to APC 5313.

After consideration of the public comments we received, we are implementing our proposal with modification for CPT code 43497 as we will update its APC assignment to APC 5331 (Complex GI Procedures). Table 78 shows the finalized status indicator and APC assignment for all of the procedure codes. We refer readers to Addendum B of this final rule with comment period for the payment rates for all codes reportable under the OPPS. Addendum B is available via the internet on the CMS website.

TABLE 78: FINAL CY 2024 OPPS APC STATUS INDICATOR ASSIGNMENTS FOR CPT CODE 43497

CPT Code	Long Descriptor	Final CY 2024 OPPS SI	Final CY 2024 OPPS APC
43497	Lower esophageal myotomy, transoral (ie, peroral endoscopic myotomy [poem]))	J1	5331

48. Transluminal Mechanical Thrombectomy, Noncoronary, Non-intracranial, Arterial or Arterial Bypass Graft, Including Fluoroscopic Guidance and Intraprocedural Pharmacological Thrombolytic Injection(s); Initial Vessel (APC 5194)

For 2024, we proposed to move CPT code 37184 (Primary percutaneous transluminal mechanical thrombectomy, noncoronary, non-intracranial, arterial or arterial bypass graft, including fluoroscopic guidance and intraprocedural pharmacological thrombolytic injection(s); initial vessel) from APC 5193 (Level 3 Endovascular Procedures) with a proposed payment rate of $10,602.57 to APC 5194 (Level 4 Endovascular Procedures) with a proposed payment rate of $17,195.36.

Comment: One commenter supported our proposal to move CPT code 37184 to APC 5194, stating that this APC assignment more accurately reflects the costs and resources associated with these procedures.

Response: We thank the commenter for the support of the CMS' proposal. Based on our examination of the latest claims data for this final rule with comment period, we believe that the assignment of CPT code 37184 to APC 5194 is appropriate for CY 2024.

In summary, after consideration of the public comment, we are finalizing our proposal without modification and assigning CPT code 37184 to APC 5194. The final CY 2024 OPPS payment rates for this code can be found in Addendum B to this final rule with comment period. In addition, we refer readers to Addendum D1 of this final rule with comment period for the SI meanings for all codes reported under the OPPS. Addenda B and D1 are available via the internet on the CMS website.

49. ProSense Cryoablation Procedure (APC 5091)

For CY 2023, we assigned CPT code 0581T (Ablation, malignant breast tumor(s), percutaneous, cryotherapy, including imaging guidance when performed, unilateral) to APC 5091 (Level 1 Breast/Lymphatic Surgery and Related Procedures) with a payment rate of $3,437.80. For CY 2024, as listed in OPPS Addendum B that was released with the CY 2024 OPPS/ASC proposed rule, we proposed to maintain the assignment to the same APC with a payment rate of $3,652.27.

Comment: A commenter disagreed with the assignment to APC 5091 for CPT code 0581T and requested a revision to APC 5092 (Level 2 Breast/Lymphatic Surgery and Related Procedures), with a payment rate $6,241.92. The commenter clarified that the procedure described by the code involves the use of a single-use device that cost $2,200. With the device cost, the commenter estimated the total procedure cost to be $7,019.79. This estimate was derived from the CY 2023 Medicare Physician Fee Schedule Final Rule CMS Public Use File, which include cost estimates for labor, equipment, time, and supply. The commenter indicated that the proposed payment rate of $3,652.27 for APC 5091 is insufficient to cover the total procedure cost, and believes the proposed payment of $6,241.92 for APC 5092 is more appropriate. This same commenter explained that in CY 2022, CPT code was assigned to ''E1,'' to indicate that the code was not

separately payable under the OPPS. To address the lack of claims data for CY 2022, the commenter performed their own data analysis that included claims for two procedures (0581T and 19105) as billed to Medicare and private payers. Based on the dataset, they found an average provider charge of $9,450 and with a maximum charge amount of $24,294 for CPT code 0581T (N=8 private payer, N=1 Medicare) based on fully paid claims for CY 2022 and the first half of 2023. The commenter further noted that CPT code 0581T violates the 2 times rule in APC 5091, and therefore, should be reassigned to APC 5092 to correct the violation.

Response: First, APC 5091 does not violate the 2 times rule. As specified in section III.B (OPPS Changes—Variations Within APCs) of this final rule with comment period, we consider only those HCPCS codes that are significant based on the number of claims to determine the APCs with2 times rule violation. For APC 5091, the geometric mean cost for the significant procedures range between approximately $2,745 (for CPT code 19120) and $4,807 (for CPT code 19371). Based on this range, APC 5091 does not violate the 2 times rule. Secondly, although CPT code 0581T was not separately payable under the OPPS during CY 2022, some HOPDs submitted CPT code 0581T on Medicare claims. For this final rule we are using claims that were submitted for services between January 1, 2022, and December 31, 2022, processed through June 30, 2023. This includes claims that potentially had different policies and SI and APC assignments applied to them in the claims year. Our ratesetting process takes those claims and simulates the prospective OPPS payment, in which we observed a geometric mean cost of approximately $4,357 for CPT code 0581T based on 37 single claims (out of 37 total claims) for this code. Based on this information, we believe that we should maintain CPT code 0581T in APC 5091 since the observed geometric mean cost of $4,357 is consistent with the geometric mean cost of approximately $3,733 for APC 5091, rather than the geometric mean cost of about $6,386 for APC 5092. As we do every year, we will reevaluate the APC assignment for CPT code 0581T for the CY 2025 rulemaking cycle. We remind the commenter, that we review, on an annual basis, the APC assignments for all services and items paid under the OPPS.

In summary, after consideration of the public comment, we are finalizing our proposal, without modification, to assign CPT code 0581T to APC 5091 for CY 2024. The final CY 2024 payment rate for the code can be found in Addendum B to this final rule with comment period. In addition, we refer readers to Addendum D1 of this final rule with comment period for the SI meanings for all codes reported under the OPPS. Addenda B and D1 are available via the internet on the CMS website.

50. Radiofrequency Ablation Procedures—CPT Codes 32998, 47382, and 50592 (APC 5361)

For CY 2023, we assigned certain radiofrequency ablation procedures, specifically, CPT codes 32998, 47382, and 50592 to APC 5361 (Level 1 Laparoscopy and Related Services), with a payment rate of $5,212.15. For CY 2024, as listed in OPPS Addendum B that was released with the CY 2024 OPPS/ASC proposed rule, we proposed to continue the assignment to APC 5361, with a payment rate of $5,544.60. Below are the long descriptors for CPT codes 32998, 47382, and 50592:

- 32998: Ablation therapy for reduction or eradication of 1 or more pulmonary tumor(s) including pleura or chest wall when involved by tumor extension, percutaneous, including imaging guidance when performed, unilateral; radiofrequency
- 47382: Ablation, 1 or more liver tumor(s), percutaneous, radiofrequency
- 50592: Ablation, 1 or more renal tumor(s), percutaneous, unilateral, radiofrequency

Comment: A commenter disagreed with the proposed assignment to APC 5361 and requested a revision to APC 5362 (Level 2 Laparoscopy and Related Services), with a payment rate of $9,871.90, based on clinical and resource homogeneity to the codes in the APC. The commenter indicated that CPT codes 32998, 47382, and 50592 are very similar to certain procedures in APC 5362, specifically, the laparoscopic ablation procedures described by CPT codes 47370, 47371, and 50542, and the percutaneous cryoablation procedures described by CPT codes 47383, 50593, and 32994.

Response: We note the CY 2024 OPPS payment rates are based on claims submitted between January 1, 2022, and December 31, 2022, processed through June 30, 2023. We analyzed our data, and below in Table 79 are the claims data for this final rule with comment period for the codes mentioned by the commenter.

TABLE 79: COST STATISTICS FOR CERTAIN RADIOFREQUENCY, LAPAROSCOPIC, AND CRYOABLATION PROCEDURES

CPT Code	Short Descriptor	Single Freq	Total Freq	Geometric Mean Cost
Radiofrequency Ablation Procedures				
32998	Ablate pulm tumor perq rf	171	174	$6,538.10
47382	Percut ablate liver rf	2,104	2,119	$7,140.84
50592	Perc rf ablate renal tumor	954	964	$6,810.13
Laparoscopic Ablation Procedures				
47370	Laparo ablate liver tumor rf	290	292	$9,467.15
47371	Laparo ablate liver cryosurg	5	5	$13,119.65
50542	Laparo ablate renal mass	62	62	$10,400.97
Percutaneous Cryoablation Procedures				
32994	Ablate pulm tumor perq crybl	265	267	$8,189.36
47383	Perq abltj lvr cryoablation	207	208	$9,269.14
50593	Perc cryo ablate renal tum	3,082	3,118	$8,596.92

As illustrated in Table 79, the resource costs associated with the laparoscopic ablation procedures and the percutaneous cryoablation procedures are higher than the resource costs associated with the radiofrequency ablation procedures. In particular, we found the geometric mean cost for CPT codes 32998, 47382, and 50592 ranged between approximately $6,538 and $7,141, which is consistent with the geometric mean cost of about $5,651 for APC 5361. We do not agree that the resource costs to perform these procedures are similar to those of the laparoscopic ablation procedures described by CPT codes 47370, 47371, and 50542, whose geometric mean cost range between $9,467 to $13,120, or the percutaneous cryoablation procedures described by CPT codes 47383, 50593, and 32994, whose geometric mean cost range between $8,189 and $9,269. We believe the resource costs related to the laparoscopic ablation procedures and percutaneous cryoablation procedures are appropriately reflected in APC 5362, whose geometric mean cost is approximately $10,081. Based on our analysis, we do not agree that the resource costs of the radiofrequency ablation procedures are similar to those of the laparoscopic ablation procedures or the percutaneous cryoablation procedures, which are in APC 5362. Therefore, we believe that CPT codes 32998, 47382, and 50592 should be maintained in APC 5361 based on clinical coherence and resource cost homogeneity.

In summary, after consideration of the public comment, we are finalizing our proposal, without modification, to assign CPT codes 32998, 47382, and 50592 to APC 5361 for CY 2024. The final CY 2024 payment rate for the code can be found in Addendum B to this final rule with comment period. In addition, we refer readers to Addendum D1 of this final rule with comment period for the SI meanings for all codes reported under the OPPS. Addenda B and D1 are available via the internet on the CMS website.

51. Radiofrequency Ablation, Posterior Nasal Nerve CPT Code 31242 (APC 5165)

For the CY 2024 OPPS final rule, we proposed that CPT code 31242 (placeholder code 3X016) (Nasal/sinus endoscopy, surgical; with destruction by radiofrequency ablation, posterior nasal nerve) be assigned to APC 5165 (Level 5 ENT Procedures) with a payment rate of around $5,647. There are currently no claims data available for the procedure.

Comment: Two commenters expressed their support of our assignment of CPT code 31242/3X016 to APC 5165.

Response: We appreciate the support of the commenters for payment rate proposal.

After consideration of the public comments we received, we are finalizing our proposal without modification for CPT code 31242 (listed as placeholder code 3X016 in the CY 2024 OPPS/ASC proposed rule with comment period) to continue to assign the procedure to APC 5165 (Level 5 ENT Procedures). Table 80 shows the finalized status indicator and APC assignment for all of the procedure codes. We refer readers to Addendum B of this final rule with comment period for the payment rates for all codes reportable under the OPPS. Addendum B is available via the internet on the CMS website.

TABLE 80: FINAL CY 2024 OPPS APC STATUS INDICATOR ASSIGNMENTS FOR CPT CODE 31242/3X016

CPT Code	Long Descriptor	Final CY 2024 OPPS SI	Final CY 2024 OPPS APC
31242	Nasal/sinus endoscopy, surgical; with destruction by radiofrequency ablation, posterior nasal nerve	J1	5165

52. Remote Physiological Monitoring Services

For CY 2024, we proposed to continue to assign CPT codes 99457 (Remote physiologic monitoring treatment management services, clinical staff/physician/other qualified health care professional time in a calendar month requiring interactive communication with the patient/caregiver during the month; first 20 minutes) and 99458 (Remote physiologic monitoring treatment management services, clinical staff/physician/other qualified health care professional time in a calendar month requiring interactive communication with the patient/caregiver during the month; each additional 20 minutes (list separately in addition to code for primary procedure) to status indicator ''B.''

At the August 21, 2023, HOP Panel Meeting, a presenter advised the Panel to request that CMS reassign CPT code 99457 to APC 5741 (Level 1 Electronic Data Analysis) with a proposed payment rate of $36.79 and CPT code 99458 is reassigned to status indicator ''N.''

Based on the information presented at the meeting, the Panel recommended that CMS considered changing the SI for CPT codes 99457 and 99458 to make them separately payable under the OPPS such that the services can be bundled with clinical visits in the month in which they occur and separately payable when no clinical visit with the appropriate supervising clinician occurs in the same month as the service.

Comment: We received one public comment, and the commenter requested a separate payment under OPPS for RPM treatment management services CPT codes 99457 and 99458. The commenter stated that separate payment under the OPPS for 99457 and 99458 is appropriate because they closely mirror the time-based chronic care management (CCM), described by CPT code 99490 (Chronic care management services with the following required elements: multiple (two or more) chronic conditions expected to last at least 12 months, or until the death of the patient, chronic conditions that place the patient at significant risk of death, acute exacerbation/decompensation, or functional decline, comprehensive care plan established, implemented, revised, or monitored; first 20 minutes of clinical staff time directed by a physician or other qualified health care professional, per calendar month), which is assigned to status indicator ''S'' and APC 5822 (Level 2 Health and Behavior Services) with a proposed payment rate of $86.86.

Response: We continue to believe that, since CPT code 99457 primarily describes the work associated with the billing of professional services, which would not be paid separately under the OPPS, and CPT code 99458 describes an add-on service to CPT code 99457, neither service is appropriate for separate payment under the OPPS. Therefore, we will continue to assign these codes to status indicator ''B'' for CY 2024.

In summary, after consideration of the public comment, we are finalizing our proposal without modification. Specifically, we are continuing to assign HCPCS codes 99457 and 99458 to status indicator ''B'' for CY 2024. We refer readers to Addendum D1 of this final rule with comment period for the status indicator (SI) meanings for all codes reported under the OPPS. Addendum D1 is available via the internet on the CMS website.

53. Remote Therapeutic Monitoring Treatment Management Services

For CY 2024, we proposed to change the status indicator for CPT codes 98980 (Remote therapeutic monitoring treatment management services, physician or other qualified health care professional time in a calendar month requiring at least one interactive communication with the patient or caregiver during the calendar month; first 20 minutes) and 98981 (Remote therapeutic monitoring treatment management services, physician or other qualified health care professional time in a calendar month requiring at least one interactive communication with the patient or caregiver during the calendar month; each additional 20 minutes (list separately in addition to code for primary procedure) from status indicator ''M'' to status indicator ''B'' since these services describe work associated with billing for professional services.

At the August 21, 2023, HOP Panel Meeting, a presenter advised the Panel to request that CMS reassign CPT code 98980 to APC 5741 (Level 1 Electronic Data Analysis) with a proposed payment rate of $36.79 and CPT code 98981 is reassigned to status indicator ''N.''

Based on the information presented at the meeting, the Panel recommended that CMS considered changing the SI for CPT code 98980 to ''S'' and assign the code to APC 5741 (Level 1 Electronic Analysis of Devices) and changed the status indicator for CPT code 98981 to ''N'' per OPPS policy.

Comment: We received one comment and the commenter requested assigning a relative value unit (RVU) value for CPT codes 98980 and 98981 and removing status indicator ''B.''

Response: We thank the commenter for the input but note that the comment related to an assignment of the RVU value is out of scope for the purposes of this OPPS/ASC final rule with comment period as RVUs are used to value services paid under the PFS. We continue to believe that, since CPT code 98980 primarily describes the work associated with the billing of professional services, which would not be paid separately under the OPPS, and CPT code 98981 describes an add-on service to CPT code 98980, neither service is appropriate for payment under the OPPS. Therefore, we will continue to assign these codes to status indicator ''B'' to indicate that the codes are not paid under OPPS and that alternate codes that are recognized by OPPS may be available.

In summary, after consideration of the public comment, we are finalizing our proposal without modification. Specifically, we are continuing to assign HCPCS codes 98980 and 98981 to status indicator ''B'' for CY 2024. We will

review these codes again for future rulemaking. We refer readers to Addendum D1 of this final rule with comment period for the status indicator (SI) meanings for all codes reported under the OPPS. Addendum D1 is available via the internet on the CMS website.

54. RNS Neurostimulator Surgical Service (APCs 5113 and 5464)

For CY 2024, the AMA CPT Editorial Board created three new CPT codes to describe the services associated with the RNS System, a skull-mounted cranial neurostimulator and treatment option for persons with medically intractable epilepsy. Specifically, effective January 1, 2024, the three new CPT codes are:

- 61889 (placeholder code 619X1)—Insertion of skull-mounted cranial neurostimulator pulse generator or receiver, including craniectomy or craniotomy, when performed, with direct or inductive coupling, with connection to depth and/or cortical strip electrode array(s).
- 61891 (placeholder code 619X2)—Revision or replacement of skull-mounted cranial neurostimulator pulse generator or receiver with connection to depth and/or cortical strip electrode array(s).
- 61892 (placeholder code 619X3)—Removal of skull-mounted cranial neurostimulator pulse generator or receiver with cranioplasty, when performed.

Because 61889 is only performed in the inpatient setting, CMS proposed to assign the code to status indicator ''C'' for CY 2024 and, therefore, did not assign the code to an APC. For CY 2024, CMS proposed to assign 61891 to APC 5463 (Level 3 Neurostimulator and Related Procedures) with a proposed payment rate of $13,899.52 and 61892 to APC 5113 (Level 3 Musculoskeletal Procedures) with a proposed payment rate of $3111.88. We note that CPT codes 61889, 61891, and 61892 were listed as placeholder codes 619X1, 619X2, and 619X3, respectively, in OPPS Addendum B and Addendum O that were released with the CY 2024 OPPS/ASC proposed rule with comment period. Because we had not received the final CPT code numbers from AMA for the new codes that would be effective January 1, 2024, in time for the publication of the proposed rule, we listed the new CPT codes with their respective placeholder codes in OPPS Addendum B and Addendum O.

Comment: We received several comments, including one from the manufacturer, requesting that we reassign CPT codes 61891 and 61892 to higher paying APCs based on cost concerns. The commenters requested that, for CY 2024, CMS assign CPT code 61891 to APC 5465 (Level 5 Neurostimulator and Related Procedures) with a proposed payment rate of $30,354.65 and CPT code 61892 to APC 5463 (Level 3 Neurostimulator and Related Procedures) with a proposed payment rate of $13,899.52. One commenter stated that the proposed APC assignments for CPT codes 61891 and 61892 would result in a 54 percent and a 78 percent reduction, respectively, in hospital outpatient payment, which they stated would impact Medicare beneficiary access. To support their requested APC changes, the commenter referred to two codes that are currently used to describe the services as predecessor codes for CPT codes 61891 and 61892. The commenter stated that for purposes of APC assignment, CMS should consider CPT code 61886 (Insertion or replacement of cranial neurostimulator pulse generator or receiver, direct or inductive coupling; with connection to 2 or more electrode arrays) as the predecessor code for 61891 and CPT code 61888 (Revision or removal of cranial neurostimulator pulse generator or receiver) as the predecessor code for 61892.

The commenter noted the change in the code descriptions of the new CPT codes (61891, 61892) compared to the code descriptors of the existing codes (61886, 61888) as related to revision procedures. The commenter stated that it was unknown to them why the new CPT codes included revision and replacement in the same code (61891) compared to the existing CPT codes where replacement is a separate code (61886) and removal and revision procedures are included in the same code (61888). However, the commenter pointed out that revisions of the RNS neurostimulator are exceedingly rare and that they expect the vast majority, if not all, of the procedures reported with 61891 to be a replacement of the RNS neurostimulator, rather than a revision, where no neurostimulator device is implanted. Finally, the commenter provided their own analyses comparing epilepsy vs non-epilepsy-related claims for CPT codes 61886 and 61888 to demonstrate that epilepsy related claims for both codes, for which the RNS neurostimulator surgical service would be used, had higher geometric mean costs than non-epilepsy related claims.

Response: We thank the commenters for their input on our proposal. First, we disagree with the commenter's assertion that we should use CPT code 61886 as the predecessor code for CPT code 61891 because the long descriptors for each code are substantially different. Specifically, while CPT code 61886 describes the insertion or replacement of a neurostimulator, where a neurostimulator device will be implanted each time the service is billed, CPT code 61891 describes the revision or replacement of the neurostimulator, where a neurostimulator device may or may not be implanted when the service is billed. While we appreciate the additional feedback from commenters explaining that revision procedures are extremely rare, we have an obligation to set APC assignments according to the long descriptor provided by the AMA. Because we believe the resource costs for a service where a high-cost neurostimulator device may or may not be implanted are lower than the resource costs for a service where a high-cost neurostimulator device is implanted each time, we disagree that CPT code 61891 should be assigned to the same APC as CPT code 61886. However, in light of the comments provided regarding the rarity of revision procedures and based on clinical similarities between CPT code 61891 and other cranial neurostimulator codes currently assigned to APC 5464 (Level 4 Neurostimulators), we believe that assigning CPT code 61891 to APC 5464 would be clinically and resource appropriate.

Regarding the assignment for CPT code 61892, we also disagree with the comments recommending that we use CPT code 61888 as the predecessor code for CPT code 61892. While CPT code 61888 may describe a removal of the neurostimulator or a revision, CPT code 61892 only describes the removal procedure. Therefore, we do not believe that CPT code 61892 should be assigned to the same APC as CPT code 61888 because the codes are different in terms of resource and clinical considerations based on the disparity between the codes' long descriptors. After review of the comments provided and further analysis from our medical advisors, we believe that the removal procedure described by CPT code 61892 is similar to the service described by CPT 69727 (Removal, entire osseointegrated implant, skull; with magnetic transcutaneous attachment to external speech processor, within the mastoid and/or involving a bony defect less than 100 sq mm surface area of bone deep to the outer cranial cortex), and should be assigned to the same clinical APC. Therefore, we continue to believe that an assignment to APC 5113 (Level 3 Musculoskeletal Procedures) is

clinically and resource appropriate for CPT code 61892.

After consideration of the public comments, we are finalizing the assignment of CPT code 61891 to APC 5464. Additionally, we are finalizing the assignment of CPT code 61892 to APC 5113. The final CY 2024 payment rate for both codes can be found in Addendum B to this final rule with comment period. We also refer readers to Addendum D1 of this final rule with comment period for the SI meanings for all codes reported under the OPPS. Addenda B and D1 are available via the internet on the CMS website.

55. Scleral Reinforcement (APC 5492)

For CY 2023, we assigned CPT code 67255 (Scleral reinforcement (separate procedure); with graft) to APC 5491 (Level 1 Intraocular Procedures) with a payment rate of $2,159.44. For CY 2024, as listed in OPPS Addendum B that was released with the CY 2024 OPPS/ASC proposed rule, we proposed to maintain assignment to APC 5491 (Level 1 Intraocular Procedures) with a payment rate of $2,255.61.

Comment: A commenter disagreed with the assignment to APC 5491 and suggested reassignment to APC 5492 (Level 2 Intraocular Procedures), with a payment rate of $3,970.62, based on the latest claims data.

Response: We reviewed our claims data for this final rule with comment period. We note the CY 2024 OPPS payment rates are based on claims submitted between January 1, 2022, and December 31, 2022, processed through June 30, 2023. Based on our examination of the claims data, we found the geometric mean cost of approximately $3,990 for CPT code 67255 based on 111 single claims (out of 111 total claims), which is consistent with the geometric mean cost of about $3,982 for APC 5492. We believe that the resource costs related to CPT code 67255 are higher compared to that of APC 5491, whose geometric mean cost is approximately $2,282, and more comparable to APC 5492. Therefore, we believe that we should reassign CPT code 67255 to APC 5492, since the procedure fits more appropriately in this APC based on clinical similarity and resource homogeneity.

In summary, after consideration of the public comment, we are finalizing the APC assignment for CPT code 67255 with modification. Specifically, we are revising the APC assignment from APC 5491 to APC 5492 for CPT code 67255 for CY 2024. The final CY 2024 OPPS payment rate for this code can be found in Addendum B to this final rule with comment period. In addition, we refer readers to Addendum D1 of this final rule with comment period for the SI meanings for all codes reported under the OPPS. Addendum D1 is available via the internet on the CMS website.

56. SpaceOAR Hydrogel Procedure (APC 5375)

CPT code 55874 (Transperineal placement of biodegradable material, peri-prostatic, single or multiple injection(s), including image guidance, when performed) describes the procedure associated with the SpaceOAR Hydrogel, a perirectal spacer made of gel-like material that temporarily creates a space between the prostate and rectum in prostate patients undergoing radiation therapy. For CY 2023, we assigned the code to APC 5375 (Level 5 Urology and Related Services), with a payment rate of $4,702.18. For CY 2024, as listed in OPPS Addendum B that was released with the CY 2024 OPPS/ASC proposed rule, we proposed to continue the assignment to APC 5376 (Level 6 Urology and Related Services) with a payment rate of $4,959.89.

Comment: Several commenters requested a reassignment to APC 5376 based on the claims data for the CY 2024 update.

Response: The CY 2024 OPPS payment rates are based on claims submitted between January 1, 2022, and December 31, 2022, processed through June 30, 2023. We reviewed the claims data for this final rule, and based on our analysis, we found the geometric mean cost of approximately $6,634 for CPT code 55874 based on 9,361 single claims (out of 9,470 total claims), is consistent with the geometric mean cost of about $5,067 for APC 5375, rather than the geometric mean cost of approximately $9,022 for APC 5376. Based on the resource costs, we believe that CPT code 55874 fits more appropriately in APC 5375 based on its clinical similarity and resource homogeneity to the procedures in the APC. We note that 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.

In summary, after consideration of the public comment, we are finalizing our proposal, without modification, to assign CPT code 55874 to APC 5375 for CY 2024. The final CY 2024 payment rate for the code can be found in Addendum B to this final rule with comment period. In addition, we refer readers to Addendum D1 of this final rule with comment period for the SI meanings for all codes reported under the OPPS. Addenda B and D1 are available via the internet on the CMS website.

57. Spinal Injection Service (APC 5115)

For CY 2024, we proposed to assign CPT codes 0627T (Percutaneous injection of allogeneic cellular and/or tissue-based product, intervertebral disc, unilateral or bilateral injection, with fluoroscopic guidance, lumbar; first level) and 0629T (Percutaneous injection of allogeneic cellular and/or tissue-based product, intervertebral disc, unilateral or bilateral injection, with ct guidance, lumbar; first level) to APC 5115 (Level 5 Musculoskeletal Procedures) with a proposed payment rate of $13,269.40.

Comment: We received a comment supporting our proposal to assign CPT codes 0627T and 0629T to APC 5115 (Level 5 Musculoskeletal Procedures).

Response: We thank the commenter for support of our proposal to assign CPT codes to APC 5115.

After consideration of the public comment received, we are finalizing our proposal without modification. The final CY 2024 payment rate for these codes can be found in Addendum B to this final rule with comment period. In addition, we refer readers to Addendum D1 of this final rule with comment period for the SI meanings for all codes reported under the OPPS. Addenda B and D1 are available via the internet on the CMS website.

58. Synchronized Diaphragmatic Stimulation (SDS) System for Augmentation of Cardiac Function

For the 2022 update, the CPT Editorial Panel established 12 new codes, specifically, CPT codes 0674T through 0685T, to describe the various services related to the synchronized diaphragmatic stimulation (SDS) system that is used to treat certain patients with chronic heart failure. The codes were effective January 1, 2022, and describe the implanting, revising, removing and replacing the implantable stimulator and leads, as well as interrogation and programming of the SDS system. The complete long descriptors for the 12 codes are listed in Table 81 below. For the 2022 and 2023 update, we assigned the codes to status indicator ''E1'' to indicate that they are not payable by Medicare when submitted on outpatient claims (any outpatient bill type) because the services associated with these codes are either not covered by any Medicare outpatient benefit category, statutorily excluded by Medicare, or not reasonable and necessary. For CY 2024, we proposed to continue to assign the codes to status indicator ''E1.''

Comment: A device manufacturer reported that the device associated with the codes received Breakthrough Device

Designation from the FDA and is scheduled to start a Category B Investigational Device Exemption (IDE) clinical trial in early 2024. In anticipation of the clinical trial and to ensure that hospitals receive Medicare reimbursement for the clinical trial, the manufacturer requested a reassignment in the status indicator, and suggested specific APCs and status indicator assignments for the 12 codes. In particular, the commenter suggested specific APC assignments for nine of the 12 codes, and recommended the assignment of status indicator ''N'' (packaged) for the three add-on codes. The manufacturer indicated that once they receive approval from the FDA for the IDE study, they intend to submit an application to CMS for Medicare coverage of their IDE clinical trial.

Response: Because the IDE study protocol has not received FDA approval, and has not been approved for Medicare coverage, we believe that we should continue to assign CPT codes 0674T through 0685T to status indicator ''E1'' for CY 2024. If this technology later meets CMS' standards for coverage, we will reassess the status indicator and APC assignments in a future quarterly update and/or rulemaking cycle.

In summary, after consideration of the public comment received, we are finalizing our proposal, without modification, to assign status indicator ''E1'' to CPT codes 0674T through 0685T. The final status indicator assignment for the codes is listed in Table 81. We refer readers to Addendum D1 of this final rule with comment period for the complete list of the OPPS payment status indicators and their definitions for CY 2024. Addendum D1 is available via the internet on the CMS website.

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TABLE 81: CY 2024 OPPS STATUS INDICATOR ASSIGNMENT FOR THE SERVICES RELATED TO THE SYNCHRONIZED DIAPHRAGMATIC STIMULATION SYSTEM CPT CODES 0674T – 0685T

CPT Code	Long Descriptor	Proposed CY 2024 OPPS SI	Final CY 2024 OPPS SI
0674T	Laparoscopic insertion of new or replacement of permanent implantable synchronized diaphragmatic stimulation system for augmentation of cardiac function, including an implantable pulse generator and diaphragmatic lead(s)	E1	E1
0675T	Laparoscopic insertion of new or replacement of diaphragmatic lead(s), permanent implantable synchronized diaphragmatic stimulation system for augmentation of cardiac function, including connection to an existing pulse generator; first lead	E1	E1
0676T	Laparoscopic insertion of new or replacement of diaphragmatic lead(s), permanent implantable synchronized diaphragmatic stimulation system for augmentation of cardiac function, including connection to an existing pulse generator; each additional lead (list separately in addition to code for primary procedure)	E1	E1
0677T	Laparoscopic repositioning of diaphragmatic lead(s), permanent implantable synchronized diaphragmatic stimulation system for augmentation of cardiac function, including connection to an existing pulse generator; first repositioned lead	E1	E1

CPT Code	Long Descriptor	Proposed CY 2024 OPPS SI	Final CY 2024 OPPS SI
0678T	Laparoscopic repositioning of diaphragmatic lead(s), permanent implantable synchronized diaphragmatic stimulation system for augmentation of cardiac function, including connection to an existing pulse generator; each additional repositioned lead (list separately in addition to code for primary procedure)	E1	E1
0679T	Laparoscopic removal of diaphragmatic lead(s), permanent implantable synchronized diaphragmatic stimulation system for augmentation of cardiac function	E1	E1
0680T	Insertion or replacement of pulse generator only, permanent implantable synchronized diaphragmatic stimulation system for augmentation of cardiac function, with connection to existing lead(s)	E1	E1
0681T	Relocation of pulse generator only, permanent implantable synchronized diaphragmatic stimulation system for augmentation of cardiac function, with connection to existing dual leads	E1	E1
0682T	Removal of pulse generator only, permanent implantable synchronized diaphragmatic stimulation system for augmentation of cardiac function	E1	E1
0683T	Programming device evaluation (in-person) with iterative adjustment of the implantable device to test the function of the device and select optimal permanent programmed values with analysis, review and report by a physician or other qualified health care professional, permanent implantable synchronized diaphragmatic stimulation system for augmentation of cardiac function	E1	E1
0684T	Peri-procedural device evaluation (in-person) and programming of device system parameters before or after a surgery, procedure, or test with analysis, review, and report by a physician or other qualified health care professional, permanent implantable synchronized diaphragmatic stimulation system for augmentation of cardiac function	E1	E1
0685T	Interrogation device evaluation (in-person) with analysis, review and report by a physician or other qualified health care professional, including connection, recording and disconnection per patient encounter, permanent implantable synchronized diaphragmatic stimulation system for augmentation of cardiac function	E1	E1

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59. Transcatheter Renal Sympathetic Denervation Procedure (APC 5192)

For CY 2023, we assigned CPT code 0338T and 0339T to APC 5192 (Level 2 Endovascular Procedures), with a payment rate of $5,215.40. For CY 2024, as listed in OPPS Addendum B that was released with the CY 2024 OPPS/ASC proposed rule, we proposed to continue the assignment to APC 5192 with a payment rate of $5,500.17. Below are the long descriptors for the codes:

- 0338T: Transcatheter renal sympathetic denervation, percutaneous approach including arterial puncture, selective catheter placement(s) renal artery(ies), fluoroscopy, contrast injection(s), intraprocedural roadmapping and radiological supervision and interpretation, including pressure gradient measurements, flush aortogram and

diagnostic renal angiography when performed; unilateral

- 0339T: Transcatheter renal sympathetic denervation, percutaneous approach including arterial puncture, selective catheter placement(s) renal artery(ies), fluoroscopy, contrast injection(s), intraprocedural roadmapping and radiological supervision and interpretation, including pressure gradient measurements, flush aortogram and diagnostic renal angiography when performed; bilateral

Comment: A commenter requested a reassignment to APC 5193 (Level 3 Endovascular Procedures, with a payment rate of $10,602.57, based on clinical similarity to the procedures in the APC.

Response: The CY 2024 OPPS payment rates are based on claims submitted between January 1, 2022, and December 31, 2022, processed through June 30, 2023. We evaluated the claims data for this final rule, and based on our review, we found no claims for CPT code 0338T. We also reviewed our historical claims data for the last 5 years, specifically, the cost statistics data that was released with the CY 2019 through CY 2023 OPPS/ASC final rules, and found that we have no claims data for CPT code 0338T. In contrast, we found some data for CPT code 0339T. For this final rule with comment period, our claims data show a geometric mean cost of about $16,423 for CPT code 0339T based on 1 single claim (out of 1 total claim). Similar to CPT code 0338T, we reviewed our historical claims data for the last 5 years and found inconsistent cost information. Specifically, our claims data show a geometric mean cost that has ranged between $651 and $1,081, based on 1 and 9 single claims. Based on the historical and current claims data for this final rule with comment period, we believe that both codes should be maintained in APC 5192.

In summary, after consideration of the public comment, we are finalizing our proposal, without modification, to assign CPT code 0338T and 0339T to APC 5192 for CY 2024. The final CY 2024 payment rate for the code can be found in Addendum B to this final rule with comment period. In addition, we refer readers to Addendum D1 of this final rule with comment period for the SI meanings for all codes reported under the OPPS. Addenda B and D1 are available via the internet on the CMS website.

60. Transnasal EGD CPT Codes 0652T–0654T (APCs 5302 and 5303)

For the CY 2024 OPPS final rule, we proposed to assign CPT code 0652T (Esophagogastroduodenoscopy, flexible, transnasal; diagnostic, including collection of specimen(s) by brushing or washing, when performed (separate procedure)) with no claims data for CY 2024 and CPT code 0653T (Esophagogastroduodenoscopy, flexible, transnasal; with biopsy, single or multiple) with a geometric mean cost of around $3,987 to APC 5302 (Level 2 Upper GI Procedures) with a payment rate of around $1,854. In addition, we proposed to assign CPT code 0654T (Esophagogastroduodenoscopy, flexible, transnasal; with insertion of intraluminal tube or catheter) with a geometric mean cost of around $2,057 to APC 5303 (Level 3 Upper GI Procedures) with a payment rate of $3,803.

Comment: One commenter supported our decision to assign CPT codes 0652T and 0653T to APC 5302. The commenter also supported our decision to assign CPT code 0654T to APC 5303.

Response: We appreciate the commenter's support for our proposals.

After consideration of the public comments we received, we are finalizing our proposal without modification to continue to assign CPT codes 0652T and 0653T to APC 5302 (Level 2 Upper GI Procedures). We also are finalizing our proposal without modification to continue to assign CPT code 0654T to APC 5303 (Level 3 Upper GI Procedures). Table 82 shows the finalized status indicator and APC assignment for all of the procedure codes. We refer readers to Addendum B of this final rule with comment period for the payment rates for all codes reportable under the OPPS. Addendum B is available via the internet on the CMS website.

TABLE 82: FINAL CY 2024 OPPS APC STATUS INDICATOR ASSIGNMENTS FOR CPT CODES 0652T – 0654T

CPT Code	Long Descriptor	Final CY 2024 OPPS SI	Final CY 2024 OPPS APC
0652T	Esophagogastroduodenoscopy, flexible, transnasal; diagnostic, including collection of specimen(s) by brushing or washing, when performed (separate procedure)	J1	5302
0653T	Esophagogastroduodenoscopy, flexible, transnasal; with biopsy, single or multiple	J1	5302
0654T	Esophagogastroduodenoscopy, flexible, transnasal; with insertion of intraluminal tube or catheter	J1	5303

61. Upper GI Tract Endoscopy Bile and Pancreatic Ducts (APC 5302)

CPT code 43275 (Endoscopic retrograde cholangiopancreatography (ERCP); with removal of foreign body(s) or stent(s) from biliary/pancreatic duct(s)) describes an endoscopy procedure that is performed to treat medical issues with the bile and pancreatic ducts. CPT code 43275 has a geometric mean cost of around $2,725 for CY 2024. In the CY 2024 OPPS proposed rule, we assigned CPT code 43275 to APC 5302 (Level 2 Upper GI

Procedures) with a payment rate of around $1,854.

Comment: One commenter requested that CPT code 43275 be reassigned to APC 5303 (Level 3 Upper GI Procedures) with a payment rate of around $3,803. The commenter states that performing endoscopic retrograde cholangiopancreatography (ERCP) requires more training and experience for gastrointestinal endoscopists as compared to other gastrointestinal endoscopic procedures leading to higher cost for the procedure described by CPT code 43275. The commenter also notes that CPT code was assigned to APC 5202 for CY 2023 where it is the lowest-cost significant procedure. Moving CPT code 43275 to APC 5302 would increase the 2 times rule threshold in APC 5303, which according to the commenter, may reduce the procedure code combinations that would be eligible for complexity adjustments. The commenter also notes that CPT code 43275 while in APC 5302 is less than $300 away from a 2 times rule violation in that APC. Finally, the commenter believes that there no significant financial impact whether CPT code 43275 is assigned to either APC 5302 or APC 5303.

Response: We appreciate the request of the commenter. We note that while CPT code 43275 would be one of the higher-paid procedures in APC 5302, the procedure will be underpaid by less than $900 and there are several other procedures in APC 5302 with similar geometric costs as CPT code 43275. Assigning CPT code 43275 to APC 5303 would make the procedure the second lowest-paid procedure in APC 5303. In addition, the payment rate of APC 5303 would be around $1,000 more than the geometric mean cost of CPT code 43275.

After consideration of the public comments we received, we are finalizing our proposal without modification for CPT code 43275 to continue to assign the procedure to APC 5302 (Level 2 Upper GI Procedures). Table 83 shows the finalized status indicator and APC assignment for all of the procedure codes. We refer readers to Addendum B of this final rule with comment period for the payment rates for all codes reportable under the OPPS. Addendum B is available via the internet on the CMS website.

TABLE 83: FINAL CY 2024 OPPS APC STATUS INDICATOR ASSIGNMENTS FOR CPT CODE 43275

CPT Code	Long Descriptor	Final CY 2024 OPPS SI	Final CY 2024 OPPS APC
43275	Endoscopic retrograde cholangiopancreatography (ercp); with removal of foreign body(s) or stent(s) from biliary/pancreatic duct(s)	J1	5302

62. Xen Glaucoma Treatment Procedure (APC 5493)

For 2017, the AMA's Editorial Panel established two new codes, specifically, CPT code 0449T and 0450T, effective January 1, 2017, to describe the surgical procedure associated with the Xen Glaucoma Treatment System. The complete long descriptors for the codes, are listed below:

- 0449T (Insertion of aqueous drainage device, without extraocular reservoir, internal approach, into the subconjunctival space; initial device)
- 0450T (Insertion of aqueous drainage device, without extraocular reservoir, internal approach, into the subconjunctival space; each additional device (list separately in addition to code for primary procedure))

For CY 2023, CPT code 0449T is assigned to APC 5492 (Level 2 Intraocular Procedures) with a payment of $3,995.58. In addition, we assigned CPT code 0450T to status indicator ''N'' to indicate that the code is packaged, and payment for the service is included in the primary code. For CY 2024, we proposed to continue the assignment to APC 5492 for CPT code 0449T. Similarly, we proposed to maintain the assignment of status indicator ''N'' (packaged) for CPT code 0450T.

Comment: A commenter reported that the proposed reassignment for CPT 66991, which is one of the existing MIG codes, from APC 1563 (New Technology—Level 26 ($4001–$4500)) to APC 5493 (Level 3 Intraocular Procedures), seems appropriate. However, the commenter indicated that the geometric mean cost for CPT code 0449T is higher than the cost of CPT code 66991, yet CPT code 0449T has been proposed to continue to be assigned to APC 5492. In addition, the commenter suggested that the work associated with CPT code 0449T is significantly more complex than that of CPT code 66991. Based on the claims data and the clinical complexity of the work associated with the service described by CPT code 0449T, the commenter urged CMS to reassign CPT code 0449T to APC 5493, which is the same APC proposed for CPT code 66991.

Response: We reviewed our claims data for this final rule with comment period. The CY 2024 OPPS payment rates are based on claims submitted between January 1, 2022, and December 31, 2022, processed through June 30, 2023. Based on our evaluation of the claims data for this final rule with comment period, we agree that the geometric mean cost for CPT code 0449T is higher compared to the geometric mean cost for CPT code 66991. Specifically, our claims data show a geometric mean cost of approximately $4,995 for CPT code 0449T based on 415 single claims (out of 421), which is higher than the geometric mean cost of about $4,943 for CPT code 66991 based on 6,011 single claims (out of 6,069) total claims. We agree that CPT code 0449T should be reassigned to APC 5493 based on clinical and resource homogeneity with the procedures assigned to APC 5493. We believe the resource costs associated with CPT code 0449T are similar to those procedures in APC 5493, rather than APC 5492. Therefore, we are revising the assignment for CPT code 0449T to APC 5493 for CY 2024.

With regard to CPT code 66991 (MIG code) mentioned by the commenter, we refer readers to section III.C (New Technology APCs) of this final rule with comment period for the discussion

related to the CY 2024 payment for the code.

In summary, after consideration of the public comments, we are finalizing the APC assignment for CPT code 0449T with modification. Specifically, we are revising the APC assignment from APC 5492 to APC 5493 for CPT code 0449T for CY 2024. We note we did not receive any comment for CPT code 0450T, therefore, we are finalizing the proposed status indicator. The final CY 2024 OPPS payment rate for all the codes payable under the OPPS can be found in Addendum B to this final rule with comment period. In addition, we refer readers to Addendum D1 of this final rule with comment period for the SI meanings for all codes reported under the OPPS. Addendum D1 is available via the internet on the CMS website.

63. XV Lung Ventilation Analysis Software (APC 5722)

Effective July 1, 2023, the CPT Editorial Panel created CPT codes 0807T (Pulmonary tissue ventilation analysis using software-based processing of data from separately captured cinefluorograph images; in combination with previously acquired computed tomography (CT) images, including data preparation and transmission, quantification of pulmonary tissue ventilation, data review, interpretation and report) and 0808T (Pulmonary tissue ventilation analysis using software-based processing of data from separately captured cinefluorograph images; in combination with computed tomography (CT) images taken for the purpose of pulmonary tissue ventilation analysis, including data preparation and transmission, quantification of pulmonary tissue ventilation, data review, interpretation and report). Both CPT codes 0807T and 0808T are used with the XV Lung Ventilation Analysis Software, which is a respiratory imaging platform to identify respiratory deficiencies. The difference between the two codes is that CPT code 0808T includes a CT scan during the service, and CPT code 0807T does not. For CY 2024, we proposed to assign CPT code 0807T to APC 5721 (Level 1 Diagnostic Tests and Related Services) with a proposed payment rate of $151 and CPT code 0808T to APC 5722 (Level 2 Diagnostic Tests and Related Services) with a proposed payment rate of $304.

Comment: We received a comment from the manufacturer of the XV Lung Ventilation Analysis Software expressing support for the proposed APC assignment for 0808T.

Response: We thank the commenter for their support for the APC assignment for CPT code 0808T and agree that the proposed APC assignment for CPT code 0808T accurately captures the costs associated with the service. Therefore, we are finalizing the APC assignment for CPT code 0808T as proposed.

Comment: The manufacturer also commented on the proposed APC assignment for CPT code 0807T. The commenter stated that the proposed APC assignment for CPT code 0807T does not properly account for the costs associated with the required fluoroscopy imaging that is a part of the service. The commenter provided the CY 2024 proposed rule geometric mean costs for two fluoroscopy codes: CPT code 76000 (Fluoroscopy (separate procedure), up to 1 hour physician or other qualified health care professional time) with a proposed geometric mean cost of $262, and CPT code 76496 (Unlisted fluoroscopic procedure (eg, diagnostic, interventional) with a proposed geometric mean cost of $133, and explained that the proposed APC assignment for CPT code 0807T would not cover the costs of the fluoroscopy based on the proposed geometric mean costs of the two fluoroscopy codes. To account for the costs of the fluoroscopy that is performed as part of the service, the commenter requested that CMS assign CPT code 0807T to APC 5722 for CY 2024.

Response: After further evaluation of CPT code 0807T, the resources required to perform the procedure, and input from our medical advisors, we believe it is appropriate to reassign CPT code 0807T to APC 5722. Based on our evaluation of the additional information provided to CMS as well as the claims data for existing fluoroscopy codes, we believe that the resource costs associated with CPT code 0807T are higher than those associated with the code's proposed APC assignment. Therefore, we are revising the APC assignment for CPT code 0807T for CY 2024.

After consideration of the public comment, we are finalizing our proposal without modification to assign CPT code 0808T to APC 5722 for CY 2024. We are also finalizing the reassignment of CPT code 0807T to APC 5722 for CY 2024. The final CY 2024 payment rate for these codes can be found in Addendum B to this final rule with comment period. We also refer readers to Addendum D1 of this final rule with comment period for the SI meanings for all codes reported under the OPPS. Addenda B and D1 are available via the internet on the CMS website. In addition, we note that CMS recognizes that software-based technologies are rapidly evolving, like the product used for HCPCS code C9786. In line with our comment solicitation on payment policy for software as a service (SaaS) procedures in the CY 2023 OPPS final rule (87 FR 72035 and 72036), CMS is considering, for future rulemaking, whether or not specific adjustments to payment policies and rate calculations are necessary in order to more accurately and appropriately pay for these products and services across settings of care. CMS remains open to feedback on these issues and welcomes engagement from interested parties, including from manufacturers, providers, and beneficiaries.

64. New Technology Applications Submitted to CMS

Comment: We received comments regarding three pending New Technology APC applications, for the TriNav™ Infusion System, Trabeculocanalicular Outflow Restoration, and Optilume Benign Prostatic Hyperplasia (BPH) services.

Response: We note that pending New Technology APC applications are reviewed via a sub-regulatory process, and therefore, application determinations are not made via rulemaking. As a result, we did not propose to create new codes for any of these services or assign them to New Technology APCs in the CY 2024 OPPS/ASC proposed rule. These New Technology APC applications are currently being reviewed and applicants will be notified of CMS's decision through our normal process.

IV. OPPS Payment for Devices

A. 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 § 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 § 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 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).

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.[14]

In the CY 2023 OPPS/ASC final rule with comment period, we finalized our policy to publicly post online OPPS device pass-through applications received on or after March 1, 2023, beginning with the issuance of the CY 2025 proposed rule and for each OPPS rulemaking thereafter. We refer readers to the CY 2023 OPPS/ASC final rule with comment period (87 FR 71934 through 71938) for a full discussion of the policy to publicly post OPPS device pass-through applications.

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. Currently, there are 15 device categories eligible for pass-through payment. These devices are listed in Table 84 of this final rule with comment where we detail the expiration dates of pass-through payment status for each of the 15 devices currently receiving device pass-through payment.

[14] To apply for OPPS transitional device pass-through status, applicants complete an application that is subject to the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501 *et seq.*). This information collection (CMS–10052) is currently approved under OMB control number 0938–0857 and has an expiration date of November 30, 2025.

In the CY 2022 OPPS/ASC final rule with comment period we used CY 2019 claims data, rather than CY 2020 claims data, to inform CY 2022 ratesetting (86 FR 63755). As a result, we utilized our equitable adjustment authority at section 1833(t)(2)(E) of the Act to provide up to four quarters of separate payment for 27 drugs and biologicals and one device category whose pass-through payment status expired between December 31, 2021 and September 30, 2022 to mimic continued pass-through payment, promote adequate access to innovative therapies for Medicare beneficiaries, and gather sufficient data for purposes of assigning these devices to clinical APCs (86 FR 63755). A full discussion of this final policy is included in section X.F of the CY 2022 OPPS/ASC final rule with comment (86 FR 63755).

Section 4141(a)(2) of the Consolidated Appropriations Act, 2023 (CAA, 2023) (Pub. L. 117–328) amended section 1833(t)(6) by adding a new subparagraph (K), which extended the device pass-through status under paragraph (6) for a 1-year period beginning January 1, 2023, for device categories whose period of pass-through status would have ended on December 31, 2022. There are five device categories for which pass-through status would have ended on December 31, 2022, but which will now end on December 31, 2023. Pass-through status began for these device categories on January 1, 2020.

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TABLE 84: DEVICES WITH PASS-THROUGH STATUS EXPIRING IN 2023, IN 2024, OR IN 2025

HCPCS Code	Long Descriptor	Effective Date	Pass-Through Expiration Date
C1824*	Generator, cardiac contractility modulation (implantable)	1/1/2020	12/31/2023
C1982*	Catheter, pressure-generating, one-way valve, intermittently occlusive	1/1/2020	12/31/2023
C1839*	Iris prosthesis	1/1/2020	12/31/2023
C1734*	Orthopedic/device/drug matrix for opposing bone-to-bone or soft tissue-to bone (implantable)	1/1/2020	12/31/2023
C2596*	Probe, image-guided, robotic, waterjet ablation	1/1/2020	12/31/2023
C1052	Hemostatic agent, gastrointestinal, topical	1/1/2021	12/31/2023
C1062	Intravertebral body fracture augmentation with implant (e.g., metal, polymer)	1/1/2021	12/31/2023
C1825	Generator, neurostimulator (implantable), nonrechargeable with carotid sinus baroreceptor stimulation lead(s)	1/1/2021	12/31/2023
C1761	Catheter, transluminal intravascular lithotripsy, coronary	7/1/2021	6/30/2024
C1831	Personalized, anterior and lateral interbody cage (implantable)	10/1/2021	9/30/2024
C1832	Autograft suspension, including cell processing and application, and all system components	1/1/2022	12/31/2024
C1833	Monitor, cardiac, including intracardiac lead and all system components (implantable)	1/1/2022	12/31/2024
C1826	Generator, neurostimulator (implantable), includes closed feedback loop leads and all implantable components, with rechargeable battery and charging system	1/1/2023	12/31/2025
C1827	Generator, neurostimulator (implantable), non-rechargeable, with implantable stimulation lead and external paired stimulation controller	1/1/2023	12/31/2025
C1747	Endoscope, single-use (i.e. disposable), urinary tract, imaging/illumination device (insertable)	1/1/2023	12/31/2025

*Device for which pass-through status was extended for a 1-year period by section (a)(2) of the Consolidated Appropriations Act, 2023 (CAA, 2023) (Pub. L. 117-328), titled "Extension of Pass-Through Status Under the Medicare Program for Certain Devices Impacted by COVID-19."

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2. New Device Pass-Through Applications for CY 2024

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 are most likely to interfere with patient access (66 FR 55852; 67 FR 66782; and 70 FR 68629).

As specified in regulations at § 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 approval or clearance and 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 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, or, for devices for which pass-through payment status will begin on or after January 1, 2020, as an alternative pathway to demonstrating substantial clinical improvement, a device is part of the FDA's Breakthrough Devices Program and has received marketing authorization for the indication covered by the Breakthrough Device designation.

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 sub-regulatory process, but the applications are 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 and 70418).

In the CY 2020 annual rulemaking process, we finalized an alternative pathway for devices that are granted a Breakthrough Device designation (84 FR 61295) and receive FDA marketing authorization for the indication covered by the Breakthrough Device designation. 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 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 are part of the Breakthrough Devices Program, have received FDA marketing authorization for the indication covered by the Breakthrough Devices designation, and meet the other criteria in the 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: *https://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 facilitate information sharing to support the evaluation of an OPPS device pass-through payment application or discuss general application criteria, including the substantial clinical improvement criterion.

b. Applications Received for Device Pass-Through Status for CY 2024

We received six complete applications by the March 1, 2023, quarterly deadline, which was the last quarterly deadline for applications to be received in time to be included in this rule. We received three of the applications in the second quarter of 2022, one of the applications in the third quarter of 2022, no applications in the fourth quarter of 2022, and two of the applications in the first quarter of 2023. One of the applications was approved for device pass-through status during the quarterly review process: MY01 Continuous Compartmental Pressure Monitor, which was submitted on May 31, 2022, and conditionally approved as HCPCS code C1834 on October 1, 2022. However, after further review, we determined that the conditional approval was in error, and consequently, we deleted code C1834 on March 31, 2023.

Applications received for the later deadlines for the remaining 2023 quarters (the quarters beginning June 1, September 1, and December 1 of 2023), if any, will be discussed in the CY 2025 OPPS/ASC proposed rule. We note that the quarterly application process and requirements have not changed because 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.*

Discussions of the applications we received by the March 1, 2023, deadline are included below.

(1) Alternative Pathway Device Pass-Through Applications

We received two device pass-through applications by the March 2023 quarterly application deadline for devices that have received Breakthrough Device designation from FDA and FDA marketing authorization for the indication for which they have a Breakthrough Device designation, and therefore are eligible to apply under the alternative pathway.

(a) CavaClear Inferior Vena Cava (IVC) Filter Removal Laser Sheath

Phillips North America, LLC submitted an application for a new device category for transitional pass-through payment status for CavaClear Inferior Vena Cava (IVC) Filter Removal Laser Sheath (CavaClear) for CY 2024. Per the applicant, CavaClear is a breakthrough device intended for tissue ablation in the removal of embedded IVC filters that have failed a previous retrieval method. IVC filters are used to capture blood clots and prevent them from moving to the lungs in patients with venous thromboembolism. Per the applicant, research has shown that IVC filters may have long-term complications, including device migration, filter fracture, and IVC occlusion; as a result, FDA issued a safety notice that recommends that physicians remove retrievable IVC filters as soon as they are no longer needed. The applicant stated that CavaClear facilitates the detachment of firmly adherent IVC filters using ultraviolet laser energy. The applicant explained that CavaClear uses circumferential tissue ablation that can aid in capturing the filter within seconds of laser activation, which can help increase physician efficiency, and may help lower costs by reducing the number of retrieval attempts to remove an embedded IVC filter.

According to the applicant, CavaClear is a 14F or 16F laser catheter used for the intra-operative removal of IVC filters. The applicant further explained that CavaClear consists of optical fibers arranged in a circle, sandwiched between inner and outer polymer tubing. The fibers terminate at the distal end within a polished tip and at the proximal end within a coupler that mates with the excimer laser. According to the applicant, inner and outer stainless-steel bands, which form a radiopaque marker, protect the optical fibers at the distal tip. The applicant also stated that CavaClear was designed to slide through an introducer sheath with an inner lumen to allow an appropriate traction platform to pass through it. Per the applicant, the device facilitates detachment of IVC filters from the IVC wall using ultraviolet laser energy and subsequent collapse of the filter, partially within the laser sheath and entirely within the introducer sheath. The laser sheath was designed for use with the CVX–300® Excimer Laser or Philips Laser System (PLS), which allows the multifiber laser sheaths to transmit ultraviolet energy to the tissue at the distal tip of the device. The applicant further explained that, when activated, the laser ablates the tissue and frees the IVC filter from overgrowth in a controllable fashion. The applicant stated that by using cool ultraviolet laser energy around the embedded IVC filter, CavaClear can assist in fast filter capture with low force.

As stated previously, to be eligible for transitional pass-through payment under the OPPS, a device must meet the criteria at § 419.66(b)(1) through (4). With respect to the newness criterion at § 419.66(b)(1), CavaClear received FDA Breakthrough Device designation effective April 23, 2021, for the ablation of tissue in the removal of IVC filters that have failed a previous retrieval method. FDA granted the applicant De Novo classification for CavaClear (laser-powered IVC filter retrieval catheter) on December 21, 2021, for the same indication as the one covered by the Breakthrough Device designation. We received the application for a new device category for transitional pass-through payment status for CavaClear on May 30, 2022, which is within 3 years of the date of the initial FDA marketing authorization.

We solicited public comment on whether CavaClear meets the newness criterion at § 419.66(b)(1).

Comment: The applicant submitted a comment reiterating that CavaClear meets the newness criterion at 42 CFR 419.66(b)(1), stating that CMS received the application for a new device category for transitional pass-through payment status for CavaClear on May 30, 2022, which is within 3 years of the date of the initial FDA marketing authorization.

Response: We appreciate the commenter's input and agree that because we received the application for CavaClear on May 30, 2022, which is within 3 years of FDA approval on April 23, 2021, that CavaClear meets the newness criterion.

With respect to the eligibility criterion at § 419.66(b)(3), according to the applicant, CavaClear is integral to the service provided, is used for one patient only, comes in contact with human tissue, and is surgically implanted or

inserted into the patient through the insertion of a laser catheter temporarily for the interoperative removal of IVC filters as required at § 419.66(b)(3).

We invited public comment on whether CavaClear meets the eligibility criterion at § 419.66(b)(3).

Comment: The applicant submitted a comment reiterating that CavaClear satisfies the eligibility criterion at 42 CFR 419.66(b)(3) because the device is integral to the service provided, is used for one patient only, comes in contact with human tissue, and is surgically implanted or inserted into the patient through the insertion of a laser catheter temporarily for the interoperative removal of IVC filters.

Response: We appreciate the commenter's input. Based on the information we have received and our review of the application, we agree with the applicant that CavaClear is integral to the service provided, used for one patient only, comes in contact with human tissue, and is surgically implanted or inserted. Therefore, we have determined that CavaClear meets the eligibility criteria at § 419.66(b)(3).

With respect to the exclusion criterion at § 419.66(b)(4), the applicant also claimed that CavaClear meets the criterion because it is not equipment, an instrument, apparatus, implement, or item of this type for which depreciation and financing expenses are recovered, and it is not a supply or material furnished incident to a service.

We invited public comment on whether CavaClear meets the exclusion criterion at § 419.66(b)(4).

Comment: The applicant submitted a comment reiterating that CavaClear satisfies the exclusion criterion at 42 CFR 419.66(b)(4) because it is not equipment, an instrument, apparatus, implement, or item of this type for which depreciation and financing expenses are recovered, and it is not a supply or material furnished incident to a service.

Response: We appreciate the commenter's input. Based on the information we have received and our review of the application, we agree with the applicant that CavaClear meets the device eligibility requirements of § 419.66(b)(4) because it is not a piece of equipment, 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 have therefore determined that CavaClear meets the device eligibility requirements of § 419.66(b)(4).

In addition to the criteria at § 419.66(b)(1) through (4), 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 described CavaClear as an IVC filter removal device that uses a laser to ablate tissue and is intended to facilitate detaching and removing indwelling IVC filters. Per the applicant, CavaClear is the first and only FDA-cleared solution for advanced IVC filter removal, and the applicant claimed that no previous device categories for pass-through payment appropriately describe CavaClear. Per the applicant, the possible existing pass-through code, HCPCS code C2629 (Introducer/sheath, other than guiding, other than intracardiac electrophysiological, laser), does not appropriately describe CavaClear because CavaClear uses a unique laser mechanism of action, unlike the snag, snare, and forceps method to remove IVC filters. Per the applicant, CavaClear is not intended to remove pacemaker and defibrillator leads like the products described by C2629, and CavaClear impacts different anatomy than the products described by C2629. Specifically, the applicant asserted that C2629 includes devices that are indicated to remove implanted pacemaker and defibrillator leads and devices via a catheter inserted into the vascular system. In addition, the applicant noted that FDA granted CavaClear De Novo classification, reflecting that there is no legally marketed predicate device for CavaClear.

In the proposed rule, we noted, based on the description the applicant provided, that CavaClear is a laser sheath intended for use in the IVC, which is not intracardiac, and thus could be encompassed by the descriptor of C2629. We also noted that another existing pass-through payment category may appropriately describe CavaClear. Specifically, we stated that we believed that C1773 (Retrieval device, insertable (used to retrieve fractured medical devices)) may appropriately describe CavaClear. Pass-through payment category C1773 is a broad category descriptor for a device that retrieves another device within a patient's vascular system. Based on the description the applicant provided, CavaClear is a device (a laser-powered sheath that uses a laser to ablate tissue in the IVC) used to retrieve another medical device (an IVC filter device), which is consistent with the descriptor for C1773. In this context, we believe CavaClear may be similar to the devices currently described by C2629 and C1773, and therefore, CavaClear may also be appropriately described by C2629 and C1773.

We invited public comment on whether CavaClear meets the device category criterion at § 419.66(c)(1).

Comment: In response to our concerns that CavaClear may be appropriately described by C2629 or C1773, the applicant and several commenters commented that CavaClear meets eligibility requirements of § 419.66(c)(1), stating that CavaClear can be distinguished from the devices currently described by HCPCS codes C2629 and C1773 and, as such, meets the device category criterion. Specifically, the commenters asserted that CavaClear differs from devices described in C2629 and C1773 by mechanism of action, clinical use, impacted anatomy, and FDA clearance pathway.

All commenters addressing the device category criterion offered support for approval of the application. Commenters stated that CavaClear's mechanism of action is unique because it uses laser energy to ablate scar tissue to facilitate the safe detachment and removal of indwelling IVC filters. Commenters also noted that CavaClear's photothermal laser tissue ablation is administered with individualized tools and a unique traction platform different from other devices. One commenter stated that there is no other device that uses excimer laser technology to ablate the scar tissue that embeds IVC filter struts. Finally, the applicant and multiple commenters provided that CavaClear is also the only device to address the unmet medical need identified by FDA safety communications on IVC retrievals.

Multiple commenters also noted that CavaClear was granted De Novo classification by FDA, reflecting FDA's determination that there is no legally marketed predicate device for CavaClear. In addition, the applicant stated that CavaClear received Breakthrough Device designation from FDA, which they believe implies that CavaClear is the first device of its kind to address the condition for which it is designed and is the only FDA-cleared treatment option for advanced IVC filter removal.

With respect to our concern that CavaClear may be appropriately described by C2629, the applicant stated that CavaClear differs significantly from devices described in the C2629 category (Introducer/sheath, other than guiding, other than intracardiac

electrophysiological, laser). First, the applicant asserted, and multiple commenters agreed, that the devices described by C2629 are used to remove pacemaker and defibrillator leads from the superior vena cava (SVC) while CavaClear removes IVC filters from the inferior vena cava. Specifically, the applicant stated that CavaClear removes a different implant (IVC filter), as compared to other devices in need of removal (pacemaker and defibrillator leads). In addition, the impacted anatomy is different than that of the other products. The applicant explained that the IVC filter is placed in the IVC and the cardiac leads are placed via the SVC.

The applicant also sought to clarify how, in comparison to the devices described in the C2629 category, CavaClear's mechanism of action is unique. The applicant asserted that CavaClear's mechanism of action is different and is based on four components: vessel access, traction platform, tissue separation, and physical removal of the implanted device. The applicant stated that the vessel access site for CavaClear is via internal jugular or femoral vein, as opposed to the subclavian vein for the other laser sheath devices. The applicant also asserted that CavaClear's traction platform is different than the other laser sheath products, with no additional rail required for traction other than a snare, and the tools used to perform extraction are specific to the CavaClear device. Further, the applicant and a few commenters provided that the photothermal cool tissue ablation cannot be administered without the individualized tools and traction platform.

Finally, the applicant provided clarification regarding the physical removal of the implanted device using CavaClear. The applicant stated that to remove the IVC filter the CavaClear device interacts to collapse the filter in combination with the application of energy. By contrast, for other devices, there is no such interaction to physically alter the explanted device.

With respect to our concern that CavaClear may be appropriately described by C1773, the applicant asserted that CavaClear differs significantly from devices described in C1773 (Retrieval device, insertable (used to retrieve fractured medical devices)).

As with devices in the C2629 category, the applicant sought to clarify how, in comparison to the devices described in the C1773 category, CavaClear's mechanism of action is unique. The applicant reiterated that CavaClear's mechanism of action is different and is based on four components: vessel access, traction platform, tissue separation, and physical removal of the implanted device through photothermal cool tissue laser ablation.

Commenters asserted that CavaClear can be distinguished from the devices broadly described in C1773 because those described devices represent mechanical (non-laser) or more rudimentary approaches to retrieval as compared to CavaClear. Specifically, the applicant provided that for the devices described in C1773 that retrieve IVC filters (for example, endovascular snares, goose neck snares), the mechanism of action relies on the device to capture the apical hook of the filter (often embedded in the wall of the IVC or encapsulated). If accessible, the snare requires straight pulling, sometimes substantially, of the filter into a sheath with equal and opposite traction/countertraction applied to the snare and sheath to disengage the filter from the IVC wall. The applicant asserted that excessive pull forces have a higher risk of vasculature injury, filter breakage and fragmentation, and a potential for fragment embolization to the heart and/or lungs.

The applicant also clarified that devices in C1773 that do not retrieve IVC filters but are used for lead extraction (for example, Tightrail), generally feature a stainless steel cutting tool to mechanically dilate tissue surrounding a pacemaker or defibrillator lead. The device's stainless steel cutting tool features a handle, trigger, and drive mechanism that allows trigger pulls of the device to be converted into torque for mechanical dilation of tissue on the distal end. By contrast, CavaClear features fiberoptics for transmission of ultraviolet light to ablate tissue surrounding an IVC filter. Finally, the applicant noted that retrieval devices included in C1773 that are used to remove pacemaker and/or defibrillator cardiac implantable electronic devices are not indicated for and should not be used for retrieving IVC filters; the physician specialty performing lead extractions are electrophysiologists and cardiac surgeons, as compared to interventional radiologists and vascular surgeons who perform IVC filter removals; and the access site for these devices is different from CavaClear as the device is typically inserted into the subclavian vein as opposed to the jugular or femoral vein for CavaClear.

Response: We appreciate the input provided by these commenters. We have taken this information into consideration in making our final determination of the device category criterion, discussed below.

Comment: Along with the applicant, commenters urged CMS to establish a new pass-through payment category that describes CavaClear. The applicant asserted that CMS has set past precedent that would allow establishment of a narrower device category to account for new innovative technologies that were not contemplated when categories were first established. For example, CMS has established narrower device pass-through categories describing neurostimulators and transluminal angioplasty catheters to facilitate pass-through status for new technologies. Commenters asserted that these examples illustrate that CMS has, in the past, exercised flexibility in establishing new device categories that involve new technologies that appear to be described by existing broad categories. In doing so, the applicant asserted, CMS recognized that historical overly broad device categories may not necessarily be appropriate for new technologies that were not contemplated when the categories were established. The applicant urged CMS to exercise similar flexibility in evaluating CavaClear and creating a narrower device category to accurately describe the new technology. Several other commenters agreed with the applicant's assertion that CMS has the flexibility to create new device categories from existing broad categories to recognize technological advances within a device class.

Response: We appreciate the commenters' input. We agree with the applicant and commenters that CMS has the flexibility to create new device categories when we recognize that the existing device categories do not accurately describe the new proposed technology. However, we note that we must clearly establish that a proposed device is not described by existing device categories prior to exercising that flexibility. After consideration of the public comments we received, we agree there is no existing pass-through payment category that appropriately describes CavaClear because no current category appropriately describes an insertable introducer/sheath retrieval device that utilizes a photothermal cool laser to ablate caval tissue and retrieve intact IVC filters that are no longer clinically indicated. Neither pass-through category C2629 nor C1773 fully describes CavaClear and its complex mechanism of action. Based on this information, we have determined that CavaClear meets the first eligibility criterion at § 419.66(c)(1).

We received additional public comments regarding § 419.66(c)(1) that

did not impact our decision on whether or not CavaClear meets the § 419.66(c)(1) criterion, however we address these comments below.

Comment: The applicant stated that they believe CMS is adopting an overly restrictive interpretation of the device category requirements, particularly as they relate to devices with FDA Breakthrough Device designation. The applicant asserted that CMS' interpretation of the criteria for a new device category for CavaClear suggests that any new technology that could be aligned to an existing category that was created more than 20 years ago, despite unique characteristics that differentiate it from other devices in the category, would automatically fail to meet the threshold for a new device category. The applicant further stated that both categories CMS identifies as potentially describing CavaClear (C2629 and C1773) were established over two decades ago and use very broad language to describe existing technologies and technology development at the time; however, technologies have advanced significantly since then, and thus, these broad categories may be unnecessarily restricting pass-through status for technologies that are indeed novel.

Response: We appreciate the commenter's feedback; however, we disagree that our current interpretation of the device category requirements suggests that any new technology that could be aligned to a previous or existing device category would automatically fail to meet the threshold for a new device category. To the contrary, as the commenters noted, CMS has historically established device codes for new and innovative technologies when it has been determined that the proposed category is not appropriately described by any of the existing categories or by any category previously in effect. Device pass-through applications in no way automatically fail to meet the threshold for a new device category, rather, CMS' goal is to evaluate each application to clearly ascertain whether the proposed device is described by any of the existing categories or by any category previously in effect in order to determine if a new device category should be established.

Comment: The applicant expressed concern that CMS' interpretation of the device category requirement will result in inappropriate limits upon the use of the Alternative Pathway for device pass-through and encouraged CMS to consider the totality of evidence when assessing whether a device falls into an existing device category. Specifically, the applicant encouraged CMS to consider factors such as different mechanisms of action, unmet medical need, and differentiated clinical use when evaluating a new category.

Response: We appreciate the commenters' feedback. We disagree that our current interpretation of the device category requirement will result in inappropriate limits upon the use of the Alternative Pathway for device pass-through. CMS has established an evaluation process that ensures that we have the information we need to evaluate applications and make determinations based on the totality of the evidence; part of that evaluation is determining if a previous or existing device code appropriately describes the proposed device. We appreciate the suggestions made by the commenters regarding the factors CMS should use to evaluate the device category requirement and appreciate their support to our current process.

Comment: The applicant requested that CMS modify the device pass-through criteria to automatically consider devices with FDA Breakthrough Device designation to not be appropriately described by any of the existing or previous device categories, and therefore, meet the § 419.66(c)(1) criterion. The applicant noted that when CMS established an alternative pathway for Breakthrough Devices seeking new technology add-on payment in the inpatient hospital setting, CMS stated, ''if a medical device is part of FDA's Breakthrough Devices Program and received FDA marketing authorization, it would be considered new and not substantially similar to an existing technology for purposes of the new technology add-on payment.'' The applicant argued that to ensure consistency in policy across payment systems, CMS should deem CavaClear new for the purpose of device pass-through, and not described by an existing or past category.

Response: We appreciate the commenters' feedback. Under the IPPS, beginning with applications for FY 2021, a medical device designated under FDA's Breakthrough Devices Program that has received marketing authorization as a Breakthrough Device, for the indication covered by the Breakthrough Device designation, may qualify for the new technology add-on payment under an alternative pathway. Under an alternative pathway, a technology will be considered not substantially similar to an existing technology for purposes of the new technology add-on payment under the IPPS and will not need to meet the requirement that it represents an advance that substantially improves, relative to technologies previously available, the diagnosis or treatment of Medicare beneficiaries. These technologies must still be within the 2- to 3-year newness period to be considered ''new'' and must also still meet the cost criterion (88 FR 58919).

When we adopted the alternative pathway for device pass-through payments under the OPPS, we stated that applications for devices that have received FDA marketing authorization and are part of the FDA Breakthrough Devices Program would not be 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 would continue to need to meet the other requirements for pass-through payment status in our regulations at § 419.66(c)(1) (84 FR 61295). The commenter is correct that under the alternative pathway for device pass-through status under the OPPS, a device must still meet the device category criterion at § 419.66(c)(1), consistent with the policy we adopted beginning in CY 2020. We recognize that this feature of the OPPS alternative pathway for Breakthrough Devices differs from the IPPS alternative pathway because Breakthrough Devices do not need to meet the substantial similarity requirement. Nonetheless, we do not believe that the current policy creates a barrier to devices with Breakthrough Device designation and note that we have previously granted OPPS device pass-through status for Breakthrough Devices that have applied for the alternative pathway, including the devices discussed in this final rule with comment period, because these devices have not been described by existing device categories or those previously in effect.

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 is included in the category that has demonstrated that it will substantially improve the diagnosis or treatment of an illness or injury or improve the functioning of a malformed body party 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 is part of FDA's Breakthrough Devices Program and has received FDA marketing authorization for the indication covered by the Breakthrough Device designation. We explained in the proposed rule that CavaClear has a Breakthrough Device designation and

marketing authorization from FDA for the indication covered by the Breakthrough Device designation, and therefore, appears to meet the criterion at § 419.66(c)(2)(ii) and is not evaluated for substantial clinical improvement.

The third criterion for establishing a device category, at § 419.66(c)(3), requires us to determine if 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 cost significance requirements. The applicant stated that CavaClear would be reported with HCPCS code listed in Table 85.

TABLE 85: HCPCS CODE REPORTED WITH CAVACLEAR

HCPCS Code	Long Descriptor	SI	APC
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	J1	5183

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. As we explained in the CY 2005 OPPS final rule with comment period (69 FR 65775), we generally use the lowest APC payment rate applicable for use with the nominated device when we assess whether a device meets the cost significance criterion, thus increasing the probability the device will pass the cost significance test. For our calculations, we used APC 5183, which had a CY 2022 payment rate of $2,923.63 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). HCPCS code 37193 had a device offset amount of $762.48 at the time the application was received.[15] According to the applicant, the cost of CavaClear is $3,165.00.

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 $3,165.00 for CavaClear is 108.26 percent of the applicable APC payment amount for the service related to the category of devices of $2,923.63 (($3,165.00/$2,923.63) × 100 = 108.26 percent). Therefore, we stated that we believed CavaClear 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 $3,165 for CavaClear is 415.09 percent of the cost of the device-related portion of the APC payment amount for the related service of $762.48 (($3,165.00/$762.48) × 100 = 415.09 percent). Therefore, we stated that we believed CavaClear 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 $3,165.00 for CavaClear and the portion of the APC payment amount for the device of $762.48 is 82.18 percent of the APC payment amount for the related service of $2,923.63 ((($3,165.00 − 762.48)/$2,923.63) × 100 = 82.18 percent). Therefore, we stated that we believed that CavaClear meets the third cost significance requirement.

We invited public comment on whether CavaClear meets the device pass-through payment criteria discussed in this section, including the cost criterion for device pass-through payment status.

Comment: The applicant reiterated that it believes it satisfies the criterion at 42 CFR 419.66(c)(3) and that the cost of the device is not insignificant as determined by CMS' analysis of the three cost significance criteria for CavaClear.

Response: We appreciate the commenter's input. Based on our findings from the first, second, and third cost significant tests, we believe that CavaClear meets the cost significance criteria specified at § 419.66(d).

We invited public comment on whether CavaClear meets the device pass-through payment criteria discussed in this section.

Comment: Several commenters, including the applicant, submitted comments in support of pass-through payment approval for CavaClear. A few commenters underlined that pass-through payment approval for CavaClear will help increase Medicare beneficiary access to technological advancements in treatment. Several commenters also stated that CavaClear addresses an unmet medical need and provides the ability to remove IVC filters that otherwise would remain in place, leaving patients with significant symptoms. They further asserted that CavaClear will have an impact on reducing complications from IVC filter removals, time spent on IVC filter removals, and associated healthcare costs.

Response: We appreciate the commenters' input on the potential impact on Medicare beneficiary access, safety, and associated healthcare costs.

After our review of the device pass-through application and consideration of the public comments we received, we have determined that CavaClear meets

[15] We noted that the applicant selected a value of $537.36 for the device offset amount. However, the value selected is inconsistent with the device offset amount related to HCPCS 37193 in APC 5183 found in Addendum P to the CY 2022 OPPS/ASC final rule with comment period, as corrected in the 2022 Correction Notification OPPS Addendum (87 FR 2060). We selected the value of $762.48, which we believe is the accurate value. Based on our initial assessment for the proposed rule, using the device offset amount of $762.48 would result in CavaClear meeting the cost significance requirement.

the requirements for device pass-through status described at § 419.66. As stated previously, 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)(i) for the purposes of determining device pass-through payment status but must meet the other criteria for device pass-through status. We believe CavaClear meets those other criteria, and therefore, effective beginning January 1, 2024, we are finalizing approval for device pass-through payment status for CavaClear under the alternative pathway for devices that have an FDA Breakthrough Device designation and have received FDA marketing authorization for the indication covered by the Breakthrough Device designation.

(b) CERAMENT® G

BONESUPPORT AB submitted an application for a new device category for transitional pass-through payment status for CERAMENT® G for CY 2024. Per the applicant, CERAMENT® G is a single-use implantable bone void filler combination device/drug that remodels into bone and elutes gentamicin. The applicant further explained that CERAMENT® G is an adjunct to systematic antibiotic therapy as part of the surgical treatment of osteomyelitis (that is, bone infection) in the extremities and is used where there is a need for supplemental bone void filler material. The applicant asserted that CERAMENT® G can reduce the recurrence of chronic osteomyelitis from gentamicin-sensitive microorganisms to protect bone healing and augment provisional hardware to help support bone fragments during the surgical procedure. The applicant stated that CERAMENT® G is the first on-label solution for a one-stage surgical approach to treating bone infections with its unique dual mode of action: (1) promote bone healing (bone remodeling), and (2) protect bone healing (elution of a local broad-spectrum antibiotic). According to the applicant, once implanted, CERAMENT® G resorbs overtime and remodels into bone in 6 to 12 months.

Per the applicant, CERAMENT® G is comprised of three key compounds: (1) hydroxyapatite (HA), (2) calcium sulfate (CaS), and (3) gentamicin sulfate. According to the applicant, by combining calcium sulfate and hydroxyapatite, a balance is achieved between implant resorption rate and bone remodeling rate. The applicant further explained that the CaS acts as a resorbable carrier for HA. The applicant described that HA has a slow resorption rate and high osteoconductivity promoting bone remodeling and thus gives long-term structural support to the newly-formed bone. The gentamicin sulfate is a broad-spectrum aminoglycoside antibiotic that is sensitive to a spectrum of aerobic bacteria, particularly gram-negative bacilli, as well as aerobic gram-positive cocci, in particular Staphylococcus aureus, some coagulase negative staphylococci (CoNS) (for example, Staphylococcus epidermidis), and some strains of streptococci. According to the applicant, the gentamicin sulfate is present in the bone void filler to prevent colonization from gentamicin-sensitive microorganisms to protect bone healing.

Per the applicant, CERAMENT® G is comprised of eight components (these components contain the three key compounds as well as other parts for the successful application of CERAMENT® G): (1) CERAMENT® CMI, a closed mixing injection system pre-packed with ceramic bone substitute (CBS), is a mixture of the CaS (60 wt percent) and HA (40 wt percent). The applicant further explained that the mixing device is comprised of a 60 mL syringe, which in its proximal part is equipped with a movable combined plunger and mixing paddle, and in its distal part with a luer-lock connection. The movable mixing paddle allows effective mixing of the material inside the syringe. Calcium Sulfate and Hydroxyapatite (CSH) are the setting component of the bone void filler, and per the applicant, this component will react to calcium sulfate dihydrate (CSD) and will be resorbed over time, giving place for natural bone to grow into the bone graft. The applicant described that CSD is added as a seeding agent to accelerate the setting reaction of CSH to CSD, and that HA is an osteoconductive mineral similar to natural bone (this part of the bone graft substitute will not be resorbed and does not need to be surgically removed). The applicant stated that CSH and CSD conform to specifications based on the monograph Calcium Sulfate Dihydrate 0982, European Pharmacopoeia (EP) and the Official Monograph for Calcium Sulfate U.S. Pharmacopoeia/National Formulary (USP) as well as internal requirements; (2) CERAMENT® ID, an injection device used to inject the paste into the bone void or gap; (3) Valve, a needleless valve needed for the transfer of the ceramic paste from the CERAMENT® CMI to the CERAMENT® ID; (4) Tip Extenders, which are sterile, plastic needles with an inner diameter of 2.55 mm and two lengths (50 and 100 mm), that are connected to the CERAMENT® ID to facilitate placement of the paste at the debridement site; (5) CERAMENT® GENTAMICIN, the gentamicin sulfate in a glass vial equipped with a stopper and a cap. The gentamicin sulfate subcomponent has a potency equivalent to ≥590μg gentamicin/mg (anhydrous substance) and is dissolved in the 0.9 percent sterile sodium chloride solution and mixed with the CBS powder. Per the applicant, the prepared paste sets to a calcium sulfate dihydrate matrix with embedded hydroxyapatite particles, and gentamicin sulfate. The applicant further explained that it delivers 17.5 mg gentamicin per mL paste. Per the applicant, the gentamicin sulfate subcomponent complies with the EP monograph for gentamicin sulfate; (6) CERAMENT® MIXING LIQUID, a sterile sodium chloride, (NaCl) solution, 9 mg per mL in a glass vial. Per the applicant, it is the liquid component of CERAMENT® G. This component contains water which is needed for the calcium sulfate reaction to occur. The liquid meets requirements of the compendial excipient of USP/EP grade and is also registered in the inactive ingredient database; (7) BONESUPPORT DP, which includes two ventilated dispensing pins to facilitate easy handling when preparing the gentamicin solution; and (8) BONESUPPORT SYRINGE, a single packed, sterile 10 mL syringe with a male/female rotator assembly, and is used when preparing the gentamicin solution.

According to the applicant, after the surgical site has been prepared and any dead bone is debrided (that is, removed), the CERAMENT® G paste is prepared by the surgeon or surgical technician by: (1) mixing the gentamicin powder with the provided saline to make a gentamicin liquid; (2) adding the gentamicin liquid to the powder in the CERAMENT® CMI syringe and mixing the gentamicin liquid and powder; and (3) transferring the resulting paste to a smaller delivery syringe. Four minutes after the start of mixing, the paste is ready to be used as a bone void filler. Per the applicant, it can be injected using the tip extenders provided in the kit or by attaching a needle to the delivery syringe, or it can be placed into a bead mold to form beads. Fifteen minutes after the start of mixing, CERAMENT® G can be drilled into, if required. At 20 minutes, it is fully set, at which time the wound can be closed.

As stated previously, to be eligible for transitional pass-through payment under the OPPS, a device must meet the criteria at § 419.66(b)(1) through (4).

With respect to the newness criterion at § 419.66(b)(1), CERAMENT® G received FDA Breakthrough Device designation effective March 12, 2020, as a resorbable, gentamicin-eluting ceramic bone graft substitute intended for use as a bone void filler as an adjunct to systemic antibiotic therapy and surgical debridement (standard treatment approach to a bone infection) as part of the surgical treatment of osteomyelitis. By eluting gentamicin, CERAMENT® G can inhibit the colonization of gentamicin-sensitive microorganisms to protect bone healing. CERAMENT® G can augment provisional hardware to help support bone fragments during the surgical procedure and is resorbed and replaced by bone during the healing process. FDA granted the applicant De Novo classification for CERAMENT® G under the generic name, ''Resorbable calcium salt bone void filler containing a single approved aminoglycoside antibacterial substance'' on May 17, 2022, for the same indication as the one covered by the Breakthrough Device designation. We received the application for a new device category for transitional pass-through payment status for CERAMENT® G on May 31, 2022, which is within 3 years of the date of the initial FDA marketing authorization.

We invited public comment on whether CERAMENT® G meets the newness criterion at § 419.6C6(b)(1).

We did not receive public comments regarding whether CERAMENT® G meets the newness criterion at § 419.66(b)(1). We received the application for a new device category for transitional pass-through payment status for CERAMENT® G on May 31, 2022, which is within 3 years of FDA Breakthrough Device designation effective March 12, 2020, and the FDA De Novo classification on May 17, 2022. As such we have concluded that CERAMENT® G meets the newness criterion.

With respect to the integral part of the service criterion at § 419.66(b)(3), the applicant did not indicate whether CERAMENT® G is integral to the service provided. However, per the applicant, CERAMENT® G is used for one patient only, comes in contact with human tissue, and is surgically implanted or inserted into the patient as required at § 419.66(b)(3).

We invited public comment on whether CERAMENT® G meets the eligibility criterion at § 419.66(b)(3).

We did not receive public comments regarding whether CERAMENT® G meets the eligibility requirements at § 419.66(b)(3). Based on the information we have received and our review of the application, we determined that CERAMENT® G is integral to the service provided, used for one patient only, comes in contact with human tissue, and is surgically implanted or inserted. Therefore, based on our review of the application, we have determined that CERAMENT® G meets the eligibility criteria at § 419.66(b)(3).

With respect to the exclusion criterion at § 419.66(b)(4), the applicant did not address whether CERAMENT® G is equipment, an instrument, apparatus, implement, or item of this type for which depreciation and financing expenses are recovered, or if CERAMENT® G is a supply or material furnished incident to a service.

We invited public comment on whether CERAMENT® G meets the exclusion criterion at § 419.66(b)(4).

We did not receive public comments regarding whether CERAMENT® G meets the eligibility requirements at § 419.66(b)(4). Based on the information we have received and our review of the application, we determined that CERAMENT® G is not a piece of equipment, 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. Therefore, based on our review of the application, we have determined that CERAMENT® G meets the eligibility criteria at § 419.66(b)(4).

In addition to the criteria at § 419.66(b)(1) through (4), 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 described CERAMENT® G as a single-use implantable bone void filler combination device/drug that remodels into bone and elutes gentamicin. The applicant asserted that there are no existing bone void filler devices cleared or approved for use in the U.S. for single stage surgical reconstruction of bone defects that provide stability, promote bone formation, and effectively support the surgical treatment of infection by antibiotic elution. However, for comparison purposes, the applicant listed HCPCS code C1734 (Orthopedic/device/drug matrix for opposing bone-to-bone or soft-tissue-to-bone (implantable), as a device category that it considers similar to CERAMENT® G's device category.[16]

The applicant stated that CERAMENT® G differs from the bone substitutes AUGMENT® and AUGMENT® Injectable [17] (devices described by HCPCS code C1734). We noted that CMS approved an application for AUGMENT® Bone Graft as a new device category for transitional pass-through payment status and established HCPCS code C1734 as a new device category beginning in CY 2020. We referred readers to the CY 2019 OPPS/ASC final rule with comment period (84 FR 61292 through 61294) for a full discussion of the AUGMENT® Bone Graft application and decision.[18] The applicant asserted that CERAMENT® G and AUGMENT® differ in terms of the product composition and mechanism of action or intended use. In addition, the applicant asserted that the products are intended for different groups of patients. With respect to composition, per the applicant, CERAMENT® G consists of HA, CaS, and gentamicin sulfate. In contrast, the applicant stated that AUGMENT® consists of beta-tricalcium phosphate (β-TCP) and recombinant human platelet-derived growth factor (rhPDGF–BB), and AUGMENT® Injectable consists of β-TCP, rhPDGF–BB, and a collagen matrix. With respect to the mechanism of action, the applicant stated that CaS in CERAMENT® G acts as a resorbable carrier for HA, which has a slow resorption rate and high osteoconductivity, providing a scaffold for new bone generation. The applicant further explained that by combining CaS and HA, a gentamicin, CERAMENT® G can reduce the recurrence of chronic osteomyelitis from gentamicin-sensitive microorganisms to protect bone healing. In contrast, according to the applicant, the rhPDGF–BB in AUGMENT® acts as

[16] HCPCS code C1734 is a device category for which pass-through status was extended for a 1-year period beginning January 1, 2023, by section (a)(2) of the Consolidated Appropriations Act, 2023 (CAA, 2023) (Pub. L. 117–328), titled ''Extension of Pass-Through Status Under the Medicare Program for Certain Devices Impacted by COVID–19.'' *https://www.cms.gov/files/document/r11801cp.pdf.*

[17] The applicant differentiates itself from AUGMENT® and AUGMENT® Injectable, but does not use the term ''AUGMENT® Bone Graft'' in the application. However, the link provided in the application goes to the AUGMENT® web page that describes AUGMENT® Regenerative Solutions, AUGMENT® Bone Graft and AUGMENT® Injectable. We use the term ''AUGMENT®'' to collectively refer to the AUGMENT® products described herein and those listed on the AUGMENT® website. The applicant provided web page (in footnote): AUGMENT BONE GRAFT website: *http://www.augmentbonegraft.com/healthcare-professionals/.*

[18] *https://www.govinfo.gov/content/pkg/FR-2019-11-12/pdf/2019-24138.pdf.*

a chemo-attractant and mitogen for cells involved in wound healing and promotes angiogenesis at the site of healing, and the β-TCP acts as a bone void filler to prevent soft tissue from collapsing into the void.

Per the applicant, CERAMENT® G is indicated for use as a bone void filler in skeletally mature patients as an adjunct to systemic antibiotic therapy and surgical debridement (standard treatment approach to a bone infection) as part of the surgical treatment of osteomyelitis in defects in the extremities. In contrast, per the applicant, AUGMENT® and AUGMENT® Injectable are indicated for use as an alternative to autograft in arthrodesis in patients who require a bone fusion, such as patients who have arthritis, avascular necrosis, joint instability or deformity, or require joint arthroplasty of the ankle and/or hindfoot. Further, the applicant asserted that AUGMENT® cannot be used in the patients for whom CERAMENT® G is indicated because AUGMENT® is specifically contraindicated in patients with an active infection at the operative site.

We noted that, based on the description of the device provided by the applicant, CERAMENT® G and AUGMENT® differ in terms of composition and intended use, but also noted that device categories are not intended to be device-specific. Rather, device categories are intended to encompass any device that can be appropriately described by the category. As such, when we evaluate a potential pass-through device to determine whether it meets the device category criterion at § 419.66(c)(1), we compare the subject device to the device category descriptor rather than to the specific device for which the device category was created. Specifically, C1734 describes any device that meets the following descriptor: Orthopedic/device/drug matrix for opposing bone-to-bone or soft-tissue-to-bone (implantable), and per the applicant, CERAMENT® G is described as an implantable device/drug matrix that, with its intended use, will oppose soft-tissue-to-bone. In this context, we stated that we believe CERAMENT® G may be similar to the devices currently described by C1734, and therefore CERAMENT® G may also be appropriately described by C1734.

We invited public comment on whether CERAMENT® G meets the device category criterion at § 419.66(c)(1).

Comment: In response to our concerns that CERAMENT® G may be appropriately described by C1734, the applicant commented that CERAMENT® G meets eligibility requirements of § 419.66(c)(1), stating that CERAMENT® G can be distinguished from the device currently described by HCPCS code C1734 and, as such, meets the device category criterion. Specifically, the applicant asserted that CERAMENT® G differs from the device described in C1734 by composition, mechanisms of action, indication for use, intended patient population, associated treatment cases and procedures, and by FDA designation and classification.

All commenters addressing the CERAMENT® G transitional pass-through application offered support for approval of the application and creation of a new device category. The applicant provided that CERAMENT® G was granted Breakthrough Device designation by FDA as a class II device with the following indication for use: CERAMENT® G is a resorbable, gentamicin-eluting ceramic bone void filler intended for use as a bone void filler in skeletally mature patients as an adjunct to systemic antibiotic therapy and surgical debridement (standard treatment approach to a bone infection) as part of the surgical treatment of osteomyelitis in defects in the extremities. The applicant further commented that one of the requirements of FDA class II designation was to assure that there is no risk of antimicrobial resistance from using the product, and that the antimicrobial properties of CERAMENT® G are unique, and robust clinical evidence demonstrates that recurrence of infection is reduced with the use of CERAMENT® G in the management of bone infection.

With respect to our concern that CERAMENT® G may be appropriately described by C1734, the applicant stated that CERAMENT® G differs significantly from the device, AUGMENT®, described in the C1734 category (Orthopedic/device/drug matrix for opposing bone-to-bone or soft-tissue-to-bone (implantable)). The applicant asserted that the most important fundamental differences between CERAMENT® G and AUGMENT® is their composition and their intended patient population. Specifically, the applicant asserted, and all commenters agreed, that the antimicrobial properties in the CERAMENT® G composition are unique. Further, the applicant reiterated that CERAMENT® G is intended for patients with bone infection as an adjunct to systemic antibiotic therapy and surgical debridement (standard treatment approach to a bone infection) as part of the surgical treatment of osteomyelitis in defects in the extremities, with all commenters stating that CERAMENT® G is the only approved bone void filler that does this. The only device described by C1734, AUGMENT®, does not contain an antimicrobial agent, is intended for patients requiring ankle and foot bone fusion due to arthritis-related conditions, avascular necrosis and/or joint instability, is not intended for use in patients with bone infection, and is contraindicated to local infection at the site of implantation.

The applicant also sought to clarify how, in comparison to the device described in C1734 category, CERAMENT® G's mechanism of action is unique. Commenters stated that CERAMENT® G's mechanism of action is unique, in that it is the only approved bone void filler that elutes antibiotics directly into the site of infection and bone. Some commenters also noted that this unique mechanism of action allows for single-stage procedures in the outpatient setting for a patient with osteomyelitis compared to treatment that consists of six weeks or more of intravenous antibiotics that can lead to adverse events such as acute kidney injury and the development of multidrug resistant bacteria. The applicant reiterated that CERAMENT® G's unique mechanism of action is that it elutes gentamicin (the antimicrobial agent) to protect against gentamicin-sensitive microorganisms. Specifically, while both CERAMENT® G's and AUGMENT®'s mechanisms of action include providing an osteoconductive scaffold for new bone generation, CERAMENT® G also elutes gentamicin to protect against microorganisms, which AUGMENT® does not. The applicant further clarified that CERAMENT® G augments provisional hardware to help support bone fragments during the surgical procedure and acts only as a temporary support media and is not intended to provide structural support during the healing process. One commenter noted that having predictable and sustained release of gentamicin with CERAMENT® G is a major differentiator which contributes to successful clinical outcomes, and that CERAMENT® G's antimicrobial property is important to protect bone healing and in turn, prevent the recurrence of infection.

The applicant also asserted that CERAMENT® G can be distinguished from the only device described in C1734, AUGMENT®, based on their associated treatment cases and procedures. The applicant reiterated that CERAMENT® G's associated treatment cases are those addressing patients with a bone infection, whereas

AUGMENT®'s associated treatment cases are those addressing patients who require ankle and foot bone fusion. Further, the applicant clarified that CERAMENT® G's associated procedures (CPT codes) are in Musculoskeletal Procedure Levels 2, 3, and 4, which correspond to APC 5112, 5113, and 5114. In contrast, the procedures indicated for AUGMENT® are for Musculoskeletal Procedures Levels 5 and 6, which correspond to APC 5115 and 5116. The applicant noted that this results in distinct APC payment ranges for CERAMENT® G and AUGMENT®. Specifically, based on the corresponding APC for each device, the Medicare payment range for CERAMENT® G would be $1,535.85 to $6,895.06, and for AUGMENT® it is $13,269.40 to $20,692.25.

Response: We appreciate the input provided by these commenters. We have taken this information into consideration in making our final determination of whether to establish a new device category for CERAMENT® G, discussed below.

Comment: Along with the applicant, commenters urged CMS to establish a new device category that describes CERAMENT® G's unique composition and mechanism of action. The applicant asserted that CMS has set past precedent that would allow establishment of a new device category to account for new-technology antimicrobial products. For example, per the applicant, CMS has routinely recognized the diversity of physician-administered drugs and biologicals within its policy for granting transitional pass-through payment status and has not lumped all drugs and biologicals into a single category. The applicant asserted this unique antimicrobial composition and mechanism of action of CERAMENT® G merits a new and different device category than that described by C1734, and that a new category should acknowledge the antimicrobial properties of CERAMENT® G. The applicant urged CMS to exercise similar flexibility in evaluating CERAMENT® G and to create a new device category to accurately describe the new technology, in this case a new device/drug antimicrobial technology.

Response: We appreciate the commenters' input. We agree with commenters that CMS has a precedent of establishing new device categories to account for new and innovative technologies not described by existing device categories. While the evaluation of physician-administered drugs and biologicals provided as an example by the applicant is not applicable to our determination of whether to grant transitional pass-through payment status for a particular device, we nevertheless agree with the applicant and commenters that there are circumstances where a new device category must be created because the existing device categories do not describe a new technology.

After consideration of the public comments we received, we agree there is no existing pass-through payment device category that appropriately describes CERAMENT® G because no current category appropriately describes bone void filler devices cleared or approved for use for single stage surgical reconstruction of bone defects that provide stability, promote bone formation, and support the surgical treatment of infection by antibiotic elution antimicrobial agent. Based on this information, we have determined that CERAMENT® G meets the first eligibility criterion at § 419.66(c)(1).

We received additional public comments regarding § 419.66(c)(1) that did not impact our decision on whether or not CERAMENT® G meets the § 419.66(c)(1) criterion, however we address these comments below.

Comment: The applicant commented that antimicrobial products should receive equal benefits in the outpatient setting as they do in the inpatient setting. The applicant suggested that CMS should acknowledge the importance of preventing antimicrobial resistance and promoting antibiotic stewardship in the hospital outpatient setting by creating new device categories for device pass-through payment that differentiate antimicrobial products from non-antimicrobial products. Specifically, the applicant proposed that CMS adopt an initiative similar to the alternative technology add-on payment pathway for Qualified Infectious Disease Products (QIDPs) established in the FY 2020 IPPS/LTCH PPS final rule.[19] The applicant urged CMS to grant new device categories to technologies that promote CMS goal of confronting antimicrobial resistance, asserting that separating these technologies acknowledges the fact that products with antimicrobial fighting properties can be more expensive and ensures that companies are adequately reimbursed for their products while avoiding excessive reimbursement of less expensive non-antimicrobial devices.

The applicant requested that CMS take the antimicrobial performance of CERAMENT® G into account when considering approval of the device pass-through payment application. Specifically, the applicant further stated that the antimicrobial properties in CERAMENT® G effectively reduce the recurrence of infection. Citing McNally et al.,[20] the applicant stated that mid- to long-term clinical outcomes of CERAMENT® G in a single-stage protocol show high levels of effectiveness where 94 percent of patients were infection-free after a mean follow-up of 6.05 years, and that in patients with recurrent infection, no cultures identified new resistance to gentamicin.

Response: We appreciate the commenters' feedback. Regarding the request to develop an alternative pathway for device pass-through payments for other special designations (other than those that are part of the FDA's Breakthrough Device program and have received marketing authorization for the indication covered by the Breakthrough Device designation, as previously discussed), we recognize that the goal of facilitating access to new technologies for Medicare beneficiaries could also apply to other designations, and we will keep these suggestions in mind for consideration in future rulemaking.

With respect to the applicant's request that CMS take the antimicrobial performance of CERAMENT® G into account when considering approval of the device pass-through payment application, we appreciate the input provided by these commenters. We have taken this information into consideration in making our final determination of whether to establish a new device category for CERAMENT® G, discussed below.

Comment: The applicant, and all commenters, asserted that without a new device category, CERAMENT® G will not be accessible in the outpatient setting because the reimbursement without a transitional pass-through payment would not cover the cost of outpatient surgery with CERAMENT® G. Specifically, the applicant reiterated the information in their application that the average cost per case treated with CERAMENT® G of $7,567 is much greater than the Medicare payment rates for the assigned APCs. The applicant further asserted that several doctors have expressed their concerns about being able to access and provide

[19] We refer readers to the FY 2020 IPPS/LTCH PPS final rule with comment period (84 FR 42294 through 42297) for a full discussion of the Qualified Infectious Disease Products (QIDPs) policy.

[20] McNally, M.A., Ferguson, J.Y., Scarborough, M., Ramsden, A., Stubbs, D.A., and Atkins, B.L. (2022) Mid- to long-term results of single-stage surgery for patients with chronic osteomyelitis using a bioabsorbable loaded ceramic carrier. *The bone & joint journal, 104.B*(9), 1095–1100.

CERAMENT® G to patients in the hospital outpatient setting without the additional transitional pass-through payment available to supplement the existing APC payment rates. Commenters noted that access to CERAMENT® G in the outpatient setting is in the interest of Medicare beneficiaries to allow for outpatient surgeries that are otherwise moved to inpatient care.

Response: We appreciate the commenters' feedback and acknowledge the cost concerns related to the utilization of CERAMENT® G in the outpatient setting. 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. We address the cost of the CERAMENT® G and the cost significance criteria below.

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 is part of the FDA's Breakthrough Devices Program and has received FDA marketing authorization for the indication covered by the Breakthrough Device designation. CERAMENT® G has a Breakthrough Device designation and marketing authorization from FDA for the indication covered by the Breakthrough Device designation (as explained in more detail in the discussion of the newness criterion) and therefore appears to meet the criterion at § 419.66(c)(2)(ii) and is not evaluated for 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 CERAMENT® G would be reported with HCPCS codes listed in Table 86.

BILLING CODE 4150–28–P

TABLE 86: HCPCS CODES REPORTED WITH CERAMENT® G

HCPCS Code	Long Descriptor	SI	APC
21510	Incision, deep, with opening of bone cortex (e.g., for osteomyelitis or bone abscess), thorax	**	**
23035	Incision, bone cortex (e.g., osteomyelitis or bone abscess), shoulder area	J1	5112
23170	Sequestrectomy (e.g., for osteomyelitis or bone abscess), clavicle	J1	5113
23172	Sequestrectomy (e.g., for osteomyelitis or bone abscess), scapula	**	**
23174	Sequestrectomy (e.g., for osteomyelitis or bone abscess), humeral head to surgical neck	**	**
23180	Partial excision (craterization, saucerization, or diaphysectomy) bone (e.g., osteomyelitis), clavicle	J1	5114
23182	Partial excision (craterization, saucerization, or diaphysectomy) bone (e.g., osteomyelitis), scapula	J1	5114
23184	Partial excision (craterization, saucerization, or diaphysectomy) bone (e.g., osteomyelitis), proximal humerus	J1	5114
23935	Incision, deep, with opening of bone cortex (e.g., for osteomyelitis or bone abscess), humerus or elbow	J1	5113
24134	Sequestrectomy (e.g., for osteomyelitis or bone abscess), shaft or distal humerus	J1	5114
24136	Sequestrectomy (e.g., for osteomyelitis or bone abscess), radial head or neck	**	**
24138	Sequestrectomy (e.g., for osteomyelitis or bone abscess), olecranon process	J1	5114
24140	Partial excision (craterization, saucerization, or diaphysectomy) bone (e.g., osteomyelitis), humerus	J1	5113
24145	Partial excision (craterization, saucerization, or diaphysectomy) bone (e.g., osteomyelitis), radial head or neck	J1	5114
24147	Partial excision (craterization, saucerization, or diaphysectomy) bone (e.g., osteomyelitis), olecranon process	J1	5113
25035	Incision, deep, bone cortex, forearm and/or wrist (e.g., osteomyelitis or bone abscess)	J1	5114
25150	Partial excision (craterization, saucerization, or diaphysectomy) of bone (e.g., for osteomyelitis); ulna	J1	5113
25151	Partial excision (craterization, saucerization, or diaphysectomy) of bone (e.g., for osteomyelitis); radius	J1	5113
26230	Partial excision (craterization, saucerization, or diaphysectomy) bone (e.g., osteomyelitis); metacarpal	J1	5113
26992	Incision, bone cortex, pelvis and/or hip joint (e.g., osteomyelitis or bone abscess)	**	**

HCPCS Code	Long Descriptor	SI	APC
27070	Partial excision, wing of ilium, symphysis pubis, or greater trochanter of femur, (craterization, saucerization) (e.g., osteomyelitis or bone abscess); superficial	**	**
27071	Partial excision, wing of ilium, symphysis pubis, or greater trochanter of femur, (craterization, saucerization) (e.g., osteomyelitis or bone abscess); deep (subfascial or intramuscular) abscess); deep (subfascial or intramuscular)	**	**
27303	Incision, deep, with opening of bone cortex, femur or knee (e.g., osteomyelitis or bone abscess)	**	**
27360	Partial excision (craterization, saucerization, or diaphysectomy) bone, femur, proximal tibia and/or fibula (e.g., osteomyelitis or bone abscess)	J1	5113
27607	Incision (e.g., osteomyelitis or bone abscess), leg or ankle	J1	5113
27640	Partial excision (craterization, saucerization, or diaphysectomy), bone (e.g., osteomyelitis); tibia	J1	5113
27641	Partial excision (craterization, saucerization, or diaphysectomy), bone (e.g., osteomyelitis); fibula	J1	5113
28005	Incision, bone cortex (e.g., osteomyelitis or bone abscess), foot	J1	5113
28120	Partial excision (craterization, saucerization, sequestrectomy, or diaphysectomy) bone (e.g., osteomyelitis or bossing); talus or calcaneus	J1	5113
28122	Partial excision (craterization, saucerization, sequestrectomy, or diaphysectomy) bone (e.g., osteomyelitis or bossing); tarsal or metatarsal bone, except talus or calcaneus	J1	5113

** Denotes a HCPCS code that was not evaluated for the cost criterion because the HCPCS code was not included in Addendum P to the CY 2022 OPPS/ASC final rule with comment period, as corrected in the 2022 Correction Notification OPPS Addendum (87 FR 2060).

BILLING CODE 4150–28–C

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. As we explained in the CY 2005 OPPS final rule with comment period (69 FR 65775), we generally use the lowest APC payment rate applicable for use with the nominated device when we assess whether a device meets the cost significance criterion, thus increasing the probability the device will pass the cost significance test. For our calculations, we used APC 5112, which had a CY 2022 payment rate of $1,422.51 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). HCPCS code 23035 had a device offset amount of $217.36 at the time the application was received. We noted that the applicant submitted cost information for two different device sizes (5 ml and 10 ml) for CERAMENT® G. Per the applicant, the average patient will require approximately 10 ml per procedure, with a weighted cost of $7,567.00 per patient.

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 $7,567.00 for CERAMENT® G is 531.95 percent of the applicable APC payment amount for the service related to the category of devices of $1,422.51 (($7,567.00/$1,422.51) × 100 = 531.95 percent). Therefore, we stated that we believe CERAMENT® G 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 $7,567.00 for CERAMENT® G is 3,481.32 percent of the cost of the device-related portion of the APC payment amount for the related service of $217.36 (($7,567.00/$217.36) × 100 = 3,481.32 percent). Therefore, we stated that we believe CERAMENT® G 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 $7,567.00 for CERAMENT® G and the portion of the APC payment amount for the device of $217.36 is 516.67 percent of the APC payment amount for the related service of $1,422.51 ((($7,567.00

− $217.36)/$1,422.51) × 100 = 516.67 percent). Therefore, we stated that we believe CERAMENT® G meets the third cost significance requirement.

We invited public comment on whether the CERAMENT® G meets the device pass-through payment criteria discussed in this section, including the cost criterion for device pass-through payment status.

We did not receive public comments regarding whether CERAMENT® G meets the cost criteria at § 419.66(d)(1) through (3). Based on the information we have received, we have determined that CERAMENT® G meets the cost criterion for device pass-through payment status.

After consideration of the public comments we received, and our review of the device pass-through application, we have determined that CERAMENT® G meets the requirements for device pass-through status described at § 419.66. As stated previously, devices that are granted an FDA Breakthrough Device designation and have marketing authorization for the indication covered by the Breakthrough Device designation are not evaluated in terms of the current substantial clinical improvement criterion at § 419.66(c)(2)(i) for the purposes of determining device pass-through payment status but must meet the other criteria for device pass-through status. We believe CERAMENT® G meets the criteria at § 419.66, and therefore, effective beginning January 1, 2024, we are finalizing approval for device pass-through payment status for CERAMENT® G under the alternative pathway for devices that have an FDA Breakthrough Device designation and have received FDA marketing authorization for the indication covered by the Breakthrough Device designation.

(2) Traditional Device Pass-Through Applications

(a) Ambu® aScope™ 5 Broncho HD

Ambu Inc. submitted an application for a new device category for transitional pass- through payment status for the Ambu® aScope™ 5 Broncho HD for CY 2024. Per the applicant, the Ambu® aScope™ 5 Broncho HD is one component of the Ambu® aScope™ 5 Broncho HD System which consists of: (1) the Ambu® aScope™ 5 Broncho HD (5.0/2.2 or 5.6/2.8), a sterile, single-use, disposable flexible/rigid bronchoscope; and (2) Ambu® aBox™ 2, a compatible, reusable display unit. The applicant is only seeking a new device category for transitional pass through payment status for the Ambu® aScope™ 5 Broncho HD component.

Per the applicant, the Ambu® aScope™ 5 Broncho HD, consists of: (1) a handle, to hold the scope (designed for left or right hand); (2) a control lever, to move the distal tip up or down in a single plane; (3) a working channel and working channel port, for instillation of fluids and insertion of endotherapy instruments; (4) a biopsy valve, to be attached to the working channel port, for insertion of endotherapy instruments or attachment of a syringe; (5) a suction connector, for connection of suction tubing; (6) a suction button, to activate suction when pressed; (7) endoscope buttons 1 and 2 (depending on settings in display unit, the two remote switches allow for direct activation on handle of four different functionalities such as image and video capturing, initiate advanced red contrast (ARC), and zoom); (8) a rotation control ring, for rotation of the insertion cord during procedure; (9) a tube connection, for fixation of tubes with standard connector during procedure; (10) an insertion cord and insertion portion, flexible airway insertion cord; (11) bending section, maneuverable part; (12) distal tip, which contains the camera, light source (two light-emitting diodes (LEDs)), and the working channel exit; (13) display unit connector, to connect to the port on the Ambu® aBox™ 2 display unit; (14) a cable, to transmit the image signal to the Ambu® aBox™ 2 display unit; (15) a protective handle cover, to protect the control lever during transport and storage; (16) a protective pipe, to protect the insertion cord during transport and storage; and (17) an introducer, to facilitate introduction of luer lock syringes.

The applicant stated that the Ambu® aScope™ 5 Broncho HD is an imaging/illumination bronchoscope device that uses an integrated camera module and built-in dual LED illumination to provide access to, and imaging of, the lungs for diagnostic and therapeutic purposes for patients with pulmonary pathology. The device is intended for endoscopy and endoscopic surgery within the lungs, also known as bronchoscopy. According to the applicant, the Ambu® aScope™ 5 Broncho HD was designed to perform a wide array of diagnostic and interventional pulmonology procedures. The applicant noted that the Ambu® aScope™ 5 Broncho HD is a single-use bronchoscope designed to be used with the Ambu® aBox™ 2 display unit, endotherapy instruments and other ancillary equipment for bronchoscopic procedures, and examination within the airways and the tracheobronchial tree. It is intended to provide visualization via the compatible display unit, the Ambu® aBox™ 2, and to allow passage of endotherapy instruments via its working channel.

Per the applicant, the Ambu® aScope™ 5 Broncho HD bronchoscope is inserted into the patient airway through either the mouth, nose, or via a tracheostomy, if present. The applicant explained that when the Ambu® aScope™ 5 Broncho HD bronchoscope has reached the correct position, endotherapy instruments can be inserted into the working channel system of the bronchoscope. Per the applicant, an introducer supplied with the bronchoscope can be attached to the working channel port via a luer lock adaptor while the bronchoscope is in use. The applicant noted that the suction system may be used to remove blood, saliva, and mucus from the airway. The applicant indicated that a bronchoscope operator monitors the field of view via the integrated camera of the Ambu® aScope™ 5 Broncho HD bronchoscope and the procedure is finished when the device is pulled out completely.

As stated previously, to be eligible for transitional pass-through payment under the OPPS, a device must meet the criteria at § 419.66(b)(1) through (4). With respect to the newness criterion at § 419.66(b)(1), on July 25, 2022, the applicant received 510(k) clearance from FDA for the Ambu® aScope™ 5 Broncho HD as a device to be used for endoscopic procedures and examination within the airways and tracheobronchial tree. We received the application for a new device category for transitional pass-through payment status for the Ambu® aScope™ 5 Broncho HD on February 28, 2023, which is within 3 years of the date of the initial FDA marketing authorization.

We invited public comment on whether the Ambu® aScope™ 5 Broncho HD meets the newness criterion at § 419.66(b)(1).

We did not receive public comments regarding whether the Ambu® aScope™ 5 Broncho HD meets the newness criterion at § 419.66(b)(1). We received the application for a new device category for transitional pass-through payment status for Ambu® aScope™ 5 Broncho HD on February 28, 2023, which is within 3 years of July 25, 2022, the date of FDA 510(k) approval to market the Ambu® aScope™ 5 Broncho HD, and as such we have concluded that the Ambu® aScope™ 5 Broncho HD meets the newness criterion.

With respect to the eligibility criterion at § 419.66(b)(3), according to the

applicant, the Ambu® aScope™ 5 Broncho HD is integral to the service provided, is used for one patient only, comes in contact with human tissue, and is surgically inserted as required by § 4189.66(b)(3).

We invited public comment on whether the Ambu® aScope ™ 5 Broncho HD meets the criterion at § 419.66(b)(3).

We did not receive any comments on whether the Ambu® aScope ™ 5 Broncho HD meets the eligibility criteria at § 419.66(b)(3). Based on the information we have received and our review of the application, we agree with the applicant that Ambu® aScope ™ 5 Broncho HD is integral to the service provided, used for one patient only, comes in contact with human tissue, and is surgically implanted or inserted. Therefore, we have determined that Ambu® aScope ™ 5 Broncho HD meets the eligibility criterion at § 419.66(b)(3).

With respect to the exclusion criterion at § 419.66(b)(4), the applicant did not address whether the Ambu® aScope ™ 5 Broncho HD is equipment, an instrument, apparatus, implement, or item of this type for which depreciation and financing expenses are recovered, or if the Ambu® aScope ™ 5 Broncho HD is a supply or material furnished incident to a service.

We invited public comment on whether the Ambu® aScope™ 5 Broncho HD meets the exclusion criterion at § 419.66(b)(4).

Comment: The applicant asserted that the Ambu® aScope™ 5 Broncho HD meets the eligibility requirements at § 419.66(b)(4). The applicant clarified that the device is not equipment, an instrument, apparatus, implement, or item for which depreciation and financing are recovered. The applicant indicated that the device is not a material or supply furnished incident to a service. The applicant stated that the device is purely an operating cost and is not subject to capitalization or a depreciation schedule.

Response: We appreciate the applicant's input. Based on the information we have received and our review of the application, we agree with the applicant that the Ambu® aScope™ 5 Broncho HD meets the device eligibility requirements of § 419.66(b)(4) because it is not a piece of equipment, 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. Therefore, we have determined that the Ambu® aScope™ 5 Broncho HD meets the eligibility criterion at § 419.66 (b)(4).

In addition to the criteria at § 419.66(b)(1) through (4), 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 described the Ambu® aScope™ 5 Broncho HD as a single-use, disposable, digital flexible/rigid bronchoscope that is used in pulmonary procedures (bronchoscopy) to diagnose and treat conditions of the lungs, including tumors or bronchial cancer, airway blockage (obstruction), narrowed areas in airways (strictures), inflammation, and infections such as tuberculosis (TB), pneumonia, fungal or parasitic lung infections, interstitial pulmonary disease, causes of persistent cough, causes of coughing up blood, spots seen on chest X-rays, and vocal cord paralysis. The applicant claimed that the Ambu® aScope™ 5 Broncho HD is different from other endoscopes because it is a single-use endoscope indicated for use in the respiratory system, the device records snapshots or video of images, and the device is temporarily inserted into the patient airway to diagnose and treat lung problems. According to the applicant, there are two possible existing pass-through device categories, represented by the following codes: C1748 (Endoscope, single-use (that is, disposable), upper gastrointestinal tract (GI), imaging/illumination device (insertable)); and C1747 (Endoscope, single-use (that is, disposable), urinary tract, imaging/illumination device (insertable)). The applicant noted that while these two codes are for single-use endoscopic devices, they are only appropriate for GI and urinary tract imaging, respectively. Therefore, the applicant asserted that these two codes would not apply to a single-use, disposable, bronchoscope for use in pulmonary procedures. We noted that while C1748 and C1747 are intended to be used in different anatomical areas of the patient, the codes for both device categories describe devices that are single use and have imaging capabilities.

We invited public comment on whether the Ambu® aScope™ 5 Broncho HD meets the device category criterion at § 419.66(c)(1).

Comment: The applicant reiterated that the device is not appropriately described by any existing device categories. The applicant noted that although HCPCS codes C1747 and C1748 do describe single-use endoscopes and have imaging capabilities, they are intended to be used in different anatomical areas, specifically the urinary tract and the upper GI tract, respectively. The applicant asserted that the device is used in pulmonary procedures and meets the device category criterion. Another commenter referenced an FDA guidance [21] on the 510(k) Program issued on July 28, 2014, to support the applicant's assertion by stating that the device was cleared for marketing under 21 CFR 874.4680, and therefore the device cannot be legally labeled for use or otherwise promoted for GI/urology use.

Response: We appreciate the applicant and commenter's input. Based on the information we have received and our review of the application, we agree there is no existing pass-through payment category that appropriately describes the Ambu® aScope™ 5 Broncho HD because no current or previously in effect category describes a single-use endoscope indicated for use in the respiratory system. Based on this information, we have determined that the Ambu® aScope™ 5 Broncho HD meets the eligibility criterion at § 419.66(c)(1).

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 is part of the FDA's Breakthrough Devices Program and has received FDA marketing authorization for the indication covered by the Breakthrough Device designation. The applicant claimed that the Ambu® aScope™ 5 Broncho HD represents a substantial clinical improvement over existing technologies by: (1) eliminating complex cleaning/reprocessing procedures, (2) reducing microbial transmission and infection since it is single-use, (3) eliminating the need for continuous training of reprocessing staff, (4) minimizing the risk of patient

[21] FDA Guidance July 28, 2014. ''The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notification [510(k)]: Guidance for Industry and Food and Drug Administration Staff''.

cross-contamination, (5) assuring that a sterilized scope will be used each time, and (6) assuring that there will be no biofilm from endoscope channels. The applicant provided four articles, an FDA guidance letter, and an FDA safety notice specifically for the purpose of addressing the substantial clinical improvement criterion.

In support of its claim that the use of the Ambu® aScope™ 5 Broncho HD eliminates complex cleaning/reprocessing procedures because it is a single-use device, the applicant referenced an FDA Reprocessing Final Guidance document [22] issued March 17, 2015. This FDA document provides guidance to medical device manufacturers on the complex activities involved in crafting and validating reprocessing instructions that ensure that the device can be used safely and for the purpose for which it is intended. The guidance document is limited to reusable medical devices and single-use medical devices that are initially supplied as non-sterile to the user and require the user to process the device prior to its use. In this guidance document, the FDA identifies a subset of reusable medical devices (including bronchoscopes and accessories) that pose a greater likelihood of microbial transmission and represent a high risk of infection (subclinical or clinical) if they are not adequately reprocessed and indicates design features which may pose a challenge to adequate reprocessing for arthroscopes, laparoscopic instruments, and electrosurgical instruments, and their respective accessories. However, the FDA guidance does not mention sterile, single-use medical devices in this document.

In support of its claim that the use of the Ambu® aScope™ 5 Broncho HD reduces microbial transmission and infection because it is single use, the applicant referenced an FDA safety notice [23] issued on September 17, 2015 (2015 FDA safety notice). The FDA notice discussed the findings of an investigation into infections associated with reprocessed reusable medical devices, including an analysis of Medical Device Reports (MDRs) submitted to FDA from manufacturers and health care facilities. The notice provided that between January 2010 and June 2015, FDA received 109 MDRs concerning infections or device contamination associated with flexible bronchoscopes. However, FDA noted that, when compared to the number of bronchoscopy procedures performed in the U.S. each year, this is considered a small number of MDRs. In 2014, FDA received 50 MDRs that mentioned infections or device contamination associated with reprocessed flexible bronchoscopes, which prompted additional investigation of this issue. FDA indicated that a small number of the reported infections were from persistent device contamination despite following the manufacturer's reprocessing instructions, however, most of the infections were the result of the failure to meticulously follow manufacturer instructions for reprocessing, or the continued use of devices despite integrity, maintenance, and mechanical issues. FDA provided additional recommendations for health care facilities and staff that reprocess flexible bronchoscopes, and for patients considering bronchoscopy procedures, but did not reference single-use bronchoscopes in the notice.

In support of its claim that the use of the Ambu® aScope™ 5 Broncho HD eliminates the need for continuous training of reprocessing staff, the applicant referenced a study by Châteauvieux et al.,[24] which assessed the organizational and economic impacts of the introduction of a single-use flexible bronchoscope (FB) (Ambu® aScope™, versions 2 and 3) in comparison with a reusable FB (Pentax®) at the hospital level. The study took place between May 2016 and October 2016 in the Georges Pompidou European Hospital, an 800-bed university hospital in France. Châteauvieux et al. noted that the introduction of single-use FBs led to a more simplified process, less stress for medical and paramedical staff in emergency situations, teaching benefits, and easier management of transport, in comparison with reusable FBs. However, the authors recommended limiting the use of single use FBs to specific situations, and to prioritize the use of reusable devices for most of the bronchoscopies for cost savings.

The applicant referred to a meta study by Barron and Kennedy [25] to support its claim that the use of Ambu® aScope™ 5 Broncho HD minimizes the risk of patient cross-contamination, ensuring that health care providers have taken optimal steps to safeguard their patients. Barron and Kennedy summarized the major advantages of single-use FBs over the standard reusable FBs in clinical scenarios. The authors noted that single-use FBs offer a safer alternative to standard reusable FBs in specific scenarios where reduced risk of cross infection was critical in the immunocompromised patient and in rare cases of prior contamination due to transmissible spongiform encephalopathies.

The applicant referred to a self-sponsored study [26] by Ofstead et al.[27] in 2019, in support of its claim that the use of the Ambu® aScope™ 5 Broncho HD ensures a sterilized scope is available for each procedure while reusable endoscopes may not be sterile even if manufacturers' cleaning protocols are followed. The study first referenced Ofstead et al.'s 2017 [28] evaluation of the effectiveness of bronchoscope processing in three large hospitals where every bronchoscope had visible defects, protein was detected on 100 percent of high-level disinfected bronchoscopes, and bacteria or mold was found on 58 percent of the patient-ready bronchoscopes. Then, in 2019, Ofstead et al. conducted a study to determine the time and cost of acquiring, maintaining, and reprocessing bronchoscopes in four hospitals (two in the Midwest and two in the West Coast). Three hospitals had obtained single-use Ambu® bronchoscopes (2018, version unspecified) for procedures done in certain departments, after hours, or in emergency situations. Per Ofstead et al.

[22] FDA Guidance March 17, 2015. ''Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling: Guidance for Industry and Food and Drug Administration Staff''. *https://www.fda.gov/downloads/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm253010.pdf.*

[23] FDA Safety Communications, Infections Associated with Reprocessed Flexible Bronchoscopes: FDA Safety Communication, issued September 17, 2015. *https://www.fdanews.com/ext/resources/files/09-15/092115-safety-notice.pdf?1442508647.*

[24] Châteauvieux, C., Farah, L., Guérot, E., Wermert, D., Pineau, J., Prognon, P., Borget, I., & Martelli, N. (2018). Single-use flexible bronchoscopes compared with reusable bronchoscopes: Positive organizational impact but a costly solution. *Journal of evaluation in clinical practice, 24*(3), 528–535. *https://doi.org/10.1111/jep.12904.*

[25] Barron, S.P., & Kennedy, M.P. (2020). Single-use (disposable) flexible bronchoscopes: the future of bronchoscopy? *Advances in therapy, 37*(11), 4538–4548. *https://doi.org/10.1007/s12325-020-01495-8.*

[26] Ofstead et al. acknowledged that this study was supported by an unrestricted research grant from Ambu Inc. The study sponsor did not participate in designing the study, identifying sites, collecting data, compiling results, interpreting the findings, or writing this article.

[27] Ofstead, C.L., Hopkins, K.M., Eiland, J.E., & Wetzler, H.P. Managing bronchoscope quality and cost: results of a real-world study. *https://www.ambu.com/Files/Files/Ambu/Investor/News/English/2019/Managing%20Bronchoscope%20cost%20a%20real%20world%20study.pdf.*

[28] Ofstead C.L., Quick M.R., Wetzler H.P., et al. (2018) Effectiveness of reprocessing for flexible bronchoscopes and endobronchial ultrasound bronchoscopes. *Chest, 154*(5):1024–34.

(2019), the cost for procedures with reusable bronchoscopes ($281 to $803) were comparable or higher than the cost of single-use bronchoscopes ($220 to $315), due to acquisition and maintenance of large inventories of bronchoscopes to ensure real-time availability for various hospital departments. Ofstead et al. (2019) suggested the use of single-use bronchoscopes and accessories for after hours and emergency situations and any procedures that do not require advanced bronchoscopy capabilities. Ofstead et al. (2019) summarized the steps that can be taken to reduce risks related to bronchoscope contamination and to focus on implementing quality management systems to improve personnel competence, bronchoscope inventory management, maintenance, reprocessing effectiveness, and storage. In addition to following manufacturer's steps for reprocessing the devices, Ofstead et al. (2019) suggest the use of single-use bronchoscopes and accessories for after hours and emergency situations and any procedures that do not require advanced bronchoscopy capabilities, which are currently available in the list of recommendations.

The applicant referenced a review article by Kovaleva et al.[29] in support of its claim that the Ambu® aScope™ 5 Broncho HD's single-use feature is free of biofilm from endoscope channels since routine cleaning procedures do not remove biofilm reliably from endoscope channels. This review presents an overview of the infections and cross-contaminations related to flexible gastrointestinal endoscopy and bronchoscopy and illustrates the impact of biofilm on endoscope reprocessing and post-endoscopic infection. Kovaleva et al. noted that the use of antibiofilm-oxidizing agents with an antimicrobial coating inside washer disinfectors could reduce biofilm build-up inside endoscopes and automated endoscope re-processors and decrease the risk of transmitting infections.[30] Per Kovaleva et al. while sterilization can be helpful to destroy microorganisms within biofilms, ethylene oxide sterilization may fail in the presence of organic debris after an inadequate cleaning procedure before reprocessing of flexible endoscopes. There was no mention of single-use bronchoscopes in the study.

The applicant cited a self-sponsored, laboratory study by Kurman et al.,[31] in general support of its application. Kurman et al. evaluated and assessed four different manufacturers' single-use flexible bronchoscopes (SFB), including the nominated device and its prior model, against their reusable flexible bronchoscopes (RFB) on a cadaver (that is, corpse) model, benchtop fixturing, and an artificial plastic lung model. The study compared the Ambu® aScope™ 5 Broncho HD with four devices: (1) Olympus H-SteriScope; (2) Verathon BFLEX; (3) Boston Scientific Exalt-B; and (4) Ambu® aScope™ 4 Broncho (the prior model of the nominated device). The study concluded that the Ambu® aScope™ 5 Broncho HD has the highest overall performance, the highest overall rating for sampling, and highest maneuverability in difficult segmental airways among the comparator devices.

The applicant indicated that the Ambu® aScope™ 5 Broncho HD differs from these comparator devices as it is the only device that is compatible with argon gas plasma coagulation, cryotherapy, and laser, with an HD (1200x800) chip, has more degrees of articulation with tools, and provides image and video capture from the scope handle with multiple programmable functions including capture photo, start/end video, enable zoom, and initiate ARC. In addition, the applicant stated that the nominated device is superior to its earlier legally marketed device in terms of maneuverability into difficult segmental airways, overall performance, and overall sampling assessment. The applicant asserted that the nominated device differs from the predicate device due to a rotation mechanism on the handle and its superior articulation, which allow for more complicated procedures to be performed such as cryotherapy and coagulation. The applicant stated that the nominated device is equipped with an HD image chip and increased depth-of-field and field-of-view, which allow interventional pulmonologists to perform inspections, biopsies, and debulking. The applicant also stated that the nominated device's programmable buttons allow for superior documentation than the earlier bronchoscope device.

We noted that the nominated device was determined to be substantially equivalent to the earlier device that the applicant had previously legally marketed. The FDA 510(k) summary indicated that both devices share similar technological characteristics including the optical system, bending section, diameter of insertion cord and distal end, and insertion portion length. Furthermore, the 510(k) summary indicated that both have the same technical characteristics, which include a maneuverable tip controlled by the user, flexible insertion cord, camera and a LED light source at the distal tip. Both are sterilized by ethylene oxide, are single-use devices, and have the ability to aspirate and collect samples in bronchoalveolar lavage and bronchial wash procedures.

We noted that in its application, the applicant provided a comparison of certain devices or device categories that it believed are most closely related or similar to the Ambu® aScope™ 5 Broncho HD. The applicant identified six reusable devices that it believed are most closely related: (1) Olympus Evis Exera Iii Bronchovideoscope Bf-h190; (2) Pentax EB–J10 Video Bronchoscope; (3) Fujifilm EB–580S Video Bronchoscope; (4) Olympus BF–Q190; (5) Olympus BF–1TH190; and (6) Olympus BF–XT190. According to the applicant, these devices are used during the same specific procedure(s) and/or services with which the Ambu® aScope™ 5 Broncho HD is used. The applicant stated that the Ambu® aScope™ 5 Broncho HD's single-use feature is unique among the comparators. According to the applicant, the single-use feature eliminates bronchoscope reprocessing. The applicant further submitted several articles reporting results on the prevalence of infection due to incomplete or inadequate processing for reusable bronchoscopes, which we summarize as follows. An article by Shimizu et al.[32] concluded that patients with larger lesions, endobronchial lesions, histology of small-cell lung cancer, and advanced-disease stage tended to develop pulmonary infectious complications more often than other patients. A 2020 systematic literature review and meta-analysis by Travis et al.[33] reported an estimated average reusable FB cross-contamination rate of 8.69 percent ± 1.86 (standard division [SD]) (95 percent confidence interval [CI]: 5.06–12.33 percent) among eight

[29] Kovaleva, J., Peters, F.T., van der Mei, H.C., & Degener, J.E. (2013). Transmission of infection by flexible gastrointestinal endoscopy and bronchoscopy. *Clinical microbiology reviews, 26*(2), 231–254. *https://doi.org/10.1128/CMR.00085-12.*

[30] *Ibid.*

[31] Kurman, J., Wagh, A., Benn, B., & Islam, S., (2023). A comparison of single-use bronchoscopes and reusable bronchoscopes for interventional pulmonology applications. Confidential. Ambu Inc., funded evaluation and testing.

[32] Shimizu, T., Okachi, S., Imai, N., Hase, T., Morise, M., Hashimoto, N., Sato, M., & Hasegawa, Y. (2020). Risk factors for pulmonary infection after diagnostic bronchoscopy in patients with lung cancer. *Nagoya journal of medical science, 82*(1), 69–77. *https://doi.org/10.18999/nagjms.82.1.69.*

[33] Travis, H.S., Russell, R.V., & Kovaleva, J. (2023). Cross-contamination rate of reusable flexible bronchoscopes: A systematic literature review and meta-analysis. *Journal of infection prevention,* 17571774231158203.

studies from the U.S. and four European countries. Travis et al.[34] attributed the infection rate to the differences in the study design and sampling methods, geography, low number of data points, clinical settings, and an aversion towards publishing negative findings among the eight studies. Furthermore, the applicant submitted a 2019 systematic review and cost-effective analysis by Mouritsen et al.,[35] which reported an average 2.8 percent cross-contamination rate from reusable, flexible bronchoscopes among 16 studies from the United Kingdom, U.S., France, Spain, Australia, and Taiwan. Mouristen et al. identified that the single-use flexible bronchoscopes were cost effective and associated with a reduction of infection risk of approximately 1.71–4.07 percent compared with reusable flexible bronchoscopes. Lastly, the applicant again cited the meta study by Barron and Kennedy [36] referencing the findings from Ofstead et al.,[37] the review by Mouristen et al., and the Emergency Care Research Institute's (ECRI's) report.[38] Of note, ECRI highlighted the recontamination of flexible endoscopes due to mishandling or improper storage as one of the top 10 health technology hazards.

Based on the evidence submitted with the application, we noted the following concerns: We noted concern about whether the Ambu® aScope™ 5 Broncho HD can be distinguished from similar devices on the market and the earlier versions of the nominated device on the market sufficiently to demonstrate substantial clinical improvement. Four of the studies the applicant submitted, Châteauvieux et al.,[39] Barron and Kennedy, Kurman et al., and Ofstead et al., investigated and provided data on the applicant's earlier models of the device, but did not provide comparisons to the nominated device. In addition, we noted that the studies provided also did not compare the nominated device to an appropriate comparator such as a single-use bronchoscope from a different manufacturer or a standard reusable bronchoscope, in a clinical setting. In addition, we noted that the applicant's self-sponsored study by Kurman, et al. was conducted in the laboratory (that is, on cadaver, benchtop fixturing, and artificial plastic lung) and not in the clinical setting. In order to demonstrate substantial clinical improvement over currently available treatments, we consider supporting evidence, preferably published peer-reviewed clinical trials, that shows improved clinical outcomes, such as reduction in mortality, complications, subsequent interventions, future hospitalizations, recovery time, pain, or a more rapid beneficial resolution of the disease process compared to the standard of care.

Furthermore, we noted that the Châteauvieux et al.[40] and Barron and Kennedy [41] studies suggested limiting the use of single-use bronchoscope device to specific situations (that is, after hours or emergency), immunocompromised patients, and in rare cases of preventing prior contamination in the inpatient setting. We believed that further investigation with comparators in these specified cases would be particularly helpful to determine whether the device demonstrates a substantial clinical improvement over currently available treatment options in the clinical setting where it is most likely to be used.

We noted concern that the application and all the articles submitted as evidence of substantial clinical improvement discuss potential adverse events from reusable bronchoscope procedures, but do not directly show any clinical improvement that results from the use of the Ambu® aScope™ 5 Broncho HD. We noted that Shimizu et al.,[42] Travis et al.,[43] Barron and Kennedy,[44] and Ofstead et al.[45] provided information about the risks associated with reprocessing reusable devices and reported mixed results.

We also noted that the 2015 FDA safety notice [46] provided preliminary information regarding infections associated with the use of reprocessed flexible bronchoscopes, but did not discuss or recommend the use of disposable, single-use devices in the notice. Furthermore, we noted the following concerns about studies on the prevalence of infection due to incomplete/inadequate reprocessing of reusable bronchoscopes. The studies authored by Châteauvieux et al.,[47] Shimizu et al.,[48] Travis et al.,[49] and Mouritsen et al.[50] have small sample sizes. Furthermore, the Barron and Kennedy,[51] Travis et al.,[52] and Mouritsen et al.[53] studies used different

[34] *Ibid.*

[35] Mouritsen, J.M., Ehlers, L., Kovaleva, J., Ahmad, I., & El-Boghdadly, K. (2020). A systematic review and cost effectiveness analysis of reusable vs. single-use flexible bronchoscopes. *Anaesthesia, 75*(4), 529–540.

[36] Barron, S.P., & Kennedy, M.P. (2020). Single-use (disposable) flexible bronchoscopes: the future of bronchoscopy? *Advances in therapy, 37*(11), 4538–4548. *https://doi.org/10.1007/s12325-020-01495-8.*

[37] Ofstead C.L., Quick M.R., Wetzler H.P., et al. (2018) Effectiveness of reprocessing for flexible bronchoscopes and endobronchial ultrasound bronchoscopes. *Chest, 154*(5):1024–34.

[38] ECRI. Top 10 health technology hazards. Executive brief. Pennsylvania: ECRI Institute, Health devices; 2019. p. 2019.

[39] Châteauvieux, C., Farah, L., Guérot, E., Wermert, D., Pineau, J., Prognon, P., Borget, I., & Martelli, N. (2018). Single-use flexible bronchoscopes compared with reusable bronchoscopes: Positive organizational impact but a costly solution. *Journal of evaluation in clinical practice, 24*(3), 528–535. *https://doi.org/10.1111/jep.12904.*

[40] *Ibid.*

[41] Barron, S.P., & Kennedy, M.P. (2020). Single-use (disposable) flexible bronchoscopes: the future of bronchoscopy? *Advances in therapy, 37*(11), 4538–4548. *https://doi.org/10.1007/s12325-020-01495-8.*

[42] Shimizu, T., Okachi, S., Imai, N., Hase, T., Morise, M., Hashimoto, N., Sato, M., & Hasegawa, Y. (2020). Risk factors for pulmonary infection after diagnostic bronchoscopy in patients with lung cancer. *Nagoya journal of medical science, 82*(1), 69–77. *https://doi.org/10.18999/nagjms.82.1.69.*

[43] Travis, H.S., Russell, R.V., & Kovaleva, J. (2023). Cross-contamination rate of reusable flexible bronchoscopes: A systematic literature review and meta-analysis. *Journal of infection prevention,* 17571774231158203.

[44] Barron, S.P., & Kennedy, M.P. (2020). Single-use (disposable) flexible bronchoscopes: the future of bronchoscopy? *Advances in therapy, 37*(11), 4538–4548. *https://doi.org/10.1007/s12325-020-01495-8.*

[45] Ofstead, C.L., Hopkins, K.M., Eiland, J.E., & Wetzler, H.P. Managing bronchoscope quality and cost: results of a real-world study. *https://www.ambu.com/Files/Files/Ambu/Investor/News/English/2019/Managing%20Bronchoscope%20cost%20a%20real%20world%20study.pdf.*

[46] FDA Safety Communications, Infections Associated with Reprocessed Flexible Bronchoscopes: FDA Safety Communication, issued September 17, 2015. *https://www.fdanews.com/ext/resources/files/09-15/092115-safety-notice.pdf?1442508647.*

[47] Châteauvieux, C., Farah, L., Guérot, E., Wermert, D., Pineau, J., Prognon, P., Borget, I., & Martelli, N. (2018). Single-use flexible bronchoscopes compared with reusable bronchoscopes: Positive organizational impact but a costly solution. *Journal of evaluation in clinical practice, 24*(3), 528–535. *https://doi.org/10.1111/jep.12904.*

[48] Shimizu, T., Okachi, S., Imai, N., Hase, T., Morise, M., Hashimoto, N., Sato, M., & Hasegawa, Y. (2020). Risk factors for pulmonary infection after diagnostic bronchoscopy in patients with lung cancer. *Nagoya journal of medical science, 82*(1), 69–77. *https://doi.org/10.18999/nagjms.82.1.69.*

[49] Travis, H.S., Russell, R.V., & Kovaleva, J. (2023). Cross-contamination rate of reusable flexible bronchoscopes: A systematic literature review and meta-analysis. *Journal of Infection Prevention,* 17571774231158203.

[50] Mouritsen, J.M., Ehlers, L., Kovaleva, J., Ahmad, I., & El-Boghdadly, K. (2020). A systematic review and cost effectiveness analysis of reusable vs. single-use flexible bronchoscopes. *Anaesthesia, 75*(4), 529–540.

[51] Barron, S.P., & Kennedy, M.P. (2020). Single-use (disposable) flexible bronchoscopes: the future of bronchoscopy? *Advances in therapy, 37*(11), 4538–4548. *https://doi.org/10.1007/s12325-020-01495-8.*

[52] Travis, H.S., Russell, R.V., & Kovaleva, J. (2023). Cross-contamination rate of reusable flexible bronchoscopes: A systematic literature review and meta-analysis. *Journal of Infection Prevention,* 17571774231158203.

[53] Mouritsen, J.M., Ehlers, L., Kovaleva, J., Ahmad, I., & El-Boghdadly, K. (2020). A systematic

Continued

study designs and sampling methodologies or were performed in various clinical settings other than outpatient, which may affect the quality and reliability of the data provided in support of the applicant's assertions. We did not believe that we had sufficient information on the prevalence of infection to evaluate the applicant's substantial clinical improvement claims for the nominated device. We sought comments on the prevalence of infection due to incomplete/inadequate processing for bronchoscopes in the U.S. and whether single-use bronchoscopes reduce the infection rate in patients to identify the extent of the problem with existing technologies.

The applicant provided evidence which seemed to rely on indirect inferences from other sources of data. We questioned the relevance of the 2015 FDA safety notice [54] to the nominated device because as stated above, the guidance applies to reprocessed flexible bronchoscopes broadly, but not to disposable, single-use devices comparable to the nominated device. We expressed concern that many of the applicant's substantial clinical improvement claims rely on an assumption that inadequate reprocessing of reusable bronchoscopes is positively correlated with heightened risk of infection. We expressed concern that the applicant provided studies with small sample sizes and other limitations, as described above, as their only support. We noted that the applicant provided background information on the established reprocessing guidelines [55] for reusable devices; however, the existence of reprocessing guidelines does not provide evidence on the prevalence of infection rates, establish a relationship between infection risk and reprocessing procedures, or substantiate that single-use disposable scopes, or the nominated device specifically, would be a substantial clinical improvement over currently available treatments.

We invited public comment on whether the Ambu® aScope™ 5 Broncho HD meets the substantial clinical improvement criterion at § 419.66(c)(2)(i).

Comment: The applicant and several commenters responded to our concern about whether the Ambu® aScopeTM 5 Broncho HD could be distinguished from similar devices on the market and the earlier versions of the nominated device on the market sufficiently to demonstrate substantial clinical improvement and that four of the studies the applicant submitted, Châteauvieux et al., Barron and Kennedy, Kurman et al.,[56] and Ofstead et al., investigated and provided data on the applicant's earlier models of the device, but did not provide comparisons to the nominated device. The applicant and commenters provided feedback that Ambu® aScope™ 5 Broncho HD improves clinical applications and reduces cross-contamination compared to other single-use and reusable bronchoscopes, including its predicate device. Several commenters stated that the device can perform advanced bronchoscopy procedures, without concern for contamination, infection, and scope damage. One commenter stated that they have witnessed the usage of this bronchoscope for advanced procedures without incident, noting that it is the preferred device in their clinical practice for valve placement, rigid bronchoscopy, and all cases outside of the endoscopy suite. Another commenter noted that reusable bronchoscopes have a complex design with variable disinfection/sterilization requirements which leads to issues with reprocessing. Multiple commenters stated that single-use bronchoscopes create an assurance that a sterilized scope will be used each time, reduce the risk of patient cross-contamination in the ICUs, and allow improved patient access and room turnover compared with reusable scopes. One commenter asserted that the nominated device is superior to other devices in specific patient populations needing interventional pulmonology procedures.

Commenters cited personal experience with Ambu® aScope™ 5 Broncho HD, asserting that transitioning to the nominated device several months ago has eliminated iatrogenic bronchoscopy-related transmission of infection in their health care facility and Ambu® aScope™ 5 Broncho HD has directly led to clinical improvement in cases of endobronchial valve insertion in their facility, as more patients can be treated with endobronchial valve insertion for bronchoscopic lung volume reduction. The applicant provided that after being commercially available for one year in Europe, the USA, Canada, Australia, New Zealand, and Japan, they observed that more than 80 percent of users have adopted the nominated device into their bronchoscopy suites for advanced procedures, including but not limited to tumor debulking, endobronchial valve placement, cryobiopsy, as well as endobronchial and transbronchial biopsies, which single-use bronchoscopes were previously unable to perform. The applicant reiterated that the device is the only single-use flexible bronchoscopy (FB) capable of performing advanced bronchoscopy as it has superior bending angles, an HD imaging chip, and is compatible with argon gas plasma coagulation, cryotherapy, and laser. The applicant also asserted that early clinical feedback suggests that the device is a viable alternative to reusable bronchoscopes due to its superior angulation range and flexibility. Further, the applicant clarified that the Kurman et al.[57] study did provide data on the nominated device, including table providing a side-by-side comparison of the technical specs of the Ambu® aScope™ 5 Broncho HD and its comparators which showed that the nominated device had better flexion and extension without tools compared to the reusable scope, the nominated device had the most degrees of flexion and extension with all accessory tools compared to other single-use scopes and the reusable scope, the nominated the device was able to reach the same anatomical location with biopsy forceps in the right-upper lobe segment, and the nominated device rated similar to the reusable scope and better than the other single-use scopes in image sharpness and near and far field resolutions.

Finally, the applicant asserted that while there are similarities between Ambu® aScope™ 5 Broncho HD and the predicate devices, the Ambu® aScope™ 5 Broncho HD can be distinguished from the predicate devices because its technical characteristics, such as a rotation mechanism on the handle and superior articulation, which allow it to perform more complex bronchoscopy procedures, are unique to the Ambu® aScope™ 5 Broncho HD.

Response: We appreciate the commenters' examples supporting the superiority of the Ambu® aScope™ 5 Broncho HD. In addition, we appreciate the clarification on the Kurman et al.[58]

review and cost effectiveness analysis of reusable vs. single-use flexible bronchoscopes. *Anaesthesia, 75*(4), 529–540.

[54] FDA Safety Communications, Infections Associated with Reprocessed Flexible Bronchoscopes: FDA Safety Communication, issued September 17, 2015. *https://www.fdanews.com/ext/resources/files/09-15/092115-safety-notice.pdf?1442508647.*

[55] FDA Guidance March 17, 2015 ''Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling: Guidance for Industry and Food and Drug Administration Staff''.

[56] Kurman, J., Wagh, A., Benn, B., & Islam, S. (2023). A comparison of single-use bronchoscopes and reusable bronchoscopes for interventional pulmonology applications. Confidential. Ambu Inc., funded evaluation and testing.

[57] *Ibid.*

[58] *Ibid.*

study along with the table providing a side-by-side comparison of the technical specs of the Ambu® aScope™ 5 Broncho HD and its comparators. After reviewing the information provided in the public comment and clarifications from the applicant on the Kurman et al.[59] study that directly compare the nominated device with other single-use scopes, we agree with the commenters' and the applicant's statements that the device can be distinguished from similar devices on the market and the earlier versions of the nominated device on the market sufficiently to demonstrate substantial clinical improvement.

Comment: In response to our concern that the nominated device was determined to be substantially equivalent to the earlier device that the applicant had previously legally marketed, and the FDA 510(k) summary indicated that both devices have the same technical characteristics, the applicant along with a few commenters expressed their belief that the FDA 510K term ''substantially equivalent'' does not imply the device is the same as its predicate device. Rather, the applicant asserted that the 510(k) term ''substantially equivalent'' indicates that a nominated device is as safe and effective as its predicate device. One commenter noted that as defined in 21 CFR part 807,[60] every 510(k)-cleared medical device has been found substantially equivalent to one or more predicate devices. One commenter suggested that the regulatory substantial equivalence cannot be used to conclude the inability to demonstrate substantial clinical improvement in the context of CFR 419.66(c)(2).

Response: We appreciate the comments regarding the FDA 510K term ''substantially equivalent'' and the reference to 21 CFR part 807.[61] We agree that FDA determination of substantial equivalence cannot alone be used to conclude that a device cannot to demonstrate substantial clinical improvement as required by the regulation at 42 CFR 419.66(c)(2). However, we note that the FDA 510(k) summary provided by the applicant indicated that both nominated and predicate devices share similar technological characteristics such as optical system, bending section, diameter of insertion cord and distal end, and insertion portion length. We expressed concern in the proposed rule regarding the language in the FDA 510(k) summary because we could not determine, based on the information available to us at the time, whether the Ambu® aScope™ 5 Broncho HD could be distinguished from similar devices on the market and the earlier versions of the nominated device on the market sufficiently to demonstrate substantial clinical improvement. Neither could we determine exactly how the nominated device is superior to its earlier legally marketed device, as per the applicant's assertion. As noted above, after reviewing the information provided in the public comment, particularly the Kurman et al.[62] study, we agree with the commenters' and the applicant's statements that the device can be distinguished from similar devices on the market and the earlier versions of the nominated device on the market sufficiently to demonstrate substantial clinical improvement.

Comment: In response to the concern that the applicant's self-sponsored study by Kurman et al.[63] may not be sufficient to show improved clinical outcomes because it was conducted in the laboratory (that is, on cadaver, benchtop fixturing, and artificial plastic lung) and not in the clinical setting, the applicant asserted that the benchtop studies in this category are considered the industry standard and have been well accepted as the best way to compare single use and reusable bronchoscopes. In support of this assertion, the applicant provided six studies[64 65 66 67 68 69] as examples and indicated that there is no feasible way to accurately measure the flexion and deflection angles of a tool in vivo. Commenters supported the applicant's assertion and indicated that benchtop studies are standard and commonly utilized throughout the medical community. The applicant referenced results of one benchtop study (among the six examples referenced earlier) by Ho et al.,[70] published prior to the device's release. The study reviewed the published evidence on the applications of single-use (SU) and reusable bronchoscopes in bronchoscopy suites and intensive care units, and concluded that the portability, immediate availability, and theoretical reduced risk of clinically relevant infections confer an advantage of using SUFB over reusable FB in certain scenarios in the bronchoscopy and intensive care units. The applicant stated that improvements in maneuverability, angle tip deflection, and image quality are critical for a broader adoption of single-use FBs in more complex procedures.

Response: We thank the commenters for their input. While we maintain our belief that data which indicates that a device demonstrates substantial clinical improvements over currently available treatments in the clinical setting where it is most likely to be used is beneficial, we recognize that obtaining such data is not always feasible. After reviewing the information provided in the public comment, including clarifications from the applicant on the Kurman et al.[71] study, the additional six benchtop studies (as referenced above) supplied by the applicant, and the comments supporting the applicant's assertion that benchtop studies for bronchoscopes are considered to be the industry standard and have been well accepted as the best way to compare single-use and reusable bronchoscopes, we agree that the applicant's self-sponsored study by Kurman et al.[72] is sufficient to show improved clinical outcomes.

Comment: In response to our concern that the submitted evidence of substantial clinical improvement

[59] *Ibid.*

[60] 21 CFR part 807, subpart E.

[61] *Ibid.*

[62] Kurman, J., Wagh, A., Benn, B., & Islam, S. (2023). A comparison of single-use bronchoscopes and reusable bronchoscopes for interventional pulmonology applications. Confidential. Ambu Inc., funded evaluation and testing.

[63] *Ibid.*

[64] Liu, L., Wahidi, M., Mahmood, K., Giovacchini, C., Shofer, S., Cheng, G. (2020) Operator perception of a single-use flexible bronchoscope: comparison with current standard bronchoscopes. *Respiratory care, 65*(11):1655–1662. Doi: 10.4187/respcare.07574. Epub 2020 Jun 2. PMID: 32487752.

[65] Darrell, N., Grant, S., Abdurrahman, H., Matthew, N., Russell, M., et al. (2022). Operator perception of the performance of multiple single-use bronchoscopes compared to standard re-usable bronchoscope. *Am J Biomed Sci & Res, 17*(2). AJBSR.MS.ID: 002333, DOI: 10.34297/AJBSR.2022.17.002333.

[66] Lamb, C.R., Yavarovich, E., Kang, V. et al. (2022). Performance of a new single-use bronchoscope versus a marketed single-use comparator: a bench study. *BMC Pulm Med 22, 189*). Retrieved from: *https://bmcpulmmed.biomedcentral.com/articles/10.1186/s12890-022-01982-4.*

[67] Ho, E., Wagh, A., Hogarth, K., Murgu, S. (2022). Single-use and reusable flexible bronchoscopes in pulmonary and critical care medicine. *Diagnostics, 12*(1):174. Retrieved from: *https://doi.org/10.3390/diagnostics12010174.*

[68] Liang, Z., Zhou, G., Li, Y. et al. (2022). Evaluation of a new developed disposable and portable bronchoscopy system. *BMC PulmMed 22, 136. https://doi.org/10.1186/s12890-022-01933-z.*

[69] Deasy, K.F., Sweeney, A.M., Danish, H., O'Reilly, E., Ibrahim, H., Kennedy, M.P. (2023). Single use or disposable flexible bronchoscopes: bench top and preclinical comparison of currently available devices. *J Intensive Care Med, 38*(6):519–528. Doi:10.1177/08850666221148645. Epub 2023 Jan 7. PMID: 36609193; PMCID: PMC10114257.

[70] Ho, E., Wagh, A., Hogarth, K., Murgu, S. (2022). Single-use and reusable flexible bronchoscopes in pulmonary and critical care medicine. *Diagnostics, 12*(1):174. Retrieved from: *https://doi.org/10.3390/diagnostics12010174.*

[71] Kurman, J., Wagh, A., Benn, B., & Islam, S. (2023). A comparison of single-use bronchoscopes and reusable bronchoscopes for interventional pulmonology applications. Confidential. Ambu Inc., funded evaluation and testing.

[72] *Ibid.*

discussed potential adverse events from reusable bronchoscope procedures, but did not directly show any clinical improvement that resulted from the use of the Ambu® aScope™ 5 Broncho HD, the applicant reiterated that the single use nature of the Ambu® aScope™ 5 Broncho HD avoids the adverse issues and risk associated with reprocessing detailed in the articles referenced in its application as there is no reprocessing or reuse of the bronchoscope. The applicant noted that, the successful Uretero 1 device pass-through application included the Bozzini et al. study which does not include the nominated device as the comparator. The applicant stated that, in the same fashion as the Uretero 1 device pass-through application, the Ambu® aScope™ 5 Broncho HD application is using the transitive property to highlight that because clinical benefits can be seen with single-use endoscopes and the nominated device is single-use, the nominated device is therefore an improvement over reusable endoscopes. Another commenter referenced the CY 2023 OPPS/ASC final rule with comment period, wherein CMS approved the Uretero 1 device pass-through application and established device pass-through code HCPCS C1747 (Endoscope, single-use (that is, disposable), urinary tract, imaging/illumination device (insertable)). Specifically, the commenter pointed out that CMS stated that we agreed that the evidence demonstrating the improved patient outcomes and reduced patient risk associated with the disposable device in comparison with reusable devices represents substantial clinical improvement. This commenter suggested that this conclusion should also apply to single-use bronchoscopes as well. The commenters believed that single-use scopes reduce reprocessing-related bronchoscope infection risk, and that this risk reduction is a substantial clinical improvement.

Response: We appreciate the commenters' input. As the applicant and commenter indicated, CMS approved Uretero1 [73] for transitional pass-through payment status in the CY 2023 OPPS/ASC final rule with comment period. We note that we expressed similar concerns relating to the lack of comparative studies between the single-use Uretero1 device and other disposable devices and indicated that, while we ultimately agreed that the totality of evidence demonstrated improved patient outcomes and reduced patient risk associated with the disposable device in comparison with reusable devices represents substantial clinical improvement, it would have been helpful to see comparative studies. The applicant and the commenter seem to suggest that because we determined that the Uretero 1 device demonstrated substantial clinical improvement despite providing a study which does not include the nominated device as a comparator, that we should similarly determine that the type of evidence submitted by Ambu® aScope™ 5 Broncho HD represents substantial clinical improvement. We note that we do not believe that this implied approach to application evaluation is appropriate. Rather, we continue to believe that our current process wherein we evaluate all evidence submitted for each device pass-through application as it applies to the nominated device is appropriate. Due to inherent differences in the devices themselves and the supporting documentation submitted, CMS may have different concerns as they relate to the nominated device. In addition, we are not precluded from evaluating evidence and expressing concerns regarding evidence submitted in support of an application simply because that type of evidence has been submitted in support of a previous application. While we encourage applicants to read the application summaries presented in previous OPPS/ASC rules as they can help applicants determine the types of documentation that have been submitted and assess areas of potential concern with their technology, we caution applicants not to rely solely on the presumption that previously submitted types of evidence, evaluated for a different device, either need not be submitted or need not be fully addressed as it relates to their technology. Further, we encourage applicants to submit all relevant supporting evidence with their device pass-through application to allow us to adequately evaluate and include the data in the notice of proposed rulemaking.

With regard to our concern that the submitted evidence of substantial clinical improvement discussed potential adverse events from reusable bronchoscope procedures but did not directly show any clinical improvement that resulted from the use of the Ambu® aScope™ 5 Broncho HD, we indicated that it would be helpful to see published peer-reviewed comparative studies between the single-use Ambu® aScope™ 5 Broncho HD device and other disposable devices. After reviewing the information provided in the public comment, specifically the 2021 FDA safety notice,[74] the Ho et al.[75] study that supported the increased risks associated with using reusable devices, and the Kurman et al. study which distinguished the device from similar devices on the market and the earlier versions of the nominated device on the market, we agree that the evidence demonstrates there are improved patient outcomes and reduced patient risk associated with the single-use Ambu® aScope™ 5 Broncho HD device in comparison with reusable devices.

Comment: In response to the concern regarding the relevance of the 2015 FDA safety notice to the nominated device, specifically that the guidance appeared to apply to reprocessed flexible bronchoscopes broadly, not to disposable, single-use devices comparable to the nominated device, and that many of the applicant's substantial clinical improvement claims rely on an assumption that inadequate reprocessing of reusable bronchoscopes is positively correlated with heightened risk of infection, the applicant submitted a 2021 FDA safety notice [76] showing FDA's analysis of Medical Device Reports (MDRs) related to infections or device contamination associated with reusable flexible bronchoscopes from 2015–2021. The document states that between January 2010 and June 2015, the FDA received 109 MDRs related to infections or device contamination associated with reusable flexible bronchoscopes, and between July 2015 and January 2021, the FDA received 867 additional MDRs. Of the 867 reports received between July 2015 and January 2021, there were seven reports of deaths. Since 2015, the number of MDRs relevant to infection or contamination submitted to the FDA has increased from under 100 per year to between 100–200 per year. In addition, the applicant noted that FDA received at

[73] In the CY 2023 OPPS/ASC final rule with comment period CMS approved Uretero1 as a new device category for transitional pass-through payment status and established HCPCS code C1747 as a new device category beginning in January 2023 (87 FR 7129 through 71934) effective January 1, 2023.

[74] FDA Safety Communications, Flexible Bronchoscopes and Updated Recommendations for Reprocessing: FDA Safety Communication, issued June 25, 2021. *https://www.fda.gov/medical-devices/safety-communications/flexible-bronchoscopes-and-updated-recommendations-reprocessing-fda-safety-communication.*

[75] Ho, E., Wagh, A., Hogarth, K., Murgu, S. (2022). Single-use and reusable flexible bronchoscopes in pulmonary and critical caremedicine. *Diagnostics, 12*(1):174. Retrieved from: *https://doi.org/10.3390/diagnostics12010174.*

[76] FDA Safety Communications, Flexible Bronchoscopes and Updated Recommendations for Reprocessing: FDA Safety Communication, issued June 25, 2021. *https://www.fda.gov/medical-devices/safety-communications/flexible-bronchoscopes-and-updated-recommendations-reprocessing-fda-safety-communication.*

least 226 bronchoscope-related MDRs from July 2021 to July 2023. The applicant asserted that the latest MDR numbers highlight the sustained increase of these MDRs. The applicant also noted that the MDR system is a passive surveillance system and may undercount the true number of bronchoscope infections and/or contaminations.

In reference to CMS's concern regarding the relevance of the 2015 FDA safety notice, the applicant stated that CMS determined that a similar communication (FDA advisory notice) was sufficient to demonstrate substantial clinical improvement for Uretero 1 in CY 2023. The applicant further provided that compared to ureteroscopes, which received 450 reports from 2017–2021 (from roughly 600,000 cases per year), reusable bronchoscopes received 867 from 2015–2021 (out of roughly 500,000 cases per year). The applicant asserted that given CMS' previous acceptance of FDA guidance documents as evidence of substantial clinical improvement and the increased incidents of MDRs for bronchoscopes when compared to ureteroscopes, the bronchoscope MDR data provided must also be considered sufficient evidence.

A few commenters, including the applicant, pointed out that the supplemental update [77] issued on June 25, 2021, directly addresses the omission of single-use medical devices from the FDA safety communication [78] originally dated September 17, 2015, regarding infections associated with reprocessed flexible bronchoscopes. The commenters stated that the supplemental update urges health care providers to consider using single-use bronchoscopes in situations where there is an increased risk of spreading infection and recommends the use of sterilization instead of high-level disinfection for all flexible bronchoscope reprocessing. One commenter clarified that some reusable flexible bronchoscopes are physically incompatible with some or all sterilization methods, while others may be capable of withstanding the sterilization process, but the manufacturers have not provided a validated sterilization process in the 510(k) cleared device labeling. Another commenter stated that the single-use flexible bronchoscopes minimize the risk of patient cross-contamination and agreed with the applicant's assertation that reusable bronchoscopes frequently lead to issues of cross-contamination and infection because of complex designs and issues with reprocessing, especially for patients who are immunocompromised.

A few commenters also provided additional data on the prevalence of inadequately reprocessed bronchoscopes posing an increased risk of remaining contaminated and cross-infecting patients with multidrug-resistant organisms. One commenter cited a recently published peer-reviewed article by Mehta and Muscarella (2020),[79] which provides evidence both for the significance of this application and the prevalence of infection due to, among other risk factors, the inadequate reprocessing of reusable bronchoscopes. The primary objectives of the study were to investigate the risk of bronchoscopes transmitting infections of carbapenem-resistant Enterobacteriaceae (CRE) and related multidrug-resistant organisms (MDROs). This study's findings suggest that bronchoscopes may pose an under-recognized potential for transmission of CRE and related MDROs, warranting greater public awareness, enhanced preventive measures, and updated reprocessing guidance. Per the commenter, this study's data suggests that the cleaning and high-level disinfection of bronchoscopes performed in accordance with published guidelines and manufacturer instructions may not always be sufficiently effective to eliminate this risk. The study concluded that inadequate reprocessing of reusable bronchoscopes is positively correlated with heightened risk of infection. Another commenter indicated that while it is important for hospitals to improve reprocessing practices in general, a clean reusable scope will never be as clean as a sterile, single-use scope, even following the most rigorous cleaning protocols. The commenter stated that while CMS highlighted the low number of reported infections given the number of bronchoscopies that occur each year, unlike many other types of endoscopes that enter a sterile or otherwise clean anatomy (ureter), patients who need a bronchoscopy often require such procedures due to potential infection which could mask bronchoscope-mediated transmission of infectious agents.

Response: We appreciate the applicant's and the commenters' responses and additional evidence. We found the data contained in the updated 2021 FDA safety notice [80] compelling. While FDA noted in the 2015 FDA safety notice submitted as part of the application that when compared to the number of bronchoscopy procedures performed in the U.S. each year this is considered a small number of MDRs, we agree with the applicant's assertion that the latest MDR numbers provided in the 2021 FDA safety notice [81] highlight the sustained increase of these MDRs. While we acknowledge some of the data limitations, after reviewing the information provided in the public comment and the 2021 FDA safety notice,[82] we agree with the commenters that reusable bronchoscopes present a risk of cross-infection due to contamination. We understand that despite strictly adhering to the manufacturers' recommendations for reprocessing, some bronchoscopes still show evidence of biofilms, which are a source of cross-contamination. The applicant and other commenters provided sources: Mehta and Muscarella (2020) [83] and the 2021 FDA safety notice,[84] that demonstrate that even ''properly'' re-processed bronchoscopes have positive microbial growth via reusable bronchoscopes which is mitigated by single-use bronchoscopes like Ambu aScope™ 5 Broncho HD sufficiently to demonstrate substantial clinical improvement in situations where there is an increased risk of spreading infection. After consideration of the public comments received, we believe that commenters have addressed our concerns regarding whether the Ambu® aScope™ 5 Broncho HD meets the substantial clinical improvement criterion and that the Ambu® aScope™ 5 Broncho HD represents a substantial clinical improvement over existing technologies due to compelling evidence from the applicant and other commenters as discussed above,

[77] *Ibid.*

[78] FDA Safety Communications, Infections Associated with Reprocessed Flexible Bronchoscopes: FDA Safety Communication, issued September 17, 2015. *https://www.fdanews.com/ext/resources/files/09-15/092115-safety-notice.pdf?1442508647.*

[79] Mehta, A.C., Muscarella, L.F. (2020). Bronchoscope-related ''superbug'' infections. *Chest, 157*(2):454–469.

[80] FDA Safety Communications, Flexible Bronchoscopes and Updated Recommendations for Reprocessing: FDA Safety Communication, issued June 25, 2021. *https://www.fda.gov/medical-devices/safety-communications/flexible-bronchoscopes-and-updated-recommendations-reprocessing-fda-safety-communication.*

[81] *Ibid.*

[82] *Ibid.*

[83] Mehta, A.C., Muscarella, L.F. (2020). Bronchoscope-related ''superbug'' infections. *Chest, 157*(2):454–469.

[84] FDA Safety Communications, Flexible Bronchoscopes and Updated Recommendations for Reprocessing: FDA Safety Communication, issued June 25, 2021. *https://www.fda.gov/medical-devices/safety-communications/flexible-bronchoscopes-and-updated-recommendations-reprocessing-fda-safety-communication.*

specifically the 2021 FDA safety notice [85] and Ho et al.[86] study that demonstrated the increased risks associated with using reusable devices

In response to the applicant's comments comparing the Uretero 1 application summary included in the CY 2023 OPPS/ASC final rule with comment period with the application summary for the nominated device included in this final rule with comment period, we note that we expressed a similar concern in the Uretero 1 application summary that the FDA advisory letter regarding ureteroscopes did not mention single-use devices and it was not clear how the recommendations in the letter supported the applicant's claims of substantial clinical improvement related to Uretero1. While we ultimately determined that evidence was sufficient to demonstrate substantial clinical improvement, we would like to reiterate that we evaluate all evidence submitted for each device pass-through application as it applies to the nominated device. While we agree that data provided regarding the increased incidents of MDRs for bronchoscopes and the nominated devices' impact of mitigating infection risk, we do not agree that CMS' previous acceptance of FDA guidance documents must be considered sufficient evidence of substantial clinical improvement for the nominated device. The ultimate determination of whether evidence demonstrates substantial clinical improvement for one application, while taken into consideration as appropriate, is not controlling on future determinations. Again, due to inherent differences in the devices themselves and the supporting documentation submitted, CMS may have different concerns as they relate to the nominated device. In addition, we are not precluded from evaluating evidence and expressing concerns regarding types of evidence submitted in support of an application simply because that type of evidence has been submitted in support of a previous application. As we stated previously, while we encourage applicants to read the application summaries presented in previous OPPS/ASC rules as they can help applicants determine the types of documentation that have been submitted and assess areas of potential concern with their technology, we caution applicants from relying solely on the presumption that previously submitted types of evidence, evaluated for a different device, either need not be submitted or need not be fully addressed as it relates to their technology. We encourage applicants to submit all relevant supporting evidence with their device pass-through application to allow us to adequately evaluate and include the data in the notice of proposed rulemaking.

Comment: In response to our concern that the Châteauvieux et al.[87] and Barron and Kennedy [88] studies suggested limiting the use of single-use bronchoscope devices to specific situations (that is, after hours or emergency), immunocompromised patients, and in rare cases of preventing prior contamination in the inpatient setting, the applicant asserted that this recommendation was made due to the potential cost burdens of reusable scopes referenced in the study. The applicant further asserted that if cost was not a barrier and facilities widely adopted single-use bronchoscopes, such as the Ambu® aScope™ 5 Broncho HD, the benefits of advanced bronchoscopy procedures would be more accessible. One commenter, writing in support of approval of the nominated device for pass-through payment, expressed concern that the cost of Ambu® aScope™ 5 Broncho HD created a barrier to utilization, and agreed with the applicant that Châteauvieux et al.[89] and Barron and Kennedy [90] suggest limiting single-use scopes to specific case types because of cost. However, this commenter noted that studies by Maerkedahl et al., Mouritsen et al., and Kurman et al. all found that single-use scopes are economically advantageous relative to reusable scopes. This commenter stated that despite these findings, cost does admittedly remain a major barrier to broader adoption of single-use scopes. This commenter noted that improving reimbursement would help mitigate this barrier and allow more physicians to use the device for advanced bronchoscopy cases where it is now the preferred option. The applicant, in response to this comment indicated that, as this section (the substantial clinical improvement section under which the comment was submitted) is not about cost, it is not relevant to whether the Ambu® aScope™ 5 Broncho HD can provide a substantial clinical improvement.

Response: We appreciate the commenters' input. While the applicant did not provide in its application additional information about situations where use of single-use bronchoscopes would be optimal, we appreciate the insight provided from the applicant and several commenters who gave specific examples for how the device allows for advanced bronchoscopy procedures to be performed with a single-use scope, without concern for contamination, specifically for procedures that include but are not limited to: transbronchial biopsy, airway inspection for high-risk/immunocompromised patients, and procedures with high-frequency tools.

While we maintain our belief that further investigation with comparators in these specified cases would more directly establish whether the device demonstrates a substantial clinical improvement over currently available treatment options in the clinical setting where it is most likely to be used, we understand that this data may not be available. We agree with the commenters that Châteauvieux et al.[91] and Barron and Kennedy [92] studies suggested limiting the use of single-use bronchoscope device to specific situations, in part, due to cost considerations. After consideration of the public comments received, we agree that the evidence demonstrates that the device is a substantial clinical improvement over currently available treatment options in the clinical setting.

In addition, we thank the commenter for their input on how approval would impact existing barriers to broader adoption of single-use scopes. While the

[85] *Ibid.*

[86] Ho, E., Wagh, A., Hogarth, K., Murgu, S. (2022). Single-use and reusable flexible bronchoscopes in pulmonary and critical caremedicine. *Diagnostics, 12*(1):174. Retrieved from: *https://doi.org/10.3390/diagnostics12010174.*

[87] Châteauvieux, C., Farah, L., Guérot, E., Wermert, D., Pineau, J., Prognon, P., Borget, I., & Martelli, N. (2018). Single-use flexible bronchoscopes compared with reusable bronchoscopes: Positive organizational impact but a costly solution. *Journal of evaluation in clinical practice, 24*(3), 528–535. *https://doi.org/10.1111/jep.12904.*

[88] Barron, S.P., & Kennedy, M.P. (2020). Single-use (disposable) flexible bronchoscopes: the future of bronchoscopy? *Advances in therapy, 37*(11), 4538–4548. *https://doi.org/10.1007/s12325-020-01495-8.*

[89] Châteauvieux, C., Farah, L., Guérot, E., Wermert, D., Pineau, J., Prognon, P., Borget, I., & Martelli, N. (2018). Single-use flexible bronchoscopes compared with reusable bronchoscopes: Positive organizational impact but a costly solution. *Journal of evaluation in clinical practice, 24*(3), 528–535. *https://doi.org/10.1111/jep.12904.*

[90] Barron, S.P., & Kennedy, M.P. (2020). Single-use (disposable) flexible bronchoscopes: the future of bronchoscopy? *Advances in therapy, 37*(11), 4538–4548. *https://doi.org/10.1007/s12325-020-01495-8.*

[91] Châteauvieux, C., Farah, L., Guérot, E., Wermert, D., Pineau, J., Prognon, P., Borget, I., & Martelli, N. (2018). Single-use flexible bronchoscopes compared with reusable bronchoscopes: Positive organizational impact but a costly solution. *Journal of evaluation in clinical practice, 24*(3), 528–535. *https://doi.org/10.1111/jep.12904.*

[92] Barron, S.P., & Kennedy, M.P. (2020). Single-use (disposable) flexible bronchoscopes: the future of bronchoscopy? *Advances in therapy, 37*(11), 4538–4548. *https://doi.org/10.1007/s12325-020-01495-8.*

applicant is correct that we do not assess cost in § 419.66(c)(2), CMS recognizes the importance of addressing cost as a barrier to utilization, and as stated in section 2.a., a goal of transitional pass-through is to target pass-through payments for those devices where cost considerations are most likely to interfere with patient access (66 FR 55852; 67 FR 66782; and 70 FR 68629). We address the cost of Ambu® aScope™ 5 Broncho HD and the cost significance criteria below.

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 be met. The applicant provided the following information in support of the cost significance requirements. The applicant stated that the Ambu® aScope™ 5 Broncho HD would be reported with HCPCS codes listed in Table 87.

BILLING CODE 4150–28–P

TABLE 87: HCPCS CODES REPORTED WITH THE AMBU® ASCOPE™ 5 BRONCHO HD

HCPCS Code	Long Descriptor	SI	APC
31615	Tracheobronchoscopy through established tracheostomy incision	T	5162
31622	Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; diagnostic, with cell washing	J1	5153
31623	Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; diagnostic, with brushing or protected brushings	J1	5153
31624	Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; diagnostic, with bronchial alveolar lavage	J1	5153
31625	Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; diagnostic, with bronchial or endobronchial biopsy(s), single or multiple sites	J1	5153
31626	Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; diagnostic, with placement of fiducial markers, single or multiple	J1	5155
31628	Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; diagnostic, with transbronchial lung biopsy(s), single lobe	J1	5154
31629	Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; diagnostic, with transbronchial needle aspiration biopsy(s). Trachea, main stem and/or lobar bronchus(i)	J1	5154
31630	Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; diagnostic, with tracheal/bronchial dilation or closed reduction of fracture	J1	5154
31631	Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; diagnostic, with placement of tracheal stent(s) (includes tracheal/bronchial dilation as required	J1	5155
31634	Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with balloon occlusion, with assessment of air leak, with administration of occlusive substance (e.g., fibrin glue), if performed	J1	5155
31635	Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; diagnostic, with removal of foreign body	J1	5153
31636	Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; diagnostic, with placement of bronchial stent(s)(includes tracheal/bronchial dilation as required), initial bronchus	J1	5155
31638	Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; diagnostic, with revision of tracheal or bronchial stent inserted at previous session (includes tracheal/bronchial dilation as required)	J1	5155
31640	Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; diagnostic, with excision of tumor	J1	5154
31641	Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; diagnostic, with destruction of tumor or relief of stenosis by any method other than excision (e.g., laser therapy, cryotherapy)	J1	5154

HCPCS Code	Long Descriptor	SI	APC
31643	Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; diagnostic, with placement of catheter(s) for intracavitary radioelement application	J1	5153
31645	Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; diagnostic, with therapeutic aspiration of tracheobronchial tree, initial	J1	5153
31646	Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; diagnostic, with therapeutic aspiration of tracheobronchial tree, subsequent, sams hospital stay	T	5152
31647	Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; diagnostic, with balloon occlusion, when performed, assessment of air leak, airway sizing, and insertion of bronchial valve(s), initial lobe	J1	5155
31648	Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; diagnostic, with removal of bronchial valve(s), initial lobe	J1	5154
31652	Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; diagnostic, with endobronchial ultrasound (EBUS) guided transtracheal and/or transbronchial sampling (e.g., aspiration(s)/biopsy[ies]), one or two mediastinal and/or hilar lymph node stations or structures	J1	5154
31653	Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; diagnostic, with endobronchial ultrasound (EBUS) guided transtracheal and/or transbronchial sampling (eg, aspiration(s)/biopsy[ies]), 3 or more mediastinal and/or hilar lymph node stations or structures	J1	5154
31660	Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with bronchial thermoplasty, 1 lobe	J1	5155
31661	Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with bronchial thermoplasty, 2 or more lobes	J1	5155
31785	Excision of tracheal tumor or carcinoma; cervical	J1	5165
32400	Biopsy, pleura, percutaneous needle	J1	5072
32550	Insertion of indwelling tunneled pleural catheter with cuff	J1	5341
32551	Tube thoracostomy, includes connection to drainage system (eg, water seal), when performed, open (separate procedure)	J1	5182
32552	Removal of indwelling tunneled pleural catheter with cuff	Q2	5181
32554	Thoracentesis, needle or catheter, aspiration of the pleural space; without imaging guidance	T	5181
31627	Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; diagnostic, with computer-assisted, image-guided navigation	**	N/A
31632	Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; diagnostic, with transbronchial lung biopsy(s), each additional lobe (list separately in addition to code for primary procedure)	**	N/A
31633	Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; diagnostic, with transbronchial needle aspiration	**	N/A

HCPCS Code	Long Descriptor	SI	APC
	biopsy(s), each additional lobe (list separately in addition to code for primary procedure)		
31637	Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; diagnostic, each additional major bronchus stented (list separately in addition to code for primary procedure)	**	N/A
31649	Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; diagnostic, with removal of bronchial valve(s), each additional lobe (list separately in addition to code for primary procedure)	**	N/A
31654	Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; diagnostic, with endobronchial ultrasound (EBUS) during bronchoscopic diagnostic or therapeutic intervention(s) for peripheral lesion(s)	**	N/A
31780	Excision tracheal stenosis and anastomosis; cervical	**	N/A
31781	Excision tracheal stenosis and anastomosis; cervicothoracic	**	N/A
31786	Excision of tracheal tumor or carcinoma; thoracic	**	N/A
32200	Pneumonostomy, with open drainage of abscess or cyst	**	N/A
32674	Thoracoscopy, surgical; with mediastinal and regional lymphadenectomy (List separately in addition to code for primary procedure)	**	N/A
32815	Open closure of major bronchial fistula	**	N/A

** Denotes a HCPCS code that was not evaluated for the cost criterion because the HCPCS code was not included in Addendum P to the CY 2022 OPPS/ASC final rule with comment period, as corrected in the 2022 Correction Notification OPPS Addendum (87 FR 2060).

BILLING CODE 4150–28–C

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. As we explained in the CY 2005 OPPS final rule with comment period (69 FR 65775), we generally use the lowest APC payment rate applicable for use with the nominated device when we assess whether a device meets the cost significance criterion, thus increasing the probability the device will pass the cost significance test. For our calculations, we used APC 5152, which had a CY 2022 payment rate of $383.33 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). We noted that the HCPCS code 31646 identified by the applicant had a device offset amount of $0.00 at the time the application was received. Accordingly, we are evaluating the cost significance requirements using $0.00 as the appropriate device offset amount. According to the applicant, the cost of the Ambu® aScope™ 5 Broncho HD is $799.00.

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 $799.00 for the Ambu® aScope™ 5 Broncho HD is 208.44 percent of the applicable APC payment amount for the service related to the category of devices of $383.33 (($799.00/$383.33) × 100 = 208.44 percent). Therefore, we stated that we believe the Ambu® aScope™ 5 Broncho HD 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). Given that there are no device-related costs in the APC payment amount, and the Ambu® aScope™ 5 Broncho HD has an estimated average reasonable cost of $799.00, we stated that we believe the Ambu® aScope™ 5 Broncho HD 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 $799.00 for the Ambu® aScope™ 5 Broncho HD and the portion of the APC payment amount for the device of $0.00 exceeds the APC payment amount for the related service of $799.00 by 208.44 percent ((($799.00 − $0.00)/$383.33) × 100 = 208.44 percent). Therefore, we stated that we believe the Ambu aScope™ 5 Broncho HD meets the third cost significance requirement.

We invited public comment on whether the Ambu® aScope™ 5 Broncho HD meets the device pass-through payment criteria discussed in this section, including the cost criterion for device pass-through payment status.

We did not receive any comments with regard to any of the cost significance requirements specified at § 419.66(d). Based on our findings from the first, second, and third cost significant tests, we believe that the Ambu® aScopeTM 5 Broncho HD device

meets the cost significance criterion specified at § 419.66(d).

After consideration of the public comments we received and our review of the device pass-through application, we have determined that the Ambu® aScope™ 5 Broncho HD meets the criteria for device pass-through status. We are approving this application because the documentation (namely the FDA document and additional studies) that were submitted in response to the proposed rule address our concerns and provide evidence of substantial clinical improvement that is required. Therefore, we are approving the Ambu® aScope™ 5 Broncho HD for transitional pass-through payment status beginning January 1, 2024.

(b) Praxis Medical CytoCore

Praxis Medical, LLC submitted an application for a new device category for transitional pass-through payment status for Praxis Medical CytoCore (CytoCore) for CY 2024. Per the applicant, CytoCore is a single-use disposable biopsy instrument. Per the applicant, at the time of biopsy, the motorized CytoCore device contains gears and an internal motor that spins a minimally invasive needle to increase cellular yields in fewer passes. The applicant further explained that CytoCore is vacuum-assisted and can easily be operated using one hand. According to the applicant, the primary use is for biopsy of any suspicious thyroid nodule.

The applicant stated that the CytoCore Biopsy Instrument device package includes: (1) a single CytoCore biopsy instrument, powered by an alkaline type battery; (2) three luer adaptors; (3) a 5ml syringe; and (4) an instructions for use (IFU) booklet. Per the applicant, the CytoCore is compatible with disposable needles of 22-to-25-gauge and 4-to-10-cm length that are intended for soft tissue biopsy procedures (needles are not included in the device package). The applicant further explained that only the CytoCore luer adapters and syringes provided by Praxis can be used on CytoCore and that the CytoCore luer adapters can only be used with the CytoCore Biopsy Instrument.

Per the applicant, the operator of CytoCore can direct the needle and draw back the plunger with only one hand, thereby diminishing the need to move the needle in an in-and-out motion to harvest cells. As with other types of biopsies, the sample collected can help make a diagnosis or rule out conditions such as cancer. The applicant claimed that CytoCore enables the physician to collect more cellular material in fewer passes and reduce the number of repeat biopsies and surgeries resulting from inadequate cellular samples obtained using standard fine needle aspiration (FNA). According to the applicant, CytoCore is designed to collect enough DNA for pathology to definitively rule in or out cancer and inform subsequent treatment at the time of the first biopsy. Per the applicant, studies report nondiagnostic rates for biopsies to be as high as 30 to 50 percent using FNA biopsy.[93]

As stated previously, to be eligible for transitional pass-through payment under the OPPS, a device must meet the criteria at § 419.66(b)(1) through (4). With respect to the newness criterion at § 419.66(b)(1), on March 31, 2020, the applicant received 510(k) clearance from FDA for CytoCore for use as a device to hold a syringe for performing a biopsy of an identified mass with one hand. We received the application for a new device category for transitional pass-through payment status for CytoCore on August 31, 2022, which is within 3 years from the date of the initial FDA marketing authorization.

We invited public comments on whether CytoCore meets the newness criterion at § 419.66(b)(1).

We did not receive public comments regarding whether CytoCore meets the newness criterion at § 419.66(b)(1). We received the application for a new device category for transitional pass-through payment status for CytoCore on August 31, 2022, which is within 3 years of the initial FDA marketing authorization on March 31, 2020, and as such, we have concluded that CytoCore meets the newness criterion.

With respect to the eligibility criterion at § 419.66(b)(3), the applicant did not assert whether CytoCore is integral to the service provided. According to the applicant, CytoCore is used for one patient only. Per the applicant, CytoCore comes into contact with human tissue and is surgically inserted via the syringe attached to the motorized CytoCore device. Per the applicant, CytoCore is used with a 22-to-25-gauge standard fine needle (not included in the device package), which is inserted into human tissue to collect cellular samples. The applicant stated that the fine needle is attached to CytoCore, inserted into the nodule, and cellular material is collected through the needle into the syringe. The applicant further explained that the cellular material is visible in the hub of the needle or the luer adapter. However, we noted that the motorized CytoCore device itself is not surgically implanted or inserted (either permanently or temporarily) or applied in or on a wound or other skin lesion, as required at § 419.66(b)(3). Further, we noted that according to the FDA 510(k) Summary and Indication for Use, CytoCore is a device to hold a syringe for performing a biopsy of an identified mass with one hand and that the device never comes in contact with the patient.

With respect to the exclusion criterion at § 419.66(b)(4), the applicant did not address whether CytoCore is equipment, an instrument, apparatus, implement, or item of this type for which depreciation and financing expenses are recovered as depreciable assets. The applicant also did not address whether CytoCore is a supply or material furnished incident to a service or whether the device is surgically implanted or inserted (either permanently or temporarily) or applied in or on a wound or other skin lesion, as required by § 419.66(b)(3). However, in the CY 2000 OPPS interim final rule with comment period (65 FR 67804 and 67805), we explained how we interpret the exclusion criterion at § 419.66(b)(3). We stated that we consider a device to be surgically implanted or inserted if it is surgically inserted or implanted via a natural or surgically created orifice or inserted or implanted via a surgically created incision. We also stated that we do not consider an item used to cut or otherwise create a surgical opening to be a device that is surgically implanted or inserted. We consider items used to create incisions, such as scalpels, electrocautery units, biopsy apparatuses, or other commonly used operating room instruments, to be supplies or capital equipment not eligible for transitional pass-through payments. We stated that we believe the function of these items is different and distinct from that of devices that are used for surgical implantation or insertion. Finally, we stated that, generally, we would expect that surgical implantation or insertion of a device occurs after the surgeon uses certain primary tools, supplies, or instruments to create the surgical path or site for implanting the device. In the CY 2006 OPPS final rule with comment period (70 FR 68516, 70 FR 68629 and 68630), we adopted as final our interpretation that the surgical insertion or implantation criterion can be met by devices that are surgically inserted or implanted via a natural or surgically created orifice, as well as those devices that are inserted or implanted via a surgically created incision. We reiterated that we maintain all of the other criteria in § 419.66 of the

[93] CMS made minor edits to the device description in this final rule with public comment to improve clarity.

regulations, namely, that we do not consider an item used to cut or otherwise create a surgical opening to be a device that is surgically implanted or inserted.

We invited public comments on whether CytoCore meets the exclusion criteria at § 419.66(b)(3) and (4).

Comment: The applicant asserted that CytoCore meets the eligibility requirements at § 419.66(b)(3) and (4). In response to our concerns that the motorized CytoCore device itself is not surgically implanted or inserted (either permanently or temporarily) or applied in or on a wound or other skin lesion, as required at § 419.66(b)(3), the applicant asserted that CytoCore is integral to the service provided for Fine Needle Aspiration (FNA) of suspicious thyroid nodules because the CytoCore motorized device is an essential component, offering precise control with a needle that is attached to the device, and CytoCore is adaptable for various lesion characteristics. Further, the applicant explained that, using ultrasound guidance, the needle is advanced through the patient's skin into the nodule, ensuring collection of adequate material.

In response to our concerns that Cytocore may be considered a supply or material furnished incident to a service as described in § 419.66(b)(4), the applicant stated that CytoCore does not function as a surgical tool. In support of this assertion, the applicant referenced the FDA definition of a manual surgical instrument (21 CFR 878.4800). The applicant stated that, because CytoCore is powered and non-resuable, it does not meet the definition of a ''surgical instrument'' per the FDA definition.

Response: We appreciate the commenter's input regarding whether CytoCore meets the eligibility criteria at § 419.66(b)(4). However, we do not believe that CytoCore meets the eligibility criteria described at § 419.66(b)(4).

With respect to the eligibility criterion at § 419.66(b)(4), while we appreciate the assertion that CytoCore may not be defined as a ''surgical instrument'' according to the FDA definition (21 CFR 878.4800), we note that FDA and CMS utilize different definitions for many terms. In this instance, CMS has established a clear definition for a supply or material furnished incident to a service for the purposes of determining OPPS device pass-through payment eligibility.

In the proposed rule, we reiterated that for the criteria at § 419.66, CMS adopted the interpretation of § 419.66(b)(4) in the CY 2006 OPPS final rule with comment period (70 FR 68629 and 68630). Specifically, we stated that CMS does not consider an item used to cut or otherwise create a surgical opening to be a device that is surgically implanted or inserted. CMS considers a device to be surgically implanted or inserted if it is surgically inserted or implanted via a natural or surgically created orifice or inserted or implanted via a surgically created incision. Further, we provided that CMS considers items used to create incisions, such as scalpels, electrocautery units, biopsy apparatuses, or other commonly used operating room instruments, to be supplies or capital equipment not eligible for transitional pass-through payments. The function of these items is different and distinct from surgical implantation or insertion and CMS expects that surgical implantation or insertion of a device occurs after the surgeon uses certain primary tools, supplies, or instruments to create the surgical path or site for implanting the device.

With respect to the eligibility criterion at § 419.66(b)(4), based on the information we received in the application and the public comments as well as discussion of the criterion in § 419.66(b)(4) that we adopted in the CY 2006 OPPS final rule with comment period (70 FR 68629 and 68630), we have determined that CytoCore is a biopsy apparatus and, as such, is a material or supply furnished incident to a service, in accordance with the device eligibility requirements in the proposed rule and, as such, does not meet the eligibility criteria at § 419.66(b)(4).

CytoCore does not meet the eligibility criteria to be considered a device for transitional pass-through payment. Therefore, we did not evaluate whether the product meets the other criteria required for transitional pass-through payment for devices, including whether it is described by existing or previous categories, whether it is a substantial clinical improvement, or whether it meets the cost criteria. We are not approving CytoCore for transitional pass-through payment status for CY 2024 because the product does not meet the eligibility criteria at § 419.66(b)(4).

We note that we received public comments with regard to the substantial clinical improvement criterion for this device, but because we have determined that the device does not meet the eligibility criteria and therefore, is not eligible for approval for transitional pass-through payment status for CY 2024, we are not summarizing comments received or making a determination on that criterion in this final rule.

(c) EchoTip®

Cook Medical submitted an application for a new device category for transitional pass-through payment status for the EchoTip® Insight Portosystemic Pressure Gradient Measurement System® (EchoTip®) for CY 2024. According to the applicant, EchoTip® is used in the diagnosis and management of patient populations with chronic liver diseases (CLDs), and especially with non-alcoholic fatty liver Disease (NAFLD). The applicant stated that EchoTip® directly measures pressures in the hepatic and portal venous vasculatures and is used in conjunction with an ultrasound endoscope. A curvilinear array echoendoscope is advanced to the stomach, and the portal and hepatic veins are visualized under ultrasound guidance. A 25-gauge needle (which is prepared prior to the endoscopy by attaching it to connection tubing and a disposable transducer) is advanced through the echoendoscope which then punctures the hepatic vein through the liver parenchyma, and a pressure measurement is obtained. Per the applicant, a total of three measurements are obtained, after which the needle is retracted into the echoendoscope which is then repositioned for portal vein access. The needle is then advanced to the portal vein where another set of three pressure measurements is obtained. The portosystemic pressure gradient is calculated by determining the difference between the two averaged measurements.

According to the applicant, EchoTip® is a single-use, disposable device comprised of the EchoTip® Insight Needle, a connecting tube, and a Compass CT transducer. EchoTip® is supplied with a 10 ml syringe. Once assembled, EchoTip® is used with an ultrasound endoscope and directly measures pressures in the hepatic and portal venous vasculatures. The EchoTip® Insight Needle is stainless steel, has a handle and protective outer sheath, and attaches to the accessory channel of the endoscope. The polyethylene connecting tube consists of a 90 cm tube, a female luer fitting, a male luer fitting, and a stopcock. The connecting tube is used to attach the transducer to the needle handle. The stopcock is used to aid priming of the assembled components. The Compass CT transducer is a self-calibrating disposable pressure transducer with integrated digital display. EchoTip® is intended for direct measurement and monitoring of physiological pressure,

including during the infusion of fluids and therapeutic and diagnostic agents.[94]

As stated previously, to be eligible for transitional pass-through payment under the OPPS, a device must meet the criteria at § 419.66(b)(1) through (4).

We invited public comment on whether EchoTip® meets the newness criterion at § 419.66(b)(1).

Comment: With respect to the newness criterion at § 419.66(b)(1), the applicant reiterated their belief that EchoTip® meets the newness criterion. The applicant stated that the FDA granted de Novo authorization on November 20, 2019, therefore meeting the criteria at § 419.66(b)(1) because the application is within 3 years of the date of the initial FDA marketing authorization on November 20, 2019.

Response: We appreciate the commenter's input and agree that because we received the application for EchoTip® on June 29, 2022, which is within 3 years of FDA approval on November 20, 2019, EchoTip® meets the newness criterion.

With respect to the eligibility criterion at § 419.66(b)(3), the applicant stated that EchoTip® 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. According to the applicant, the hepatic vein and portal vein are punctured through the liver parenchyma to obtain pressure measurements.

We invited public comment on whether EchoTip® meets the integral part of the service criterion at § 419.66(b)(3).

Comment: The applicant asserted that EchoTip® meets the eligibility requirements at § 419.66(b)(3), stating that EchoTip® is a prescription, single-use device consisting of the EchoTip® Insight Needle, a connecting tube, and a Compass CT transducer that is integral to the service provided.

Response: After consideration of the public comments we received, we agree that the applicant meets the eligibility criterion at § 419.66(b)(3) because it is integral to the service provided, is used for one patient only, and punctures the hepatic vein and portal vein through the liver parenchyma to obtain pressure measurements.

With respect to the exclusion criterion at § 419.66(b)(4), the applicant claimed that EchoTip® meets the device eligibility requirements because it is not equipment, an instrument, apparatus, implement, or item of this type for which depreciation and financing expenses are recovered, and it is not a supply or material furnished incident to a service.

We invited public comment on whether EchoTip® meets the exclusion criterion at § 419.66(b)(4).

Comment: The applicant asserted that EchoTip® meets the device eligibility requirements because it is not equipment, an instrument, apparatus, implement, or item of this type for which depreciation and financing expenses are recovered, and it is not a supply or material furnished incident to a service.

Response: We appreciate the commenter's input. We agree with the applicant that EchoTip® meets the device eligibility requirements at § 419.66(b)(4) because it is not a piece of equipment, 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. Therefore, based on the public comments we have received and our review of the application, we have determined that EchoTip® meets the eligibility criteria at § 419.66(b)(4).

In addition to the criteria at § 419.66(b)(1) through (4), 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 described EchoTip® as the only device authorized by the FDA with an indication to directly access and measure pressure in the hepatic and portal venous vasculatures in conjunction with an ultrasound endoscope. Per the applicant, FDA established that there is no recognized predicate product, or other similar approved device with a similar mechanism of action. Per the applicant, no previous device categories for pass-through payment have encompassed EchoTip® and there are no similar device categories. We stated in the CY 2024 OPPS/ASC proposed rule that, upon review, it does not appear that there are any existing pass-through payment categories that might apply to EchoTip®.

We invited public comment on whether EchoTip® meets the device category criterion at § 419.66(c)(1).

Comment: Regarding the eligibility criterion at § 419.66(c)(1), the applicant reiterated that there is no comparable existing pass-through payment category that describes EchoTip®.

Response: We appreciate the commenter's input. After consideration of the public comments we received, we continue to believe that there is not an existing pass-through payment category that describes EchoTip®, and therefore, EchoTip® meets the device category eligibility criterion at § 419.66(c)(1).

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 is part of the FDA's Breakthrough Devices Program and has received FDA marketing authorization for the indication covered by the Breakthrough Device designation. The applicant claimed that EchoTip® represents a substantial clinical improvement over existing technologies in the diagnosis and management of chronic liver disease because: (1) Endoscopic ultra-sound-guided direct portal-systemic pressure gradient measurement (EUS–PPG)-guided measurement is clinically safer and more accurate than the current standard transjugular endovascular indirect measurement, referred to as the hepatic venous pressure gradient (HVPG); (2) EUS–PPG is technically feasible and superior to HVPG; (3) EUS–PPG has benefits in non-cirrhotic patients; and (4) EUS–PPG has utility in the evaluation of ESRD patients and kidney transplant candidacy. The applicant provided four articles specifically for the purpose of addressing the substantial clinical improvement criterion claims. The applicant also included one background article that discussed social determinants of health and disparities in liver disease.[95]

[94] CMS made minor edits to the device description in this final rule with public comment to improve clarity.

[95] Kardashian, A., Wilder, J., Terrault, N. Price, J. (2021). Addressing social determinants of liver disease during the COVID–19 pandemic and beyond: A call to action. *Hepatology, 73*(2): 811–820.

In support of the first claim, the applicant submitted an article on a prospective, single-armed, single-academic center study.[96] Patients with suspected liver disease or cirrhosis were enrolled prospectively from 2020 to 2021. EUS–PPG was measured by calculating the difference between the mean portal pressure and the mean hepatic vein pressure. PH was defined as PPG >5 mm Hg and clinically significant PH as PPG<10 mm Hg. The primary outcomes were procedural technical success rate and correlation of EUS–PPG with fibrosis stage obtained from concurrent EUS-guided liver biopsy sampling and the correlation of EUS–PPG with patients' imaging, clinical, and laboratory findings. The secondary outcome was occurrence of procedural adverse events. EUS–PPG measurement was successful in 23 patients, leading to a technical success rate of 96 percent. The authors reported that there was no statistically significant correlation between the fibrosis stage on histology and measured PPG (P=.559). According to the authors, this did not change after excluding three patients without established chronic liver disease from the analysis. The authors reported that one patient experienced a mild adverse event with postprocedural abdominal pain resulting in an emergency department visit. The authors also reported that five patients (28 percent) received oral acetaminophen in the post anesthesia care unit for mild abdominal pain after the procedure, which resolved in all cases before discharge without the need for further pharmacotherapy.

In support of its second claim, the applicant submitted a single-center retrospective study on patients with various CLDs undergoing EUS–PPG and EUS-guided liver biopsy (EUS-bx) to assess correlation with histological hepatic fibrosis stage and various clinical, laboratory, endoscopic and imaging variables indicative of advanced liver disease.[97] Cases with EUS–PPG were identified at the University of California Irvine, a tertiary endoscopy center, between January 2014 and March 2020. Three different ways of evaluating the EUS–PPG outcomes were assessed: (1) success rate of the EUS–PPG measurement; (2) performance; and (3) safety profile. The primary outcome evaluated was the association between EUS–PPG and the presence of histologic liver fibrosis, stage ≥ 3. EUS–PPG procedures were successfully completed in all 64 cases. On multivariate analysis, EUS–PPG ≥ 5 mmHg was significantly associated with fibrosis stage ≥ 3 on EUG-liver biopsy (LR 27.0, 95 percent CI = 1.653–360.597, p = 0.004), independent from C-cirrhosis, clinical portal hypertension, thrombocytopenia, splenomegaly, aspartate aminotransferase to platelet ration index score > 2, and fibrosis-4 score > 3.25. There were six complications in total, including abdominal pain (n = 3) and sore throat (n = 3). The authors reported that there were no subjects who had post-EUS–PPG emergency room (ER) visits or hospital admissions.

In support of its third claim, the applicant submitted a review of endoscopic ultrasound guided interventions. The article [98] discussed the diagnosis and treatment of portal hypertension and treatment of gastric varices (GV) and compared liver biopsy, HVPG, and EUS–PPG. With respect to the utility of HVPG, the authors explained that in the absence of fibrosis/nodules (that is, cirrhosis) the pressure equalizes throughout the interconnected sinusoidal network, and results in minimal gradient (that is, normal; up to 4 mmHg). Thus, according to the authors, HVPG does not provide useful information regarding prehepatic or presinusoidal portal hypertension (PH) (that is, non-cirrhotic causes of PH). In comparison, EUS-guided portal pressure gradient (PPG) measurements employ a direct sampling technique. Thus, the study authors found direct measurement of the portal vein pressure could be considered the gold standard because it is not an estimate of sinusoidal pressure as is HVPG. The difference in the mean measurement of these pressures is termed the PPG which is analogous to the HVPG, with the caveat that direct portal vein measurement also allows for the assessment of prehepatic/presinusoidal PH; a limitation of the transjugular approach. The study authors cited a study by Huang et al.[99] that used a porcine animal model with a novel EUS-guided system which included a manometer attached to a 25-gauge fine needle aspiration (FNA) needle for directly measuring pressures in the hepatic and portal veins. The purpose of this animal study was to assess clinical feasibility and assess correlation with the standard of care: HVPG measurement through transjugular approach. The study authors further cited a pilot study involving 28 patients between the age of 18–75 years with a history of liver disease or suspected cirrhosis that underwent EUS–PPG measurements using the technique and equipment in the animal study. The portal vein and hepatic vein were targeted via a transgastric–transduodenal approach (inferior vena cava (IVC) was substituted for hepatic vein when not technically feasible). The technical success rate of EUS–PPG measurement was 100 percent without any adverse events. The study authors concluded that EUS–PPG measurement was a safe and feasible alternative to HVPG measurement.

In support of its fourth claim, the applicant submitted a letter in which the author described a retrospective, single-center study to determine feasibility, safety, and utility of EUS–PPG using EUS-liver biopsy as comparison in patients with end stage renal disease (ESRD) and suspected portal hypertension.[100] According to the letter author, the purpose of the study was to investigate the use of EUS–PPG to assess pressure and the recommendation to decide between kidney transplant (KT) or combined liver KT. According to the letter author, the study suggested that new endoscopic and EUS findings were discovered with successful/reproducible EUS–PPG in 10 out of 11 (91 percent) subjects. The author stated there were no significant adverse events such as bleeding related to venous punctures, transfusions, or EUS–PPG-related hospitalizations. The author referenced conclusions from the study citing the need for further studies correlating EUS–PPG with wedged hepatic vein pressure gradient (WHVPG), assessing patient experience, and analyzing cost/benefit of one-stop versus piecemeal procedures. It is also noted in the letter that WHVPG may not always be feasible in ESRD patients due to catheter-related suprapubic thromboses. We noted that

[96] Hajifathalian, K., Westerveld, D., Kaplan, A. et al. (2022). Simultaneous EUS-guided portosystemic pressure measurement and liver biopsy sampling correlate with clinically meaningful outcomes. *Gastrointestinal endoscopy 95*(4): 703–710.

[97] Choi, A., Chang, K., Samaransena, J. et al. (2022). Endoscopic ultrasound-guided porto-systemic pressure gradient measurement correlates with histological hepatic fibrosis. *Digestive Diseases and Sciences. https://doi.org/10.1007/s10620-022-07418-7.*

[98] Rudnick, S., Conway, J., Russo, M. (2021). Current state of endohepatology: Diagnosis and treatment of portal hypertension and its complications with endoscopic ultrasound. *World Journal of Hepatology, 13*(8): 887–895.

[99] Huang, J.Y., Samarasena, J.B., Tsujino, T., Chang, K.J. (2016). EUS-guided portal pressure gradient measurement with a novel 25-gauge needle device versus standard transjugular approach: A comparison animal study. *Gastrointest Endosc, 84:* 358–362 [PMID: 26945557 DOI: 10.1016/j.gie.2016.02.032].

[100] Rubin, R, Mehta, M., Rossi, A., Joeslon, D., Shrestha, R. (2021). Letter to the Editor: Endoscopic ultrasound guided portal-systemic pressure gradient measurement to determine candidacy for kidney transplant alone versus combined liver kidney transplant in patients with advanced fibrosis or cirrhosis. *Transplant International 2021*(34): 2903–2904.

this source did not include the original retrospective study, only a letter referencing it and highlighting its potential value to further research.

Based on the evidence submitted with the application, we noted the following concerns: a lack of direct comparison of EUS–PPG with HVPG and non-invasive methods, a lack of consistent correlation with liver biopsy, the reliance on non-peer reviewed studies, and small sample sizes.

In the first two claims, the applicant asserted EUS–PPG is clinically safer and more accurate than HVPG and technically superior to HVPG. However, the applicant did not directly compare EUS–PPG and HVPG. The Hajifathalian et al. study,[101] which was submitted in support of the first claim, stated EUS–PPG offers an alternative and potentially superior methodology to measure PPG regardless of liver disease etiology, without showing evidence of a direct comparison between EUS–PPG and HVPG. The Choi et al. study,[102] which was submitted in support of the second claim, directly compared EUS–PPG with EUS-liver biopsy, but it did not compare EUS–PPG with HVPG. The authors cited the lack of direct comparison between EUS–PPG and HVPG as a limitation in the study. Further these two studies had small sample sizes and were conducted at a single site; the Hajifathalian et al. study included 24 patients while the Choi et al. study included 64 patients.

In addition, we noted that the Hajifathalian et al. study results did not demonstrate correlation with fibrosis stage obtained from concurrent EUS-guided liver biopsy sampling. According to the authors, there was no statistically significant correlation between the fibrosis stage on histology and measured PPG (P=.559). We expressed concern that the lack of correlation would not support the claim that EUS-guided PPG measurement is more accurate than the current method using an indirect measurement with the use of HVPG.

In support of its fourth claim, we noted that the applicant relied on a letter to the editor that provides a study description rather than submitting the study directly as evidence for its claim.[103] In the enclosed letter, the author also noted that future studies are needed to correlate EUS–PPG with WHVPG. Lastly, the article the applicant provided in support of social determinants of health and disparities did not directly discuss the device. Additional supporting evidence, preferably published peer-reviewed clinical trials that show improved clinical outcomes would help with our assessment of whether EchoTip® demonstrates substantial clinical improvement over existing technologies.

We invited public comment on whether EchoTip® meets the substantial clinical improvement criterion at § 419.66(c)(2)(i).

Comment: In response to our concern that the applicant has not demonstrated the endoscopic ultra-sound-guided direct portal-systemic pressure gradient measurement (EUS–PPG) is clinically safer and more accurate than hepatic venous pressure gradient (HVPG) and technically superior to HVPG without directly comparing EUS–PPG and HVPG, we received comments from the applicant reiterating that the Huang et al.[104] studies compared EchoTip® direct EUS–PPG with the indirect HVPG method in a swine model using rapid dextran infusion to create transient portal hypertension and confirmed EchoTip® direct EUS–PPG matches pressures measured using a transjugular balloon catheter. The applicant asserted that the findings comparing preoperative EchoTip® direct EUS–PPG with HVPG in patients with cirrhosis or suspected cirrhosis undergoing abdominal surgery showed results that match findings from literature substantiating that direct portal vein pressures (PVP) correlate to the indirect Wedged Hepatic Vein Pressures (WHVP). The applicant commented that an additional finding was that patients preferred the EchoTip® procedure to the transjugular HVPG.

The applicant further summarized multiple historical documents from the 1950s,[105] [106] 1970s,[107] [108] [109] 1980s,[110] and early 2000s [111] [112] demonstrating the limitations of HVPG especially in diabetic patients. The applicant, through these historical studies, asserted that it has been well established that direct measurement of portal venous pressure correlates with indirect measurement of portal pressure using WHVP, and that the HVPG determined using either direct PVP or indirect WHVP correlate with one another in patients with sinusoidal portal hypertension.

The applicant asserted that direct measurement with EchoTip® addresses known limitations of the transjugular HVPG and non-invasive assessment. The applicant asserted HVPG with the indirect method can provide erroneous results. According to the applicant, Tandon et al. has shown good interobserver agreement between appropriately performed transjugular HVPG, but that adherence to specific techniques is critical for accurate measurement.[113] However, because of the variety of complicated portal hemodynamics and because the procedure is so complicated, the HVPG may not always reflect the substantial severity of portal hypertension in over 16 percent of patients with sinusoidal portal hypertension. The applicant also submitted preliminary findings from the Lim, et al. study comparing preoperative EchoTip® direct EUS–PPG with HVPG

[101] Hajifathalian, K., Westerveld, D., Kaplan, A. et al. (2022). Simultaneous EUS-guided portosystemic pressure measurement and liver biopsy sampling correlate with clinically meaningful outcomes. *Gastrointestinal Endoscopy 95*(4): 703–710.

[102] Choi, A., Chang, K., Samaransena, J. et al. (2022). Endoscopic ultrasound-guided porto-systemic pressure gradient measurement correlates with histological hepatic fibrosis. *Digestive Diseases and Sciences*. P.7. *https://doi.org/10.1007/s10620-022-07418-7*.

[103] Rubin, R, Mehta, M., Rossi, A., Joeslon, D., Shrestha, R. (2021). Letter to the Editor: Endoscopic ultrasound guided portal-systemic pressure gradient measurement to determine candidacy for kidney transplant alone versus combined liver kidney transplant in patients with advanced fibrosis or cirrhosis. *Transplant International 2021*(34): 2903–2904.

[104] Huang, J.Y., Samarasena, J.B., Tsujino, T., et al. (2016). EUS-guided portal pressure gradient measurement with a novel 25-gauge needle device versus standard transjugular approach: a comparison animal study. *Gastrointest Endosc 84*(2); 358–362.

[105] Meyers, J.D., Taylor, J.W. (1951). An estimation of portal venous pressure by occlusive catheterization on a hepatic venule. *J Clin Invest 30:* 662.

[106] Taylor, J.W., Myers, J.D. (1956). Occlusive hepatic venous catheterization in the study of normal liver, cirrhosis of the liver, and noncirrhotic portal hypertension. *Circulation 13:*368–379.

[107] Reynolds, T.B., Ito, S., Iwatsuki, S. (1970). Measurement of portal pressure and its clinical application. *Am J Med 49:* 649–657.

[108] Grozmann, R.J., Glickmann, M., Blei, A., et al. (1979). Wedged and free hepatic venous pressure measured with a balloon catheter. *Gastroenterology 77:* 253–258.

[109] Viallet, A., Joly, J.G., Marleau, D., Lavoie, P. (1970). Comparison of free portal venous pressure and wedged hepatic venous pressure in patients with cirrhosis of the liver. *Gastroenterology, 59:*372–5.

[110] Marleau, D., Cote, J., et al. (1985). Presinusoidal portal hypertension in nonalcoholic cirrhosis. *Hepatology, 5:* 415–8.

[111] Keiding, S., Vilstrup, H. (2002). Intrahepatic heterogeneity of hepatic venous pressure gradient in human cirrhosis. *Scand J Gastroenterol, 37:* 960–4.

[112] Thalheimer, U., Leandro, G., Samonakis, D.N., et.al. (2005). Assessment of the agreement between wedge hepatic vein pressure and portal vein pressure in cirrhotic patients. *Digestive and Liver Disease, 37:*601–608.

[113] Tandon, P., Ripoll, C., Assis, D., et. al. (2016). The interpretation of hepatic venous pressure gradient tracings—excellent interobserver agreement unrelated to experience. *Liver Int, 36*(8): 1160–6.

in patients with cirrhosis or suspected cirrhosis undergoing abdominal surgery. The applicant stated that the study showed the median pressure gradient was similar between the EUS–PPG measurements and transjugular HVPG measurements, with a high correlation coefficient between the two techniques (r = 0.972; P = 0.006). The applicant stated that while only six patients were included, the results match findings from the considerable literature substantiating that direct portal vein pressures (PVP) correlate to the indirect Wedged Hepatic Vein Pressures (WHVP). The applicant stated that an additional finding was that patients preferred the EchoTip® procedure to the transjugular HVPG.

Response: We thank the applicant for their comments. However, we maintain the concerns we articulated in the proposed rule. While we agree that the limitations of HVPG for obtaining clinical information are well established, the additional literature provided does not address our concern about the lack of data comparing EUS–PPG to HVPG. The additional literature is based on patient data that is several decades out of date that may not be comparable to more recent patient data or clinical practices and does not rely on direct comparison between HVPG and other measurements, and rather only cites the limitations of HVPG in certain patient populations. The applicant restated its references to the Huang, et al. study, which offers the only direct comparison between EchoTip® and HVPG and provided new references to the Lim et al. study, in which the human patient model only included six study participants. We do not agree that data from animal studies is sufficient to extrapolate to human populations for the purposes of demonstrating substantial clinical improvement. Furthermore, we cited concerns about small sample sizes specifically in the Hajifathalian et al. and the Choi et al. studies, which included 24 and 64 patients respectively, while the applicant's more recently submitted data in the Lim et al. study includes even fewer patients.

Comment: In response to our concern that the Hajifathalian et al. study results did not achieve correlation with fibrosis stage obtained from concurrent EUS-guided liver biopsy sampling, the applicant asserted that the lack of correlation was due to a small heterogenous sample, but offered that the authors noted good correlation in true negatives and true positives. The applicant further asserted that direct comparison between EchoTip® PPG and HVPG and concurrent liver biopsy during the same encounter could only be accomplished in a highly specialized and controlled setting due to the need for simultaneous endoscopic ultrasound and transjugular catheterization. The applicant reiterated that in the Choi, et al. study included in their application, EUS–PPG was significantly associated with fibrosis stage ≥ 3 on EUG-liver biopsy (LR 27.0, 95 percent CI = 1.653–360.597, p = 0.004).[114]

Response: We thank the applicant for their comments and the additional context. However, we maintain the concerns we articulated in the proposed rule, specifically, as indicated by the applicant, that the Hajifathalian et al. study is too small to show significant clinical improvement. In addition, the comments do not address our earlier concerns with the Hajifathalian et al. and Choi et al. studies regarding the lack of direct comparison between HVPG and EUS–PPG.

Comment: In response to our concern that supporting evidence, preferably published peer-reviewed clinical trials, that show improved clinical outcomes would help inform our assessment of whether EchoTip® demonstrates substantial clinical improvement over existing technologies, the applicant submitted comments stating that the goal for both the referring physician and general gastroenterologist is to identify patients truly in need of specialized care from the hepatology specialist. The applicant stated that most gastroenterology practices have access to interventional gastroenterologists who can perform the EchoTip® procedure and can identify patients who need to be referred to the appropriate practitioner for intervention to manage their disease. In addition, EchoTip® fits into existing workflow in the endoscopy suite and eliminates the concerns with the high false positive rates found with non-invasive tests such as transient elastography and various risk score calculations. The applicant stated that therefore, EchoTip® does meet the criterion for substantial clinical improvement by offering an efficient way to identify patients needing specialty hepatology care, overcomes the issues with the traditional transjugular HVPG in the population with metabolic associated steatohepatitis (MASH) and metabolic dysfunction-associated steatotic liver disease (MASLD), and prevents misclassification of disease severity with non-invasive tests.

In support of the claim that direct portal vein pressure measurement is more accurate for determining the presence of portal hypertension in certain cases, the applicant submitted additional literature on the use of EchoTip® in clinical care. The applicant discussed the Jirapinyo et al. study,[115] in which the author found a significant reduction in PPG, with 79 percent of patients experiencing a reduction of over 20 percent within 6 months after use of EchoTip® during the endoscopic gastric plication (EGP) procedure. The applicant also referenced a case study in which EchoTip® was used to clear a patient for a successful EGP after previous endoscopic findings showed esophageal varicosities.[116] The applicant also asserted that EchoTip® can be used by gastroenterologists, in addition to hepatology specialists who may be less accessible.

Response: We thank the applicant for their comments and additional literature. However, while the literature discusses the limitations of HVPG and the need for direct measurement, it did not provide peer-reviewed literature on whether EchoTip® improves clinical outcomes in comparison to HVPG. In addition, while the applicant referenced the Jirapinyo et al. study and a case study to show a significant reduction in PPG associated with a reduction in the risks of variceal bleeding and death, the full studies were not included with the submitted comments. We understand the applicant claims EchoTip® may be more readily available in settings where hepatologists are not easily accessible, however, the applicant has not addressed our concern as to whether EchoTip® direct EUS–PPG is a substantial clinical improvement over HVPG.

Comment: Several commenters stated support for EchoTip®'s eligibility for transitional pass-through status, stating that EchoTip® is helpful in the measurement of portal hypertension and diagnosis of multiple conditions related to elevated pressures of the liver.

One commenter asserted EchoTip® meets substantial clinical improvement because EchoTip® identifies patients that need intensive hepatology care

[114] Choi, A., Chang, K., Samaransena, J. et al. (2022). Endoscopic ultrasound-guided porto-systemic pressure gradient measurement correlates with histological hepatic fibrosis. *Digestive Diseases and Sciences. https://doi.org/10.1007/s10620-022-07418-7.*

[115] Jirapinyo, P., Thompson, C., Garcia-Tsao, L., et al. (2023). Endoscopic gastric plication reduces portosystemic pressure gradients in patients with nafld and compensated advanced chronic liver disease. *Endoscopy.* DOI: 10.1055/a–2146–8857.

[116] Krishnan, A., Shah-Khan, S.M., Hadi, Y., et al. (2023). Convergence of endobariatrics and endohepatology for evaluation and treatment of obesity and nonalcoholic fatty liver disease. *Endoscopy, 55:* E841–E843. DOI 10.1055/a–2094–9794.

based on the gold standard of portal pressure measurement. According to the commenter, it offers a solution to the inaccuracies in the current standard of care (transjugular hepatic venous pressure gradient (HVPG)) in patients who have pre-sinusoidal conditions, such as nonalcoholic steatohepatitis (NASH) and nonalcoholic fatty liver disease (NAFLD). The commenter also asserted EchoTip® improves patient safety by eliminating radiation exposure risks with HVPG.

A few commenters stated EchoTip® allows for a single procedure in a single setting compared to other clinical options that might require multiple visits across multiple specialties. In addition, a few commenters stated their patients preferred EchoTip® to other procedures. One commenter stated using EchoTip® was particularly useful for patients with morbid obesity where other options may not be available or as accurate, further stating that in such cases PPG measurement has been invaluable because it has given very good and accurate clinical information that could not be obtained from other means such as CT scan, fibroscan, etc. The commenter also stated that EchoTip® has significant clinical value because it obviates the need for patient to go to two separate procedures—HVPG measurement and then a separate session to get a percutaneous liver biopsy. One commenter stated that EchoTip® has been very beneficial by differentiating patients that have cirrhosis as a new diagnosis and those that were mislabeled, leading to life-changing consequences. One commenter stated that EchoTip® allows them to determine which patients with liver disease are safe to undergo surgery. Another commenter stated that EchoTip® has a unique yet intuitive design that offers the capability to accurately measure portal pressures and commented that a distinctive feature is its echogenic tip. The commenter opined that this aspect of the device dramatically enhances procedural accuracy, ensuring that the needle tip is correctly positioned within the desired vein each time. The commenter stated that additionally, the use of a 25-gauge needle simplifies access to both the portal and hepatic veins, minimizing tissue disruption and elevating the overall patient experience. The commenter further praised the device's compact design, and integration of a display with the system's self-calibrating transducer which provides clear, real-time pressure readings to aid in making informed clinical decisions. The commenter concluded that the device has significantly enhanced diagnostic precision for cases indicating portal hypertension, thereby assisting their team in treatment planning and improved patient outcomes.

Response: We thank the commenters for their responses. We appreciate that EchoTip® has changed the way some physicians practice, but due to the concerns stated above concerning small sample size and a lack of peer-reviewed direct comparison between EchoTip® and HVPG, we do not believe there is enough data to support the applicant's claims about significant clinical improvement over existing methods for measurement of portal gradient pressures. Further, despite the prognostic information measurement of portal gradient pressure provides, given all other current and evolving non-invasive technologies, it remains unclear whether obtaining this measurement is the standard of care in the management of patients with CLD. As noted by Rudnick et al., with the exception of intrahepatic portosystemic shunts and trans-jugular liver biopsies, HVPG measurements are not routinely obtained.[117] Additionally, we were not provided any literature to support the claim that EchoTip® eliminates radiation exposure risks with HVPG.

After consideration of the public comments we received, we are not approving EchoTip® for transitional pass-through payment status in CY 2024 because the technology does not meet the substantial clinical improvement criterion at § 419.66(c)(2)(i). Because we have determined that EchoTip® does not meet the substantial clinical improvement criterion, we are not evaluating whether the device meets the cost criterion.

We note that we received public comments with regard to the cost criteria for EchoTip®, but because we have determined that the device does not meet the substantial clinical improvement eligibility criterion and therefore, is not eligible for approval for transitional pass-through payment status for CY 2024, we are not summarizing comments received or making a determination on those criteria in this final rule.

(d) FLEX Vessel Prep™ System

Venture Med Group, Inc. submitted an application for a new device category for transitional pass-through payment status for FLEX Vessel Prep™ System (FLEX VP™) for CY 2024. Per the applicant, FLEX VP™ is an endovascular, over-the-wire, retractable, sheathed catheter with a three-strut treatment element at the distal tip used to help resolve stenoses occluding vascular access in patients with End-Stage Renal Disease (ESRD) on hemodialysis. According to the applicant, FLEX VP™ is used with percutaneous transluminal angioplasty (PTA) catheters to facilitate dilation of stenoses and for the treatment of in-stent restenosis of balloon expandable and self-expanding stents in the peripheral vasculature. The applicant asserted that FLEX VP™ consists of three integrated components: (1) control handle, which includes the flush and guidewire ports and sheath and treatment element actuators; (2) catheter shaft; and (3) treatment element, which includes three proximally mounted micro-surgical blades on protective skids. The struts are radially opposed, and the proximal portion of each strut includes a micro-surgical blade. A radiopaque marker is located distally to assist in the positioning of the catheter.

According to the applicant, when deployed, FLEX VP™'s struts independently engage with neointimal hyperplastic stenoses occluding an arteriovenous fistula or graft used for hemodialysis. As the device is pulled back through the lesion, the blades create three continuous, parallel micro-incisions, approximately 250 microns in depth, along the lesion's entire length. The applicant provided that this is a non-balloon-based device where the struts exert a consistent force of approximately one atmosphere on the vessel wall. Per the applicant, additional micro-incisions may be created by using several passes of the device. According to the applicant, the device breaks the lesion surface to facilitate the effectiveness of a percutaneous transluminal balloon angioplasty, which immediately follows use of the device in restoring patency to the vascular access.

The applicant asserted that the micro-incisions improve acute luminal gain and vessel compliance by releasing circumferential tension in the lesion. The applicant asserted that this preparation could help reduce vessel trauma and complications (including severe dissection and need for a bail-out stent) and the need for high pressure balloons (which risk barotrauma). Per the applicant, the interventionalist advances FLEX VP™ past the lesion, then unsheathes and expands the treatment element and slowly draws the catheter back, allowing each micro-surgical blade to simultaneously and independently engage with the lesion.

[117] Rudnick, S., Conway, J., Russo, M. (2021). Current state of endohepatology: Diagnosis and treatment of portal hypertension and its complications with endoscopic ultrasound. *World Journal of Hepatology, 13*(8): 887–895.

This step produces three continuous, parallel micro-incisions along the lesion's length. According to the applicant, this process may be repeated several times; once the lesion is crossed on the first pass, the treatment element is re-sheathed, advanced again through the lesion, and rotated approximately 30 to 90 degrees. The treatment element is then re-deployed and the process is repeated.[118]

As stated previously, to be eligible for transitional pass-through payment under the OPPS, a device must meet the criteria at § 419.66(b)(1) through (4). With respect to the newness criterion at § 419.66(b)(1), on September 11, 2020, the applicant received 510(k) clearance from FDA for FLEX VP™ for use with PTA catheters to facilitate dilation of stenoses in the femoral and popliteal arteries and treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae. The device is also indicated for treatment of in-stent restenosis of balloon expandable and self-expanding stents in the peripheral vasculature. We received the application for a new device category for transitional pass-through payment status for FLEX VP™ on February 28, 2023, which is within 3 years of the date of the initial FDA marketing authorization.

We invited public comment on whether FLEX VP™ meets the newness criterion at § 419.66(b)(1).

Comment: With respect to the newness criterion at § 419.66(b)(1), the applicant reiterated that FLEX VP™ received 510(k) clearance from the FDA on September 11, 2020, and that CMS received VentureMed Group's application for a new device category on February 28, 2023, which is within 3 years of the date of FDA clearance. Since CMS received the application within the required 3 years, the applicant stated that it is clear FLEX VP™ meets the newness criterion.

Response: We appreciate the applicant's input and agree that because we received the application for FLEX VP™ on February 28, 2023, which is within 3 years of the FDA clearance date of September 11, 2020, FLEX VP™ meets the newness criterion.

With respect to the eligibility criterion at § 419.66(b)(3), according to the applicant, FLEX VP™ is integral to the service provided, is used for one patient only, comes in contact with human skin, and is applied through an incision (for hemodialysis patients, the incision is in the wrist or arm area). Prior to balloon angioplasty, FLEX VP™ is inserted through an incision, over an endovascular guidewire until the device is positioned distal to the lesion to be treated.

We invited public comment on whether FLEX VP™ meets the integral part of the service criterion at § 419.66(b)(3).

Comment: With respect to the eligibility criterion at § 419.66(b)(3), the applicant reiterated that FLEX VP™ is integral to the service provided, is used for one patient only, comes in contact with human skin, and is applied through an incision. Because of these attributes the applicant stated it is clear that FLEX VP™ meets the eligibility criteria at § 419.66(b)(3).

Response: We appreciate the applicant's input. We agree with the applicant and have determined that FLEX VP™ meets the eligibility criterion at § 419.66(b)(3).

With respect to the exclusion criterion at § 419.66(b)(4), the applicant claimed that FLEX VP™ meets the device eligibility requirements of § 419.66(b)(4) because it is not equipment, an instrument, apparatus, implement, or item of this type for which depreciation and financing expenses are recovered, and it is not a supply or material furnished incident to a service.

We invited public comment on whether FLEX VP™ meets the exclusion criterion at § 419.66(b)(4).

Comment: With respect to the exclusion criterion at § 419.66(b)(4), the applicant reiterated that FLEX VP™ is not equipment, an instrument, apparatus, implement or item of this type for which depreciation and financing expenses are recovered, and it is not a supply or material furnished incident to a service. Accordingly, the applicant stated it is clear that FLEX VP™ meets the exclusion criterion at § 419.66(b)(4).

Response: We appreciate the applicant's input. We agree with the applicant and have determined that FLEX VP™ meets the exclusion criterion at § 419.66(b)(4).

In addition to the criteria at § 419.66(b)(1) through (4), 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 described FLEX VP™ as an endovascular, over-the-wire, retractable, sheathed catheter with a three-strut treatment element at the distal tip used to help resolve stenoses occluding vascular access in patients with ESRD on hemodialysis. Per the applicant, no previous device categories for pass-through payment have encompassed FLEX VP™ and there are no similar device categories. Upon review, it did not appear that there are any existing pass-through payment categories that might apply to FLEX VP™.

We invited public comment on whether FLEX VP™ meets the device category criterion at § 419.66(c)(1).

Comment: With respect to the new device category criterion at § 419.66(c)(1), the applicant reiterated that no pass-through payment categories now exist that might apply to the FLEX VP™ and, therefore, the device meets the new device category criterion at § 419.66(c)(1).

Response: We appreciate the applicant's input. We continue to believe that there is not an existing pass-through payment category that describes FLEX VP™, and therefore, that FLEX VP™ meets the device category eligibility criterion at § 419.66(c)(1).

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 is part of FDA's Breakthrough Devices Program and has received FDA marketing authorization for the indication covered by the Breakthrough Device designation. The applicant stated that FLEX VP™ represents a substantial clinical improvement over existing technologies by: (1) improving clinical outcomes for the hemodialysis patient population with dysfunctional arteriovenous (AV) access; and (2) reducing the rate of device-related complications. The applicant cited two studies describing the findings of a single clinical trial specifically for the purpose of addressing the substantial clinical improvement criterion.

The first study presented findings six months after patients were treated with FLEX VP™ followed by balloon angioplasty (Aruny et al.),[119] and the

[118] CMS made minor edits to the device description in this final rule with public comment to improve clarity.

[119] Aruny et al. Real-world results of a novel vessel preparation device prior to balloon

second study presented findings at 12 months post-treatment with FLEX VP™ followed by balloon angioplasty (author not identified in the manuscript for the 12-month follow up).[120] Both studies focused on results from methods used to show the durability of the treatments of blocked vascular accesses with FLEX VP™. The trial was a prospective, observational controlled clinical trial. A total of 148 lesions or blockages were treated with FLEX VP™ prior to a PTA in 114 subjects (the population was 53.5 percent female; 65.8 percent Black or African American (B/AA)), treated at eight clinical sites. All subjects were hemodialysis patients with vascular blockages. Of the 114 subjects, 104 patients had prior treatments to correct stenoses before enrolling in the trial. A primary endpoint was anatomic success, defined as angiographic confirmation of <30 percent residual stenosis post-procedure without adverse event. Additional assessments included dialysis circuit primary patency or vascular openness, clinical success and procedural success. The trial also measured the target lesion primary patency (TLPP) and freedom from target lesion restenosis (FFTLR) to determine if there is a decreased rate of subsequent therapeutic interventions. The two studies of the single clinical trial also examined the rate of device-related complications. No serious adverse events were reported initially (Aruny et al.), or in the 12-month follow-up (author not identified in the manuscript for the 12-month follow-up). The studies looked at differences in outcomes based on race and sex and found no significant differences. Per the applicant, the results suggest that FLEX VP™ followed by angioplasty can substantially reduce the number and burden of maintenance procedures for hemodialysis patients with arteriovenous fistula (AVF), arteriovenous graft (AVG), and AV disfunctions that cause cephalic arch stenoses.

In support of its first claim, that FLEX VP™ improves clinical outcomes for the hemodialysis patient population with dysfunctional AV access, the applicant asserted that FLEX VP™ decreased both the rates of therapeutic interventions and subsequent therapeutic interventions. The applicant provided the following evidence from the clinical trial and two studies. FLEX VP™ treatment prior to angioplasty benefits hemodialysis patients by improving the level of openness of blocked (or stenosed) arteriovenous access; a recurring issue that occurs because of the fistulas created to facilitate hemodialysis. The use of FLEX VP™ also allows the site with prior blockage (also known as lesions) to stay open for a longer period of time, reducing the frequency of future angioplasty procedures. The applicant discussed how the initial study (Aruny et al.), found that patients treated with FLEX VP™ prior to PTA (FLEX+PTA) had 6 months TLPP of 63.7 percent openness, versus the 15.6 percent to 50.5 percent rates of vascular openness after PTA alone, observed in other publications. This study also presented results for FFTLR, a calculation to determine an average number of days of durability of the percentage of the patency or lesion openness reported; for the overall hemodialysis population studied it was 206.7 days. The applicant also described results for patients with only AVFs or AVGs. For FLEX+PTA in AVF patients, TLPP was 70.6 percent and FFTLR was 219.7 days. For FLEX+PTA in AVG patients, TLPP was 46.6 percent and FFTLR was 173.9 days. Confirmation of reliability of the findings was shown by dialysis access circuit primary patency: 54.3 percent (AVF 54.1 percent; AVG 47.4 percent). According to the applicant, per the literature, the results of dialysis access circuit primary patency with only angioplasty performed, ranged from 0 percent to 48 percent. The applicant also presented results 12 months post-treatment (author not identified in the manuscript for the 12-month follow up) supporting the durability of the FLEX+PTA. Per the applicant, results generally accord with Aruny et al.'s 6-month results and exceed PTA-only results from the literature. Overall, TLPP was 45.7 percent (versus 62.2 percent at 6 months) and FFTLR was 250.9 days (versus literature (PTA only), 131.4 days). Per the applicant, this result suggests that compared to the durability of PTA only, FTA+PTA would result in a lower frequency of treatments to remove stenosis in hemodialysis patients overall. For AVFs, TLPP was 47.4 percent (versus 67.5 percent at 6 months); FFTLR was 258.5 days (versus literature, 156.9 days). For AVGs, TLPP was 43.8 percent (versus 52.4 percent at 6 months); FFTLR was 239.4 days (versus literature, 76.6 days). Overall, 12 months circuit primary patency was 36.5 percent (versus 54.3 percent at 6 months).[121]

In further support of the applicant's first claim, the applicant presented results from the clinical trial comparing B/AA patients to non-B/AA patients. In support of FLEX VP™ prior to PTA improving clinical outcomes for B/AA hemodialysis patient population with dysfunctional AV access, the applicant discussed the initial Aruny et al. study, in which B/AA patients had better results with FLEX VP™ intervention than did non-B/AA patients. The B/AA cohort (65.8 percent of sample) had TLPP of 63.76 percent versus 58.8 percent for the non-B/AA cohort after treatment with FLEX+PTA. FFTLR was 207.8 days for B/AA versus 192.2 days for non-B/AA. For B/AA patients with cephalic arch lesions, TLPP was 78.6 percent versus 58.3 percent for non-B/AA. The applicant asserted that these results were achieved despite pre-existing disparities in patient's experience with AV access care. B/AA patients had more years since they started hemodialysis ($p<0.01$), suggesting a possibility of increased severity or complexity of lesions in the B/AA patients.[122] The applicant also presented results 12 months post-treatment.[123] In terms of B/AA patient outcomes comparable to the overall sample, the B/AA cohort (65.8 percent of sample) had TLPP of 45.9 percent versus 45.7 percent overall patients and FFTLR was 257.8 days for B/AA versus 250.9 days overall patients. In B/AA patients with cephalic arch lesions, TLPP was 71.8 percent versus 59.7 percent overall patients.

Furthermore, in support of the applicant's first claim, the applicant provided the following evidence from the clinical trial. In support of FLEX VP™ improving clinical outcomes for a female hemodialysis patient population with dysfunctional AV access, the applicant stated that in the initial Aruny et al. study, females differed from males significantly in their pre-existing experiences with AV care. Female patients had more years since they started hemodialysis ($p<0.01$) and since AV access creation ($p<0.01$); females had more prior AV access interventions ($p<0.05$). According to the applicant, this potentially suggests that female

angioplasty for arteriovenous access repair in diverse populations on dialysis, under review, JVA, Feb. 2023.

[120] Durability of arteriovenous access repair involving vessel preparation by longitudinal micro-incisions before balloon angioplasty, unpublished manuscript (no author identified).

[121] *Ibid.*

[122] Aruny et al. Real-world results of a novel vessel preparation device prior to balloon angioplasty for arteriovenous access repair in diverse populations on dialysis, under review, JVA, Feb. 2023.

[123] Durability of arteriovenous access repair involving vessel preparation by longitudinal micro-incisions before balloon angioplasty, unpublished manuscript (no author identified).

patients are more prone to complexity of lesions or recurrence of stenosis. However, no statistically significant differences in results of TLPP and FFTLR measures at 6 months post treatment were observed between females and males treated with FLX VP™ followed by PTA. Therefore, females receiving a FLEX VP™ intervention prior to PTA achieved results comparable to males, notwithstanding pre-existing disparities.[124]

In further support of the applicant's first claim, the applicant explained that cephalic arch (CA) stenoses are notoriously difficult to treat effectively and have some of the worst dialysis access and frequency of recurrence results. The applicant explained that complications are also high. In this sample, the target stenosis was in the CA in 25/114 patients (21.9 percent). TLPP following FLEX+PTA at 6 months (Aruny et al.) was 70.6 percent overall patients, and 76.8 percent in the B/AA cohort. According to the applicant comparable figures in the literature ranged from 0 percent to 51.6 percent. Access dialysis circuit primary patency obtained from the literature for PTA only was 66.4 percent for CA cases.[125] The applicant also presented results 12-month post-treatment (author not identified in the manuscript for the 12-month follow up). TLPP for these patients following FLEX+PTA at 12 months was 59.7 percent for overall patients and 71.8 percent in the B/AA cohort. According to the applicant, comparable figures in the clinical literature ranged from 0 percent to 33.9 percent and access dialysis circuit primary patency was 55.3 percent for CA cases.[126]

In support of the applicant's second claim, the applicant asserted that no serious adverse events were reported from the initial study (Aruny et al.). Five procedural complications and one dissection related to the FLEX VP™ device were recorded. Three dissections were associated with PTA.[127] The applicant also presented results 12 months post-treatment (author not identified in the manuscript for the 12-month follow-up), noting that no serious adverse events were reported during 12-month follow-up.

According to the applicant, these findings confirm the safety record for FLEX VP™, which is better when compared to the Journal of Vascular and Interventional Radiology (JVIR) Quality Improvement Guidelines thresholds for AVF and AVG. According to the applicant, in the literature, up to 15 percent cephalic arch lesions result in vessel rupture and about 12 percent of PTAs in B/AA patients are reported to result in major complications.[128]

Ultimately, the applicant concluded that FLEX VP™ is safe and effective, notably in patients with AVGs and those with CA stenoses, and furthermore, despite observed differences in time since hemodialysis onset, clinical success was similar across sex and race, suggesting an opportunity to enhance health equity.[129] The applicant also added that FLEX VP™, when used with PTA, provides sustained clinical improvement over existing technologies by increasing the patency and time to reintervention of PTA procedures in AVFs and AVGs at 12 months (author not identified in the manuscript for the 12-month follow-up), while reducing the potential for serious complications, such as perforations and vessel rupture. Favorable results at 6 months for the B/AA cohort reported in Aruny et al.'s article were sustained in the 12 month results. Further, according to the applicant, the use of FLEX VP™ offers the prospect of improved treatment of unresponsive or difficult to treat stenosis in the cephalic arch.[130]

Based on the evidence submitted in the application, we noted the following concerns: The applicant presented two studies (Aruny et al. [a 6-month follow up], and an unpublished manuscript which did not identify an author [12-month follow up] submitted with the application that are based on a single clinical trial of 114 patients followed for 12 months. Per the applicant, the results from the 6-months follow up are not yet published, and the results from 12-months post-treatment are also unpublished and only available at the FLEX VP™ registry. Therefore, we noted that the evidence presented on benefits to patients in hemodialysis is not peer-reviewed and this may reduce the strength of the evidence presented and the opinion of peers on study quality. In order to demonstrate substantial clinical improvement over currently available treatments, we consider supporting evidence, preferably published peer-reviewed clinical trials, that shows improved clinical outcomes, such as reduction in mortality, complications, subsequent interventions, future hospitalizations, recovery time, pain, or a more rapid beneficial resolution of the disease process compared to the standard of care. We also noted that, due to the clinical trial design, there is insufficient data on the impact of angioplasty with the drug-coated balloon option. The drug in these balloons may play a role in the improvement of patency or openness durability and additional studies to strengthen the initial observations presented by the applicant would be helpful.

Lastly, we noted the applicant did not show a clear crosswalk of findings or data in terms of device-related complications (including dissection and embolectomy) observed in the trial and compared to those referenced in literature. For example, procedural complications and dissection were mentioned in the FLEX VP™ group while rupture and major complications were mentioned in the literature. The clinical trial results presented one dissection attributed to FLEX VP™ after 148 lesions were treated with FLEX VP™ plus PTA. Per the applicant, there are approximately 732,000 interventions per year in the U.S. to maintain lifesaving arteriovenous access and FLEX VP™ could potentially be used in a fraction of those; this increases the concern for frequency of complications and therefore, additional studies may be needed to strengthen the second substantial clinical improvement claim.

We invited public comment on whether FLEX VP™ meets the substantial clinical improvement criterion at § 419.66(c)(2)(i).

Comment: All commenters addressing the substantial clinical improvement criterion offered support for approval of the FLEX VP™ application. Commenters highlighted a number of added benefits when FLEX VP™ was used prior to PTA in hemodialysis patents, including: positive outcomes for a cephalic arch and AV graft case; reduction on barotrauma associated with angioplasty; and its effectiveness and easy usability, specifically during AV interventions. A few commenters,

[124] Aruny et al. Real-world results of a novel vessel preparation device prior to balloon angioplasty for arteriovenous access repair in diverse populations on dialysis, under review, JVA, Feb. 2023.

[125] *Ibid.*

[126] Durability of arteriovenous access repair involving vessel preparation by longitudinal micro-incisions before balloon angioplasty, unpublished manuscript (no author identified).

[127] Aruny et al. Real-world results on a novel vessel preparation device prior to balloon angioplasty for arteriovenous access repair in diverse populations on dialysis, under review, JVA, Feb. 2023.

[128] Durability of arteriovenous access repair involving vessel preparation by longitudinal micro-incisions before balloon angioplasty, unpublished manuscript (no author identified).

[129] Aruny et al. Real-world results of a novel vessel preparation device prior to balloon angioplasty for arteriovenous access repair in diverse populations on dialysis, under review, JVA, Feb. 2023.

[130] Durability of arteriovenous access repair involving vessel preparation by longitudinal micro-incisions before balloon angioplasty, unpublished manuscript (no author identified).

including the applicant, explained that reporting procedural complications was based on the Society of Interventional Radiology (SIR) typology and under this typology all complications reported in the AV registry were minor. With zero major complications reported, all commenters agreed on the safety of FLEX VP™ compared to what is reported in the peer-reviewed literature. One commenter stated that FLEX VP™ substantially reduced procedural complications for patients by lowering the need for bail-out stenting. Several commenters, including the applicant, stated that the use of FLEX VP™ prior to PTA enables a longer and lasting patency for AV procedures, thereby reducing the frequency of interventions as patients treated using the device returned for access repair less often than patients without the use of FLEX VP™. A few commenters, including the applicant, noted the FLEX VP™ benefits for patient populations underserved and underrepresented in trials as demonstrated through the studies submitted with the application. One commenter stated that dialysis patients should have every option available that will improve clinical outcomes for their AV access and quality of care.

Response: We appreciate the input provided by these commenters. We have taken this information into consideration in making our final determination of whether FLEX VP™ meets the substantial clinical improvement criterion, discussed below.

Comment: To address our concerns that the evidence presented with the application regarding the benefits to patients on hemodialysis was not peer-reviewed; the applicant and a commenter noted that the data in the application is now published in three separate peer-reviewed journals.[131] [132] [133]

Response: We appreciate the applicant's and the commenter's responses to our concern regarding publication of the data presented in the application and for including the references. We agree with commenters that the published peer-reviewed clinical data shows improved clinical outcomes through the reduction in the frequency of subsequent interventions to maintain patency in hemodialysis patients with AV grafts.

Comment: To address our concerns that, due to the clinical trial design, there was insufficient data on the impact of angioplasty with drug coated balloons (DCBs), as presented by the applicant, and that the drug in these balloons may play a role in the improvement of patency or openness durability, the applicant commented that DCBs are not the standard of care for AV access interventions, and that is the reason for the low number of DCB interventions captured in the FLEX VP™ Registry (also referred to as the AV Registry by commenters). Additionally, the applicant discussed the results of a meta-analysis suggesting that DCBs did not improve primary patency in target lesions at six months and 12 months when compared to conventional balloon angioplasty.[134] A few commenters also stated that DCBs are not the standard of care relative to angioplasty with traditional balloons for AV access procedures. The applicant asserted that DCBs are not approved for use with AV grafts in the United States. In addition to the applicant, a few commenters noted that drug collated balloons (DCBs) were infrequently included in the real-world registry used on the studies presented in the application. A commenter stated that although the body of positive evidence for DCBs is growing, debate remains about their broad application to AV access procedures and suggested that FLEX VP™ may enhance the benefits of DCBs.

Response: We appreciate the applicant's and other commenters' responses to our concern that there is insufficient data on the impact of angioplasty with DCB. We have taken this information into consideration in making our final determination of the substantial clinical improvement criterion, discussed below.

Comment: To address our concerns that the applicant did not present a clear crosswalk of findings or data in terms of device-related complications (including dissection and embolectomy) observed in the trial and compared to those referenced in the literature, the applicant asserted that specific data was collected in the AV Registry related to the following procedural complications: dissections, perforations, and embolization. The applicant stated that the data collected in the AV Registry on procedural complications would be considered minor complications in the SIR typology. One commenter agreed with the approach to use SIR typology to address complications. The applicant stated that the AV Registry data shows zero major complications for FLEX VP™ plus PTA in their studies. The applicant added that a review of recent literature found that: ''The major complication rates following PTA for failing AVFs ranged from 0 to 2.1 percent, while for the AVGs ranged from 2.1 to 6 percent. Papers with mixed AVGs and AVFs reported major complication rates of 3–5 percent.'' [135]

Response: We appreciate the applicant's and commenter's responses to our concerns that the applicant did not present a clear crosswalk of findings or data in terms of device-related complications (including dissection and embolectomy) observed in the trial and compared to those referenced in the literature. We agree with the commenter's assertions, including the applicant, that according to SIR typology, the data on procedural complications using FLEX VP™ resulted in minor complications only. We agree with the applicant's and commenter's assertions that DCB interventions were infrequent in the AV Registry because this procedure is not the standard of care for AV interventions. We also agree with the suggestion from the applicant and the commenters that FLEX VP™ could enhance the benefits of DCBs. Finally, we agree with the applicant's and commenter's assertions that the published peer-reviewed clinical data shows improved clinical outcomes through the reduction in the frequency of subsequent interventions to maintain patency. After consideration of the

[131] Aruny, J., et al. (2023). Longitudinal micro-incision creation prior to balloon angioplasty for treatment of arteriovenous access dysfunction in a real-world patient population: 6-month cohort analysis. *Hemodialysis International 2023 Aug 17:* 1–10. (Online ahead of print) *https://onlinelibrary.wiley.com/doi/10.1111/hdi.13111.*

[132] Aruny et al. (2023). Longitudinal micro-incision prior to balloon angioplasty for treatment of arteriovenous access dysfunction in a real-world patient population: 12-month cohort analysis. *Journal of Interventional Nephrology, 6*(4): 88–97. *https://www.openaccessjournals.com/articles/longitudinal-microincisions-prior-to-balloon-angioplasty-for-treatment-ofarteriovenous-access-dysfunction-in-a-realworld-patient-16713.htm.*

[133] Davis, O., et al. (2023). Novel device prior to balloon angioplasty for dysfunctional arteriovenous access: Analysis of a real-world registry by race and sex cohorts. *Journal of Interventional Nephrology, 6*(4): 158–164. *https://www.openaccessjournals.com/articles/novel-device-prior-to-balloon-angioplasty-for-dysfunctional-arteriovenousaccess-analysis-of-a-realworld-registry-by-race-and-sex-16852.html.*

[134] Liao, M.T., et al. (2020). Drug-coated balloon versus conventional balloon angioplasty of hemodialysis arteriovenous fistula or graft: A systematic review and meta-analysis of randomized controlled trials. *PloS One, 15*(4): e0231463. DOI: 10.1371/jounal.pone.0231463.

[135] Raman, L., et al. (2023). Dialysis access maintenance: Plain balloon angioplasty. *Cardiovascular Interventional Radiology,* published online May 8, 2023. *https://doi.org/10.1007/s00270-023-03441-x.* Internal footnotes to the studies summarized are omitted in this quotation. (''The most significant complications reported are thrombosis, rupture and dissection requiring either stent graft placement or surgical revision of the fistula.'')

applicant's response and the public comments received, we believe that commenters have addressed our concerns regarding whether FLEX VP™ meets the substantial clinical improvement criterion and that FLEX VP™ represents a substantial clinical improvement over existing technologies.

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 FLEX VP™ would be reported with HCPCS codes listed in Table 88.

TABLE 88: HCPCS CODES REPORTED WITH FLEX VP™

HCPCS Code	Long Descriptor	SI	APC
36902	Introduction of catheters, dialysis circuit, with transluminal balloon angioplasty	J1	5192
36903	Introduction of catheters, dialysis circuit, with transcatheter placement of intravascular stent and all angioplasty	J1	5193
36905	Percutaneous transluminal mechanical thrombectomy, dialysis circuit, with transluminal balloon angioplasty	J1	5193
36906	Percutaneous transluminal mechanical thrombectomy, dialysis circuit, with transcatheter placement of intravascular stent and all angioplasty	J1	5194

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. As we explained in the CY 2005 OPPS final rule with comment period (69 FR 65775), we generally use the lowest APC payment rate applicable for use with the nominated device when we assess whether a device meets the cost significance criterion, thus increasing the probability the device will pass the cost significance test. For our calculations, we used APC 5192, which had a CY 2022 payment rate of $5,061.89 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). HCPCS code 36902 had a device offset amount of $1,271.04 at the time the application was received.[136] According to the applicant, the cost of FLEX VP™ is $1,995.00.

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 $1,995.00 for FLEX VP™ is 39.41 percent of the applicable APC payment amount for the service related to the category of devices of $5,061.89 (($1,995.00/$5,061.89) × 100 = 39.41 percent). Therefore, we stated that we believe FLEX VP™ 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 $1,995.00 for FLEX VP™ is 156.96 percent of the cost of the device-related portion of the APC payment amount for the related service of $1,271.04 (($1,995.00/$1,271.04) × 100 = 156.96 percent). Therefore, we stated that we believe that FLEX VP™ 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 $1,995.00 for FLEX VP™ and the portion of the APC payment amount for the device of $1,271.04 is 14.30 percent of the APC payment amount for the related service of $5,061.89 ((($1,995.00 − $1,271.04)/$5,061.89) × 100 = 14.30 percent). Therefore, we stated that we believed that FLEX VP™ meets the third cost significance requirement.

We invited public comment on whether FLEX VP™ meets the device pass-through payment criteria discussed in this section, including the cost criterion for device pass-through payment status.

Comment: With respect to cost significance criteria, the applicant reiterated that FLEX VP™ meets all three of the cost significance criteria.

Response: We appreciate the commenter's input. Based on our findings from the first, second, and third cost significant tests, we believe that FLEX VP™ meets the cost significance criteria specified at § 419.66(d).

Comment: A commenter expressed concerns on how the device offset amounts are calculated and stated that CMS should calculate the device-related portion of APCs for purposes of determining transitional pass-through eligibility and the device offset using only the cost of the devices replaced by the proposed transitional pass-through device category. The commenter asserted that this approach results in adequate reimbursement to facilities. The commenter recommended that CMS

[136] We noted that the applicant selected a value of $1391.99 for the device offset amount. However, the value selected is inconsistent with the device offset amount related to HCPCS 36902 in APC 5192 found in Addendum P to the CY 2022 OPPS/ASC final rule with comment period, as corrected in the 2022 Correction Notification OPPS Addendum (87 FR 2060). We selected the value of $1271.04, which we believe is the accurate value. Based on our initial assessment for the proposed rule, using the device offset amount of $1271.04 would result in FLEX VP™ meeting the cost significance requirement.

apply this methodology to FLEX VP™ if applicable.

Response: We appreciate the commenter's input. As we have done in prior years, CMS continues to evaluate the application of the device offset amount on a case-by-case basis to ensure the appropriate payment is made for a device on pass-through status. In cases where a device on pass-through status replaces previously existing technologies, we continue to believe it is appropriate to apply the device offset amount. We have reviewed FLEX VP™ offset amounts and confirm that the device offset amount is accurate.

After considering the public comments we received and consideration of the cost criterion, we have determined that FLEX VP™ meets the cost criterion for device pass-through status.

After considering the public comments we received and our review of the device pass-through application, we have determined that FLEX VP™ meets the criteria for device pass-through status. Therefore, we are finalizing approval for device pass-through payment status for FLEX VP™ effective beginning January 1, 2024.

B. 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 and 66873) applies to device-intensive procedures and is discussed in detail in section IV.B.4 of this final 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) and is discussed in detail in section IV.B.3 of this final rule. 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, under the device-intensive methodology we 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 APC designations 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 their APC assignment.

Under our existing policy, procedures that meet the criteria listed in section IV.C.1.b of this final 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.C.3 and IV.C.4 of this final rule.

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 interested parties that the criteria excluded some procedures that interested parties believed should qualify as device-intensive procedures. Specifically, we were persuaded by interested party 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 §§ 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:

++ 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

++ 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, 37109, 58945, and 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 or insertion 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 few 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.

Comment: Commenters requested that we assign device-intensive status to the following procedures:

- CPT code 0581T (Ablation, malignant breast tumor(s), percutaneous, cryotherapy, including imaging guidance when performed, unilateral)
- CPT code 31242 (Nasal/sinus endoscopy, surgical; with destruction by radiofrequency ablation, posterior nasal nerve)
- CPT code 52284 (Cystourethroscopy, with mechanical urethral dilation and urethral therapeutic drug delivery by drug-coated balloon catheter for urethral stricture or stenosis, male, including fluoroscopy, when performed)
- CPT code 53854 (Transurethral destruction of prostate tissue; by radiofrequency generated water vapor thermotherapy)
- HCPCS code C9757 (Laminotomy (hemilaminectomy), with decompression of nerve root(s), including partial facetectomy, foraminotomy and excision of herniated intervertebral disc, and repair of annular defect with implantation of bone anchored annular closure device, including annular defect measurement, alignment and sizing assessment, and image guidance; 1 interspace, lumbar);
- HCPCS code C9761 (Cystourethroscopy, with ureteroscopy and/or pyeloscopy, with lithotripsy, and ureteral catheterization for steerable vacuum aspiration of the kidney, collecting system, ureter, bladder, and urethra if applicable (must use a steerable ureteral catheter)

Response: Based on CY 2022 claims data available for this final rule, the procedures requested by commenters do not have device offset percentages that exceed the 30-percent threshold required for device-intensive status under the OPPS or ASC payment system and, therefore, are not eligible to be assigned device-intensive status. CPT codes 31242 and 52284 were issued after publication of the proposed rule and have an effective date of January 1, 2024. CPT code 52284 is replacing CPT code 0499T (Cystourethroscopy, with mechanical dilation and urethral therapeutic drug delivery for urethral stricture or stenosis, including fluoroscopy, when performed), which has a device offset percentage of 25.33 percent based on the most recent claims data. Since the predecessor code of CPT code 52284, CPT code 0499T, would not meet our criteria for device-intensive status, we are not accepting the commenter's recommendation to assign device-intensive status to CPT code 52284 for CY 2024.

However, CPT code 31242 does not have claims data from a predecessor code that may be used to determine a device offset percentage. After reviewing the clinical description and characteristics of the procedure, we agree with commenters that CPT code 31242 meets our requirements to be assigned device-intensive status. Therefore, for CY 2024, we are assigning CPT code 31242 device-intensive with a default device offset percentage of 31 percent.

Comment: Two commenters requested that we assign the device offset percentage for CPT codes 0816T (Open insertion or replacement of integrated neurostimulation system for bladder dysfunction including electrode(s) (eg, array or leadless), and pulse generator or receiver, including analysis, programming, and imaging guidance, when performed, posterior tibial nerve; subcutaneous) and 0817T (Open insertion or replacement of integrated neurostimulation system for bladder dysfunction including electrode(s) (eg, array or leadless), and pulse generator or receiver, including analysis, programming, and imaging guidance, when performed, posterior tibial nerve; subfascial) using claims data from CPT code 64590 (Insertion or replacement of peripheral, sacral, or gastric neurostimulator pulse generator or receiver, direct or inductive coupling requiring pocket creation and connection between electrode array and pulse generator or receiver) rather than using the default 31 percent device offset percentage. Commenters suggested claims data for CPT code 64590 would provide a more accurate device offset amount.

Response: We are not accepting the commenters' recommendation. While we may assign device-intensive status to new procedures that have significant device costs, we generally assign the percentage of such device costs at 31 percent of total procedure costs until claims data become available. However, if there is available claims data from the predecessor code of a new procedure or claims data from a clinically similar procedure that uses the same device, our current policy allows us to use this proxy claims data to establish a device offset percentage in lieu of the default 31 percent. We do not agree that CPT code 64590 was the predecessor code for either CPT code 0816T or 0817T and believe that CPT code 64999 (Unlisted procedure, nervous system) was the CPT code previously used when reporting the procedures described by the new CPT codes 0816T and 0817T. CPT code 64999 does not exceed our device-intensive threshold under the OPPS; and, since this CPT code can be used for various types of unlisted procedures, we do not believe this procedure would be an accurate reflection of the device costs of CPT code 0816T or 0817T. Because 0816T and 0817T do not have claims data from a predecessor code or a similar code that uses the same device, we are finalizing our proposal to assign the default 31 percent device offset percentage to CPT codes 0816T and 0817T for CY 2024.

Comment: Two commenters requested that we increase the device offset for CPT code 0629T (Percutaneous injection of allogeneic cellular and/or tissue-based product, intervertebral disc, unilateral or bilateral injection, with ct guidance, lumbar; first level) to be in alignment with CPT code 0627T (Percutaneous injection of allogeneic cellular and/or tissue-based product, intervertebral disc, unilateral or bilateral injection, with fluoroscopic guidance, lumbar; first level) as both procedures use the same device.

Response: We thank the commenters for their suggestion. We stated in the CY 2023 OPPS/ASC final rule with comment period (87 FR 71941) that we did not have any claims data for CPT code 0629T to determine a device offset percentage. Under our current policy, we may assign an alternative device offset percentage if we have claims data from a clinically similar procedure code that uses the same device. We agreed with commenters to apply the device offset percentage from claims data for CPT code 0627T to CPT code 0629T for CY 2023 as the procedures are clinically similar and utilize the same device. Similarly, for CY 2024, because we do not have claims data to determine a device offset percentage for CPT code 0629T, we are accepting the commenters' recommendation and will continue to use the most recent claims data from CPT code 0627T to assign the device offset percentage for CPT code 0629T.

Comment: One commenter requested that we reexamine the claims data for CPT codes 31296, 31297, and 31298 and designate them as device-intensive procedures.

Response: After examining the claims data for CPT codes 31296, 31297, and 31298, we have determined that the device offset percentages for these procedures do not exceed the 30 percent device-intensive threshold. Therefore, we are not assigning device-intensive status to these procedures for CY 2024.

The full listing of the final CY 2024 device-intensive procedures can be found in Addendum P to this final rule with comment period (which is available via the internet on the CMS website). Further, our claims accounting narrative contains a description of our device offset percentage calculation. Our claims accounting narrative for this final rule with comment period can be found under supporting documentation for this CY 2024 OPPS/ASC final rule with comment period on our website at: *https://www.cms.gov/medicare/medicare-fee-for-service-payment/hospitaloutpatientpps.*

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 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.'' In the CY 2023 OPPS/ASC final rule with comment period (87 FR 71830), we described a commenter's concern about the potentially inadequate payment rate for APC 5495 (Level 5 Intraocular Procedures) and their recommendation that we use our equitable adjustment authority to limit the potential reduction in the CY 2023 APC payment rate by applying a 10 percent cap on the reduction in relative weights for Low Volume APCs in CY 2023. While we did not accept the commenter's recommendation to limit a Low Volume APC's decline in relative weight to no more than 10 percent, we stated we would continue to monitor the costs and payment rates for procedures assigned to Low Volume APCs to determine if additional changes or refinements to our current policy are needed.

In our review of claims data for CPT code 0308T (Insertion of ocular telescope prosthesis including removal of crystalline lens or intraocular lens prosthesis), we noticed unusual coding, charge, and cost data in the claims data from CY 2017, CY 2018, CY 2019, and CY 2021. Some claims did not report the correct device code—HCPCS code C1840 (Lens, intraocular (telescopic))—and such claims had substantially lower costs than claims that reported the correct device code. In particular, claims that reported the correct device code had an average device cost of $15,030.04, while claims that did not report the correct device code had an average device cost of $430.72. The vast majority of claims for CPT code 0308T in our 4-year analysis did report the correct device code; however, the limited number of claims that either reported the wrong procedure code or reported the wrong device code had an outsized impact on the APC payment rate because of the very low volume of claims for this APC. Because payment stability for this Low Volume APC relies so critically on accurate reporting of the procedure's associated costs, we believe this APC would benefit from a procedure-to-device edit—a claims processing edit that requires a certain device code to be included on the claim when hospitals report a specific procedure code. The procedures associated with the Level 5 Intraocular APC, which we proposed to reassign to a new Level 6 Intraocular APC (APC 5496) in section III.E of the CY 2024 OPPS/ASC proposed rule, describe the implantation of specific device codes:

- CPT code 0308T (Insertion of ocular telescope prosthesis including removal of crystalline lens or intraocular lens prosthesis) describes the implantation of device HCPCS code C1840 (Lens, intraocular (telescopic));
- CPT code 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) describes the implantation of device HCPCS code C1839 (Iris prosthesis);
- CPT code 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) describes the implantation of device HCPCS code C1839 (Iris prosthesis); or
- CPT code 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) also describes the implantation of device HCPCS code C1839 (Iris prosthesis).

We proposed to establish a procedure-to-device edit for the four aforementioned procedures assigned to APC 5496 (Level 6 Intraocular Procedures) and require hospitals to report the correct device HCPCS codes when reporting any of the four procedures. While some interested parties have previously recommended in past rulemaking that we reestablish all of our previous procedure-to-device edits, we do not expect to extend this policy beyond the procedures assigned to APC 5496 (Level 6 Intraocular Procedures). We explained that we continue to rely on hospitals' accurate reporting and believe our current device edits policy of requiring device-intensive procedures to be subject to an additional device reporting edit has improved our ratesetting for hospital outpatient department procedures without placing an undue burden on hospitals. However, we noted that we believe this APC represents a unique situation—the APC (which was the Level 5 Intraocular APC in previous years) has been a Low Volume APC (fewer than 100 claims in a claims year) since we established our Low Volume APC policy, the procedures associated with this APC have significant procedure costs often greater than $15,000, and the procedures associated with this APC require the implantation of a high-cost intraocular device. We stated that we believe requiring a procedure-to-device edit for procedures assigned to the APC 5496 (Level 6 Intraocular Procedures), would not be administratively burdensome to hospitals given the low volume of services associated for this APC and will have a meaningful and significant impact on the payment rate for this APC and the stability of the payment rate in the future.

We solicited comments on our proposal to modify our device edits policy to require a procedure-to-device edit for procedures assigned to APC 5496 (Level 6 Intraocular Procedures) for CY 2024.

Comment: We received one comment in support of the proposed procedure-to-device edit for CPT code 0308T. We also received one comment in support of the proposed procedure-to-device edits for CPT codes 0616T, 0617T, and 0618T.

Response: We thank the commenters for their support. After consideration of the public comments we received, we are finalizing our proposal to modify our device edits policy to require a procedure-to-device edit for procedures assigned to APC 5496 (Level 6 Intraocular Procedures) for CY 2024.

Comment: One commenter requested that CMS restore the device-to-procedure and procedure-to-device edits. The commenter recommended that we apply such edits to specific procedures, such as total hip arthroplasty or total knee arthroplasty procedures, and require a specific device code rather than any device code. We also received one comment requesting that we create device-to-procedure edit for HCPCS code C9761 and CPT code 0715T due to rejected claims.

Response: We are not accepting the commenters' recommendations and do not believe additional device-to-procedure edits are warranted for the situations the commenters described. We are finalizing our proposal to reinstate device-to-procedure edits for procedures assigned APC 5496 (Level 6 Intraocular APC) to improve the payment structure for that APC as well as the Intraocular APC family. The high cost, low-volume nature of that APC represents a unique situation that we believe would benefit from a device-to-procedure edit and place extremely little reporting burden on providers. However, as we stated in the CY 2015 OPPS/ASC final rule with comment period (79 FR 66794) and have reiterated in subsequent rulemaking, we continue to believe that the elimination of device-to-procedure edits and procedure-to-device edits is appropriate due to the experience hospitals now have in coding and reporting these claims fully. Under our current policy, hospitals are still expected to adhere to the guidelines of correct coding and append the correct device code to the claim when applicable. We believe our current device edits policy, which requires that a device code be reported on a claim for procedures that have significant device costs, continues to accurately capture the device costs associated with device-intensive procedures and provides the necessary flexibility to hospitals to code claims accurately.

Comment: One commenter suggested that there is confusion among hospitals as to whether to report a device code for certain procedures in the HCPCS C-code range and urged CMS establish a device-to-procedure edit for all C-code procedures to ensure appropriate device costs are collected.

Response: We thank the commenter for the suggestion; however, we believe our current policy already addresses the commenter's concern. We are not aware of any provider confusion as to reporting device costs for certain device-intensive procedures in the HCPCS C-code range. However, if such procedures are assigned device-intensive status, then they are subject to our device edits policy; and hospitals would already be required to report a device code on the claim when billing the procedure code.

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 and 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 and 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. We adopted this change in policy in the preamble of the CY 2014 OPPS/ASC final rule with comment period and discussed it in sub-regulatory guidance, including Chapter 4, Section 61.3.6 of the Medicare Claims Processing Manual. Further, in the CY 2021 OPPS/ASC final rule with comment period (85 FR 86017, 86018, and 86302), we made conforming changes to our regulations at § 419.45(b)(1) and (2) that codified this policy.

We did not propose any changes, and we did not receive any public comments related to our policies regarding payment for no cost/full credit and partial credit devices for CY 2024.

V. OPPS Payment for Drugs, Biologicals, and Radiopharmaceuticals

A. 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 this final rule with comment period, the term ''biological'' is used because this is the term that appears in section 1861(t) of the Act. A ''biological'' as used in this final rule with comment period includes (but is not necessarily limited to) a ''biological product'' or a ''biologic'' as defined under section 351 of the PHS 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 drug as a hospital outpatient service under Medicare Part B. Final CY 2024 pass-through drugs and biologicals and their designated APCs are assigned status indicator ''G'' in Addenda A and B to this CY 2024 OPPS/ASC final rule with comment period (which are available on the CMS website).[137]

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 this final rule with comment period, 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: *https://www.cms.gov/medicare/payment/fee-for-service-providers/part-b-drugs/average-drug-sales-price.*

The pass-through application[138] and review process for drugs and biologicals

[137] *https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient.*

[138] To apply for OPPS transitional Pass-Through Payment Status and New Technology Ambulatory Payment Classification (APC), applicants complete

is described on our website at: *https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient/pass-through-payment-status-new-technology-ambulatory-payment-classification-apc.*

2. Transitional Pass-Through Payment Period for 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 drug or biological 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 approved pass-through drugs and biologicals on a quarterly basis through the next available OPPS quarterly update after the approval of a drug's or biological'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 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 for which pass-through payment status is ending during the calendar year is included in the quarterly OPPS Change Request transmittals.

3. Drugs and Biologicals With Expiring Pass-Through Payment Status in CY 2023

There are 43 drugs and biologicals for which pass-through payment status expires by December 31, 2023, as listed in Table 89. These drugs and biologicals will have received OPPS pass-through payment for 3 years during the period of April 1, 2020, through December 31, 2023. In accordance with the policy finalized in CY 2017 and described earlier, pass-through payment status for drugs and biologicals 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 will be $135 for CY 2024), as discussed further in section V.B.1 of this final rule with comment period. If the estimated per day cost for the drug or biological is less than or equal to the applicable OPPS drug packaging threshold, we 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 provide separate payment at the applicable ASP methodology-based payment amount (which is generally ASP plus 6 percent), as discussed further in section V.B.2 of this final rule with comment period.

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an application that is subject to the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501 *et seq.*). This information collection (CMS–10008) is currently approved under OMB control number of 0938–0802 and has an expiration date of January 31, 2025.

TABLE 89: DRUGS AND BIOLOGICALS FOR WHICH PASS-THROUGH PAYMENT STATUS WILL END BY DECEMBER 31, 2023

CY 2023 HCPCS Code	Long Descriptor	CY 2023 Status Indicator	CY 2023 APC	Pass-Through Payment Effective Date	Pass-Through Payment End Date
J0179	Injection, brolucizumab-dbll, 1 mg	G	9340	04/01/2020	03/31/2023
J0223	Injection, givosiran, 0.5 mg	G	9343	04/01/2020	03/31/2023
J0791	Injection, crizanlizumab-tmca, 1 mg	G	9359	04/01/2020	03/31/2023
J1201	Injection, cetirizine hydrochloride, 1 mg	G	9361	04/01/2020	03/31/2023
J7331	Hyaluronan or derivative, synojoynt, for intra-articular injection, 1 mg	G	9337	04/01/2020	03/31/2023
Q5114	Injection, trastuzumab-dkst, biosimilar, (ogivri), 10 mg	G	9341	04/01/2020	03/31/2023
Q5115	Injection, rituximab-abbs, biosimilar (truxima), 10 mg	G	9336	04/01/2020	03/31/2023
Q5120	Injection, pegfilgrastim-bmez, biosimilar, (ziextenzo) 0.5 mg	G	9345	04/01/2020	03/31/2023
J0742	Injection, imipenem 4 mg, cilastatin 4 mg and relebactam 2 mg	G	9362	07/01/2020	06/30/2023
J0896	Injection, luspatercept aamt, 0.25 mg	G	9347	07/01/2020	06/30/2023
J1429	Injection, golodirsen, 10 mg	G	9356	07/01/2020	06/30/2023
J1738	Injection, meloxicam, 1 mg	G	9371	07/01/2020	06/30/2023
J3032	Injection, eptinezumab-jjmr, 1 mg	G	9357	07/01/2020	06/30/2023
J3241	Injection, teprotumumab-trbw, 10 mg	G	9355	07/01/2020	06/30/2023

CY 2023 HCPCS Code	Long Descriptor	CY 2023 Status Indicator	CY 2023 APC	Pass-Through Payment Effective Date	Pass-Through Payment End Date
J7204	Injection, factor VIII, antihemophilic factor (recombinant), (esperoct), glycopegylated-exei, per iu	G	9354	07/01/2020	06/30/2023
J7402	Mometasone furoate sinus implant, 10 micrograms (Sinuva)	G	9346	07/01/2020	06/30/2023
J9177	Injection, enfortumab vedotin-ejfv, 0.25 mg	G	9364	07/01/2020	06/30/2023
J9358	Injection, fam-trastuzumab deruxtecan-nxki, 1 mg	G	9353	07/01/2020	06/30/2023
Q5116	Injection, trastuzumab-qyyp, biosimilar, (trazimera), 10 mg	G	9350	07/01/2020	06/30/2023
Q5118	Injection, bevacizumab-bvcr, biosimilar, (Zirabev), 10 mg	G	9348	07/01/2020	06/30/2023
Q5119	Injection, rituximab-pvvr, biosimilar, (Ruxience), 10 mg	G	9367	07/01/2020	06/30/2023
A9591	Fluoroestradiol F 18, diagnostic, 1 millicurie	G	9370	10/01/2020	09/30/2023
C9067	Gallium ga-68, dotatoc, diagnostic, 0.01 mCi	G	9323	10/01/2020	09/30/2023
J7351	Injection, bimatoprost, intracameral implant, 1 microgram	G	9351	10/01/2020	09/30/2023
J9144	Injection, daratumumab, 10 mg and hyaluronidase-fihj	G	9378	10/01/2020	09/30/2023
J9227	Injection, isatuximab-irfc, 10 mg	G	9377	10/01/2020	09/30/2023
J9281	Mitomycin pyelocalyceal instillation, 1 mg	G	9374	10/01/2020	09/30/2023
J9317	Injection, sacituzumab govitecan-hziy, 2.5 mg	G	9376	10/01/2020	09/30/2023
J9318	Injection, romidepsin, non-lyophilized, 0.1 mg	G	9428	10/01/2020	09/30/2023
Q5112	Injection, trastuzumab-dttb, biosimilar, (Ontruzant), 10 mg	G	9382	10/01/2020	09/30/2023
Q5113	Injection, trastuzumab-pkrb, biosimilar, (Herzuma), 10 mg	G	9349	10/01/2020	09/30/2023
Q5121	Injection, infliximab-axxq, biosimilar, (AVSOLA), 10 mg	G	9381	10/01/2020	09/30/2023

CY 2023 HCPCS Code	Long Descriptor	CY 2023 Status Indicator	CY 2023 APC	Pass-Through Payment Effective Date	Pass-Through Payment End Date
A9592	Copper Cu-64, dotatate, diagnostic, 1 millicurie	G	9383	01/01/2021	12/31/2023
J0699	Injection, cefiderocol, 10 mg	G	9380	01/01/2021	12/31/2023
J1427	Injection, viltolarsen, 10 mg	G	9386	01/01/2021	12/31/2023
J1437	Injection, ferric derisomaltose, 10 mg	G	9388	01/01/2021	12/31/2023
J1554	Injection, immune globulin (Asceniv), 500 mg	G	9392	01/01/2021	12/31/2023
J9037	Injection, belantamab mafodontin-blmf, 0.5 mg	G	9384	01/01/2021	12/31/2023
J9198	Gemcitabine hydrochloride, (Infugem), 100 mg	G	9387	01/01/2021	12/31/2023
J9223	Injection, lurbinectedin, 0.1 mg	G	9389	01/01/2021	12/31/2023
J9316	Injection, pertuzumab, trastuzumab, and hyaluronidase-zzxf, per 10 mg	G	9390	01/01/2021	12/31/2023
J9349	Injection, tafasitamab-cxix, 2 mg	G	9385	01/01/2021	12/31/2023
Q2053	Brexucabtagene autoleucel, up to 200 million autologous anti-cd19 car positive viable t cells, including leukapheresis and dose preparation procedures, per therapeutic dose	G	9391	01/01/2021	12/31/2023

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Comment: One commenter requested CMS use its equitable adjustment authority to extend the pass-through eligibility period for three radiopharmaceuticals whose pass-through payment status will expire between September 30, 2023, and December 31, 2023. The commenter stated that if CMS does not unpackage diagnostic radiopharmaceuticals in 2024, they recommended extending pass-through status through at least CY 2024 due to the effect of the PHE on claims data used for ratesetting. This same commenter supported CMS's policy under which radiopharmaceuticals are treated as drugs that are eligible for pass-through status. This commenter additionally commended CMS for proposing to continue its policy to provide for quarterly expiration of pass-through payment status.

Response: We thank the commenter for their comment, but we continue to believe that the data collected for CY 2024 ratesetting will result in the necessary cost data being collected and incorporated into the costs for expiring pass-through drugs, biologicals, and devices into the procedure APC rate. Therefore, we believe that the claims data used in CY 2024 OPPS ratesetting for procedures including these drugs, biologicals, and devices with expiring pass-through status is sufficient and an additional extension of separate payment to mimic pass-through status is neither necessary nor appropriate. We refer readers to section IV of the CY 2023 OPPS/ASC final rule with comment period (87 FR 71887) for a full discussion of CMS's final decision not to provide any additional quarters of separate payment for any drug, biological, or device category whose pass-through payment status will expire between December 31, 2022, and December 31, 2023. We appreciate commenters' support for our policy to treat radiopharmaceuticals as drugs that are eligible for drug pass-through status and to continue quarterly expiration of pass-through status.

4. Drugs, Biologicals, and Radiopharmaceuticals With Pass-Through Payment Status Expiring in CY 2024

We proposed to end pass-through payment status in CY 2024 for 25 drugs and biologicals. These drugs and biologicals, which were initially approved for pass-through payment status between April 1, 2021, and January 1, 2022, are listed in Table 90. The APCs and HCPCS codes for these drugs and biologicals, which have pass-through payment status that will end by December 31, 2024, are assigned status indicator ''G'' (Pass-Through Drugs and Biologicals) in Addenda A and B to the CY 2024 OPPS/ASC proposed rule (which are available on the CMS website).[139] The APCs and HCPCS codes for these drugs and biologicals are assigned status indicator ''G'' only for the duration of their pass-through status.

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 2024 and subsequent years, we proposed to continue to pay for pass-through drugs and biologicals using the ASP methodology, meaning a payment rate based on ASP, WAC, or AWP, as applicable. This payment rate is generally ASP plus 6 percent, equivalent to the payment rate these drugs and biologicals would receive in the physician's office setting in CY 2024. We note that, under the OPD fee schedule, separately payable drugs assigned to an APC are generally payable at ASP plus 6 percent. Therefore, we proposed that a $0 pass-through payment amount would be paid for pass-through drugs and biologicals under the CY 2024 OPPS, and in subsequent years, because the difference between the amount authorized under section 1842(o) of the Act, which is generally ASP plus 6 percent, and the portion of the otherwise applicable OPD fee schedule that the Secretary determines is appropriate, which is also proposed to be the same payment rate, which is generally ASP plus 6 percent, is $0. We proposed that this policy and the other policies proposed in this section would apply in both CY 2024 and subsequent years as they have been our longstanding policies under the OPPS. Therefore, we explained that we do not believe the policies need to be reproposed annually and should apply for subsequent years until such time as we propose to change them.

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 a payment rate calculated using the ASP methodology, meaning a payment rate based on ASP, WAC, or AWP. We proposed that this payment rate would generally be ASP plus 6 percent for CY 2024 and subsequent years, 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 final rule with comment period. We proposed 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 and therefore, there are associated OPD fee schedule amounts for them.

We proposed to continue to update pass-through payment rates on a quarterly basis on the CMS website during CY 2024 and subsequent years 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 2024 and subsequent years, consistent with our CY 2023 policy for diagnostic and therapeutic radiopharmaceuticals, we proposed to continue 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 2024 or subsequent years, we proposed 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 generally ASP plus 6 percent. If ASP data are not available for a radiopharmaceutical, we proposed to provide pass-through payment at WAC plus 3 percent (consistent with our policy in section V.B.2.a of the CY 2024 OPPS/ASC proposed rule (88 FR 49680)), the equivalent payment provided for pass-through drugs and biologicals without ASP information. Additional detail on the WAC plus 3 percent payment policy can be found in section V.B.2.a of this CY 2024 OPPS/ASC final rule with comment period. If WAC information also is not available, we proposed to provide payment for the pass-through radiopharmaceutical at 95 percent of its most recent AWP.

We refer readers to Table 90 below for the list of drugs and biologicals with pass-through payment status expiring during CY 2024. We did not receive any public comments on this section.

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[139] *https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient.*

TABLE 90: DRUGS AND BIOLOGICALS WITH PASS-THROUGH PAYMENT STATUS EXPIRING IN CY 2024

CY 2023 HCPCS Code	CY 2024 HCPCS Code	Long Descriptor	CY 2023 Status Indicator	CY 2023 APC	Pass-Through Payment Effective Date	Pass-Through Payment End Date
J0224	J0224	Injection, lumasiran, 0.5 mg	G	9407	04/01/2021	03/31/2024
J7212	J7212	Factor viia (antihemophilic factor, recombinant)-jncw (sevenfact), 1 microgram	G	9395	04/01/2021	03/31/2024
Q5122	Q5122	Injection, pegfilgrastim-apgf, biosimilar, (nyvepria), 0.5 mg	G	9406	04/01/2021	03/31/2024
A9593	A9593	Gallium ga-68 psma-11, diagnostic, (ucsf), 1 millicurie	G	9409	07/01/2021	06/30/2024
A9594	A9594	Gallium ga-68 psma-11, diagnostic, (ucla), 1 millicurie	G	9410	07/01/2021	06/30/2024
J0741	J0741	Injection, cabotegravir and rilpivirine, 2mg/3mg	G	9414	07/01/2021	06/30/2024

CY 2023 HCPCS Code	CY 2024 HCPCS Code	Long Descriptor	CY 2023 Status Indicator	CY 2023 APC	Pass-Through Payment Effective Date	Pass-Through Payment End Date
J1305	J1305	Injection, evinacumab-dgnb, 5mg	G	9416	07/01/2021	06/30/2024
J1426	J1426	Injection, casimersen, 10 mg	G	9412	07/01/2021	06/30/2024
J1448	J1448	Injection, trilaciclib, 1mg	G	9415	07/01/2021	06/30/2024
J9247	J9247	Injection, melphalan flufenamide, 1mg	G	9417	07/01/2021	06/30/2024
J9348	J9348	Injection, naxitamab-gqgk, 1 mg	G	9408	07/01/2021	06/30/2024
J9353	J9353	Injection, margetuximab-cmkb, 5 mg	G	9418	07/01/2021	06/30/2024
Q2054	Q2054	Lisocabtagene maraleucel, up to 110 million autologous anti-cd19 car-positive viable t cells, including leukapheresis and dose preparation procedures, per therapeutic dose	G	9413	07/01/2021	06/30/2024
Q5123	Q5123	Injection, rituximab-arrx, biosimilar, (riabni), 10 mg	G	9411	07/01/2021	06/30/2024
J1823	J1823	Injection, inebilizumab-cdon, 1 mg	G	9394	10/01/2021	09/30/2024
J2406	J2406	Injection, oritavancin (kimyrsa), 10 mg	G	9427	10/01/2021	09/30/2024
J9061	J9061	Injection, amivantamab-vmjw, 10 mg	G	9432	10/01/2021	09/30/2024
J9272	J9272	Injection, dostarlimab-gxly, 100 mg	G	9431	10/01/2021	09/30/2024
J9359	J9359	Injection, loncastuximab	G	9205	10/01/2021	09/30/2024

CY 2023 HCPCS Code	CY 2024 HCPCS Code	Long Descriptor	CY 2023 Status Indicator	CY 2023 APC	Pass-Through Payment Effective Date	Pass-Through Payment End Date
		tesirine-lpyl, 0.075 mg				
Q2055	Q2055	Idecabtagene vicleucel, up to 460 million autologous b-cell maturation antigen (bcma) directed car-positive t cells, including leukapheresis and dose preparation procedures, per therapeutic dose	G	9422	10/01/2021	09/30/2024
A9595	A9595	Piflufolastat f-18, diagnostic, 1 millicurie	G	9430	01/01/2022	12/31/2024
J0219	J0219	Injection, avalglucosidase alfa-ngpt, 2 mg	G	9433	01/01/2022	12/31/2024
J0491	J0491	Injection, anifrolumab-fnia, 1 mg	G	9434	01/01/2022	12/31/2024
J9021	J9021	Injection, asparaginase, recombinant, (rylaze), 0.1 mg	G	9437	01/01/2022	12/31/2024
J9071	J9071	Injection, cyclophosphamide, (auromedics), 5 mg	G	9203	01/01/2022	12/31/2024

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5. Drugs, Biologicals, and Radiopharmaceuticals With Pass-Through Payment Status Continuing Through CY 2024

We proposed to continue pass-through payment status in CY 2024 for 42 drugs and biologicals. These drugs and biologicals, which were approved for pass-through payment status with effective dates beginning between April 1, 2022, and October 1, 2023, are listed in Table 91. The APCs and HCPCS codes for these drugs and biologicals, which have pass-through payment status that would continue after December 31, 2024, are assigned status indicator ''G'' in Addenda A and B to this final rule with comment period (which are available on the CMS website).[140]

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 2024 and subsequent years, we proposed to continue to pay for pass-through drugs and biologicals at a payment rate based on the ASP methodology, which may be based on ASP, WAC, or AWP, but is generally ASP plus 6 percent, which is equivalent to the payment rate these drugs and biologicals would receive in the physician's office setting in CY 2024. We proposed that a $0 pass-through payment amount would be paid for pass-through drugs and biologicals that are not policy-packaged under the

[140] *https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient.*

CY 2024 OPPS or in subsequent years, because the difference between the amount authorized under section 1842(o) of the Act, which would generally be ASP plus 6 percent, and the portion of the otherwise applicable OPD fee schedule that the Secretary determines is appropriate, which would also generally be ASP plus 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 a payment rate based on the ASP methodology, which may be based on ASP, WAC, or AWP, but would generally be ASP plus 6 percent for CY 2024, minus a payment offset for any predecessor drug products contributing to the pass-through payment as described in section V.A.6 of this final rule with comment period. We proposed 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 and therefore, there are associated OPD fee schedule amounts for them.

We proposed to continue to update pass-through payment rates on a quarterly basis on our website during CY 2024, and in subsequent years, 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 2024 and subsequent years, consistent with our CY 2023 policy for diagnostic and therapeutic radiopharmaceuticals, we proposed to continue 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 2024, we will continue to follow the standard ASP methodology to determine the pass-through payment rate that drugs receive under section 1842(o) of the Act, which would generally be ASP plus 6 percent. If ASP data are not available for a radiopharmaceutical, we would provide pass-through payment at WAC plus 3 percent (consistent with our policy in section V.B.2.a of this final rule with comment period), the equivalent payment provided to pass-through drugs and biologicals without ASP information. Additional detail on the WAC plus 3 percent payment policy can be found in section V.B.2.a of this final rule with comment period. If WAC information also is not available, we would provide payment for the pass-through radiopharmaceutical at 95 percent of its most recent AWP.

We proposed that the other policies in this section would apply in both CY 2024 and subsequent years as they have been our longstanding policies under the OPPS. Therefore, we do not believe the policies need to be reproposed-annually and should apply for subsequent years until such time as we propose to change them.

The drugs and biologicals that we proposed would have pass-through payment status expire after December 31, 2024, are shown in Table 91. We did not receive any public comments on this section.

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TABLE 91: DRUGS AND BIOLOGICALS WITH PASS-THROUGH PAYMENT STATUS EXPIRING AFTER CY 2024

CY 2023 HCPCS Code	CY 2024 HCPCS Code	Long Descriptor	CY 2023 Status Indicator	CY 2023 APC	Pass-Through Payment Effective Date	Pass-Through Payment End Date
J0248	J0248	Injection, remdesivir, 1 mg	G	9200	04/01/2022	03/31/2025
J9304	J9304	Injection, pemetrexed (PEMFEXY), 10mg	G	9442	04/01/2022	03/31/2025
C9092	J3299	Injection, triamcinolone acetonide, suprachoroidal (xipere), 1 mg	G	9358	04/01/2022	03/31/2025
C9093	J2779	Injection, ranibizumab, via sustained release intravitreal implant (susvimo), 0.1 mg	G	9439	04/01/2022	03/31/2025
C9091	J9331	Injection, sirolimus protein-bound particles, 1 mg	G	9241	04/01/2022	03/31/2025
C9090	J2998	Injection, plasminogen, human-tvmh, 1 mg	G	9206	04/01/2022	03/31/2025
J9273	J9273	Injection, tisotumab vedotin-tftv, 1 mg	G	9204	04/01/2022	03/31/2025
C9088	C9088	Instillation, bupivacaine and meloxicam, 1 mg/0.03 mg	G	9440	04/01/2022	03/31/2025
Q2056	Q2056	Ciltacabtagene autoleucel, up to 100 million autologous b-cell maturation antigen (bcma)	G	9498	07/01/2022	06/30/2025

CY 2023 HCPCS Code	CY 2024 HCPCS Code	Long Descriptor	CY 2023 Status Indicator	CY 2023 APC	Pass-Through Payment Effective Date	Pass-Through Payment End Date
		directed car-positive t cells, including leukapheresis and dose preparation procedures, per therapeutic dose				
J1302	J1302	Inj, sutimlimab-jome, 10 mg	G	9444	07/01/2022	06/30/2025
A9596	A9596	Gallium ga-68 gozetotide, diagnostic, (illuccix), 1 millicurie	G	9443	07/01/2022	06/30/2025
J9274	J9274	Inj, tebentafusp-tebn, 1 mcg	G	9446	07/01/2022	06/30/2025
J1306	J1306	Injection, inclisiran, 1 mg	G	9004	07/01/2022	06/30/2025
Q5125	Q5125	Injection, filgrastim-ayow, biosimilar, (releuko), 1 microgram	G	9447	07/01/2022	06/30/2025
J2356	J2356	Injection, tezepelumab-ekko, 1 mg	G	9008	07/01/2022	06/30/2025
J2777	J2777	Inj, faricimab-svoa, 0.1 mg	G	9496	07/01/2022	06/30/2025
J9332	J9332	Injection, efgartigimod alfa-fcab, 2 mg	G	9010	07/01/2022	06/30/2025
A9800	A9800	Gallium ga-68 gozetotide, diagnostic, (locametz), 1 millicurie	G	9055	10/01/2022	09/30/2025
C9101	C9101	Injection, oliceridine, 0.1 mg	G	9049	10/01/2022	09/30/2025
A9607	A9607	Lutetium lu 177 vipivotide tetraxetan, therapeutic, 1 millicurie	G	9054	10/01/2022	09/30/2025
J9298	J9298	Injection, nivolumab and relatlimab-rmbw, 3 mg/1 mg	G	9057	10/01/2022	09/30/2025

CY 2023 HCPCS Code	CY 2024 HCPCS Code	Long Descriptor	CY 2023 Status Indicator	CY 2023 APC	Pass-Through Payment Effective Date	Pass-Through Payment End Date
A9602	A9602	Fluorodopa f-18, diagnostic, per millicurie	G	9053	10/01/2022	09/30/2025
J1952	J1952	Leuprolide injectable, camcevi, 1 mg	G	9050	10/01/2022	09/30/2025
Q5126	Q5126	Injection, bevacizumab-maly, biosimilar, (alymsys), 10 mg	G	9048	10/01/2022	09/30/2025
J0225	J0225	Injection, vutrisiran, 1 mg	G	9009	01/01/2023	12/31/2025
J1932	J1932	Injection, lanreotide, (cipla), 1 mg	G	9051	01/01/2023	12/31/2025
J2327	J2327	Injection, risankizumab-rzaa, intravenous, 1 mg	G	9013	01/01/2023	12/31/2025
Q5124	Q5124	Injection, ranibizumab-nuna, biosimilar, (byooviz), 0.1 mg	G	9017	01/01/2023	12/31/2025
C9144	C9144	Injection, bupivacaine (posimir), 1 mg	G	9106	04/01/2023	03/31/2026
C9145	C9145	Injection, aprepitant, (aponvie), 1 mg	G	9107	04/01/2023	03/31/2026
J9063	J9063	Injection, mirvetuximab soravtansine-gynx, 1 mg	G	9109	04/01/2023	03/31/2026
J9347	J9347	Injection, tremelimumab-actl, 1 mg	G	9110	04/01/2023	03/31/2026
J9380	J9380	Injection, teclistamab-cqyv, 0.5 mg	G	9111	04/01/2023	03/31/2026
J9381	J9381	Injection, teplizumab-mzwv, 4 mcg	G	9112	04/01/2023	03/31/2026
J0218	J0218	Injection, olipudase alfa-rpcp, 1 mg	G	9113	04/01/2023	03/31/2026

CY 2023 HCPCS Code	CY 2024 HCPCS Code	Long Descriptor	CY 2023 Status Indicator	CY 2023 APC	Pass-Through Payment Effective Date	Pass-Through Payment End Date
J1411	J1411	Injection, etranacogene dezaparvovec-drlb, per therapeutic dose	G	9138	04/01/2023	03/31/2026
J1449	J1449	Injection, eflapegrastim-xnst, 0.1 mg	G	9114	04/01/2023	03/31/2026
J1747	J1747	Injection, spesolimab-sbzo, 1 mg	G	9115	04/01/2023	03/31/2026
J1954	J1954	Injection, leuprolide acetate for depot suspension (lutrate), 7.5 mg	G	9136	04/01/2023	03/31/2026
J2403	J2403	Chloroprocaine hcl ophthalmic, 3% gel, 1 mg	G	9116	04/01/2023	03/31/2026
Q5128	Q5128	Injection, ranibizumab-eqrn (cimerli), biosimilar, 0.1 mg	G	9117	04/01/2023	03/31/2026
Q5130	Q5130	Injection, pegfilgrastim-pbbk (fylnetra), biosimilar, 0.5 mg	G	9118	04/01/2023	03/31/2026
J2329	J2329	Injection, ublituximab-xiiy, 1 mg	G	9149	07/01/2023	6/30/2026
J1440	J1440	Fecal microbiota, live - jslm for rectal use, 1 ml	G	9142	07/01/2023	6/30/2026
Q5129	Q5129	Injection, bevacizumab-adcd (vegzelma), biosimilar, 10 mg	G	9159	07/01/2023	6/30/2026
J9056	J9056	Injection, bendamustine hydrochloride (vivimusta), 1 mg	G	9154	07/01/2023	6/30/2026
J0208	J0208	Injection, sodium thiosulfate,100 mg	G	9119	07/01/2023	6/30/2026
J2781	J2781	Injection, pegcetacoplan, 1 mg	G	9158	07/01/2023	6/30/2026

CY 2023 HCPCS Code	CY 2024 HCPCS Code	Long Descriptor	CY 2023 Status Indicator	CY 2023 APC	Pass-Through Payment Effective Date	Pass-Through Payment End Date
J1961	J1961	Injection, lenacapavir, 1 mg	G	9155	07/01/2023	6/30/2026
J9350	J9350	Injection, mosunetuzumab-axgb, 1 mg	G	9150	07/01/2023	6/30/2026
C9152	C9152	Injection, aripiprazole, (abilify asimtufii), 1 mg	G	9246	10/01/2023	9/30/2026
J7214	J7214	Injection, factor viii/von willebrand factor complex, recombinant (altuviiio), per factor viii i.u.	G	9277	10/01/2023	9/30/2026
C9153	C9153	Injection, amisulpride, 1 mg	G	9247	10/01/2023	9/30/2026
J9058	J9058	Injection, bendamustine hydrochloride (apotex), 1 mg	G	9151	10/01/2023	9/30/2026
C9154	C9154	Injection, buprenorphine extended-release (brixadi), 1 mg	G	9249	10/01/2023	9/30/2026
C9155	C9155	Injection, epcoritamab-bysp, 0.16 mg	G	9250	10/01/2023	9/30/2026
C9156	C9156	Flotufolastat F 18, diagnostic, 1 millicurie	G	9254	10/01/2023	9/30/2026
C9157	C9157	Injection, tofersen, 1 mg	G	9262	10/01/2023	9/30/2026
C9158	C9158	Injection, risperidone, (uzedy), 1 mg	G	9266	10/01/2023	9/30/2026

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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 regulation at 42 CFR 419.2(b)(15), 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 the regulation at 42 CFR 419.2(b)(16), 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. Finally, under the regulation at 42 CFR 419.2(b)(4), anesthesia drugs are packaged in the OPPS. 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 policy-packaged drugs, which include 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 2024 and subsequent years, as we did in CY 2023, we proposed 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. We proposed that these policies would apply in both CY 2024 and subsequent years as they are our longstanding policies under the OPPS, and we do not believe they need to be reproposed annually. Instead, we believe they should apply for subsequent years until such time as we propose to change them or until such time as the APCs to which a payment offset may be applicable for certain products change. The 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 92. We note that in the CY 2024 OPPS/ASC proposed rule (88 FR 49676), we erroneously labeled these APCs as ''CY 2023'' rather than the correct ''CY 2024.''

TABLE 92: APCs TO WHICH A POLICY-PACKAGED DRUG OR RADIOPHARMACEUTICAL OFFSET MAY BE APPLICABLE IN CY 2024

CY 2024 APC	CY 2024 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 proposed to continue to post annually on our website at: *https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient/annual-policy-files* 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.

Comment: One commenter requested that we establish a ''two-times rule'' for diagnostic radiopharmaceuticals since they are packaged into the cost of the associated testing or administration procedure. While the commenter did not describe their precise goal, it appears they support a policy where, if the per-day cost of a diagnostic radiopharmaceutical is more than twice the cost of testing or the administration procedure where the product would be used, we should use our process under the OPPS to create a temporary HCPCS code to describe a new testing or administration procedure. The temporary HCPCS code for the new testing or administrative procedure would only be used with high-cost diagnostic radiopharmaceuticals for which the commenter believes payment is not sufficient. The commenter believed creating a temporary code for testing or administrative procedures for

use only with high-cost diagnostic radiopharmaceuticals would better reflect the cost of the high-cost diagnostic radiopharmaceutical products as lower-cost products would not be billed with, and would thus be excluded from the cost of, the test or procedure for which the temporary HCPCS would be established.

Response: Our packaged payment policies for diagnostic radiopharmaceuticals are designed to encourage the use of the most cost-effective items and services for Medicare beneficiaries. Creating separate HCPCS codes for procedures utilizing high-cost diagnostic radiopharmaceuticals would segment payment for diagnostic radiopharmaceuticals and would reduce the prospective nature of the OPPS. We believe that the policy the commenter is suggesting may discourage the use of effective, lower-cost products.

However, we appreciate the comment and will consider it as we explore possible changes to our diagnostic radiopharmaceutical payment policy, which may include new payment and coding approaches for high-cost diagnostic radiopharmaceuticals in the outpatient hospital setting in future rulemaking. Additionally, please refer to section II.A.3 of this final rule with comment period for a discussion of our comment solicitation regarding possible new approaches for the payment of diagnostic radiopharmaceuticals.

Comment: One commenter asked for an analysis of how we incorporate the cost of diagnostic radiopharmaceuticals with pass-through status into the payment for the associated test or administration procedure when the pass-through status of the diagnostic radiopharmaceutical ends.

Response: We identify single procedure claims that describe a procedure where a diagnostic radiopharmaceutical whose pass-through status is ending is used. The separate cost of the diagnostic radiopharmaceutical is added to the payment rate of the associated single procedure minus any existing drug offset for the service. We then calculate the geometric mean cost of all existing claims for the associated procedure. In many cases, there may be several diagnostic radiopharmaceuticals that can be used with a given procedure. The cost of the procedure will reflect the resource cost to perform the procedure along with the share of the procedures performed with the drug for which pass-through status is ending and the share of other diagnostic radiopharmaceuticals that may already be packaged into the cost of the associated procedure.

We advise the commenter to refer to the CY 2024 OPPS final rule claims accounting narrative and to section II.A.3 of this final rule with comment period for information on how costs from drugs, including diagnostic radiopharmaceuticals, and other ancillary services are included in the cost of their associated procedures when payment for those drugs and ancillary services is packaged.

Comment: One commenter requested that CMS release a copy of the APC offset file with future OPPS/ASC proposed rules to enable the public to calculate the percentage of APC payment associated with packaged drug costs using APC offset data for the upcoming calendar year.

Response: We thank the commenter for their suggestion, and we will consider it for future rulemaking.

Comment: One commenter supported keeping four payment levels (APC 5591 through APC 5594) for the Nuclear Medicine and related services APC.

Response: We appreciate the support of the commenter.

After consideration of the public comments we received, we are finalizing our proposals without modification regarding the APCs where drug offsets for policy-packaged drugs or radiopharmaceuticals could apply. We are also finalizing our proposal, without modification, to continue to annually post a file that contains the APC offset amounts.

B. OPPS Payment for Drugs, Biologicals, and Radiopharmaceuticals Without Pass-Through Payment Status

1. Criteria for Packaging Payment for Drugs, Biologicals, and Radiopharmaceuticals

a. 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 and 68086)), we set the packaging threshold for establishing separate APCs for drugs and biologicals at $135 for CY 2023 (87 FR 71960 and 71961).

Following the CY 2007 methodology, for the CY 2024 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 2024 and rounded the resulting dollar amount ($138.44) to the nearest $5 increment, which yielded a figure of $140. 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 IHS Global, Inc. IGI is a nationally recognized economic and financial forecasting firm with which CMS contracts to forecast the various price indexes including the PPI Pharmaceuticals for Human Use (Prescription). Based on these calculations using the CY 2007 OPPS methodology, we proposed a packaging threshold for CY 2024 of $140.

Comment: One commenter requested that the drug packaging threshold not be increased for CY 2024, but instead be maintained at $135 per day. The commenter believes that the level of the drug packaging threshold has increased faster over the last several years than the rate of increase in OPPS payment rates.

Response: Consistent with our longstanding policy and practices, for the final rule, we recalculated the drug packaging threshold amount with updated data for the four-quarter moving average PPI level. When we trended the $50 threshold forward from the third quarter of CY 2005 to the third quarter of CY 2024 and rounded the resulting dollar amount ($137.36) to the nearest $5 increment, we calculated a threshold amount of $135, which is $5 less than our proposed threshold. We note, however, that we are not changing the methodology by which we calculate the threshold. Rather, recalculating the threshold amount using the updated data for the four-quarter moving average PPI level resulted in a lower amount that rounded to $135.

After consideration of the public comments we received and consistent with our standard methodology, we are finalizing our proposal with modification. We will maintain the drug packaging threshold for CY 2024 at $135 per day, as the updated threshold amount calculated rounded to the

nearest $5 increment is now $135, rather than the proposed $140.

b. Packaging of Payment for HCPCS Codes That Describe Certain Drugs, Certain Biologicals, and Certain Therapeutic Radiopharmaceuticals Under the Cost Threshold (''Threshold-Packaged Drugs'')

To determine the proposed CY 2024 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 that had a HCPCS code in CY 2022 and were paid (via packaged or separate payment) under the OPPS. We used data from CY 2022 claims processed through June 30, 2022, 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 this final rule with comment period, or for the following policy-packaged items that we propose to continue to package in CY 2024: 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 2024, we used the methodology that was described in detail in the CY 2006 OPPS proposed rule (70 FR 42723 and 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 based on the ASP methodology, which is generally ASP plus 6 percent (which is the payment rate we proposed for separately payable drugs and biologicals) for CY 2024, as discussed in more detail in section V.B.2.b of this final rule with comment period) to calculate the CY 2024 proposed rule per day costs. We used the manufacturer-submitted ASP data from the fourth quarter of CY 2022 (data that were used for payment purposes in the physician's office setting, effective April 1, 2023) to determine the proposed rule per day cost.

As is our standard methodology, for CY 2024, we proposed to use payment rates based on the ASP data from the fourth quarter of CY 2022 for budget neutrality estimates, packaging determinations, impact analyses, and completion of Addenda A and B to the CY 2024 OPPS 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 CY 2024 OPPS proposed rule. These data also were the basis for drug payments in the physician's office setting, effective April 1, 2023. 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 2022 hospital claims data to determine their per day cost.

We proposed to package items with a per day cost less than or equal to $140 and identify items with a per day cost greater than $140 as separately payable unless they are policy-packaged. Consistent with our past practice, we cross-walked historical OPPS claims data from the CY 2022 HCPCS codes that were reported to the CY 2023 HCPCS codes that we display in Addendum B to the OPPS CY 2024 proposed rule (which is available on the CMS website) [141] for proposed payment in CY 2024.

Our policy during previous cycles of OPPS rulemaking 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 the CY 2024 OPPS proposed rule, we proposed to use ASP data from the fourth quarter of CY 2022, 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, 2023, along with updated hospital claims data from CY 2022. We note that we also proposed to use these data for budget neutrality estimates and impact analyses for the CY 2024 OPPS proposed rule.

Payment rates for HCPCS codes for separately payable drugs and biologicals included in Addenda A and B of the CY 2024 OPPS proposed rule are based on ASP data from the second quarter of CY 2023. 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, 2023. These payment rates would then be updated in the January 2024 OPPS update, based on the most recent ASP data to be used for physicians' office and OPPS payment as of January 1, 2024. For items that do not currently have an ASP-based payment rate, we calculated their mean unit cost from all of the CY 2022 claims data and updated cost report information available for the CY 2024 OPPS proposed rule to determine their final per day cost.

Consequently, the packaging status of some HCPCS codes for drugs, biologicals, and therapeutic radiopharmaceuticals in the OPPS/ASC proposed rule may be different from the same drugs' HCPCS codes' packaging status determined based on the data used for this 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 2024 OPPS drug packaging threshold and the drug's payment status (packaged or separately payable) in CY 2023. 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 2024 and subsequent years, consistent with our historical practice, we proposed to apply the following policies to those 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 2023 and that are proposed for separate payment in CY 2024, and that then have per day costs equal to or less than the CY 2024 final rule drug packaging threshold, based on the updated ASPs and hospital claims data used for the CY 2024 final rule, would continue to receive separate payment in CY 2024.
- HCPCS codes for drugs and biologicals that were packaged in CY 2023 and that are proposed for separate payment in CY 2024, and that then have per day costs equal to or less than the CY 2024 final rule drug packaging threshold, based on the updated ASPs and hospital claims data used for the CY 2024 final rule, would remain packaged in CY 2024.
- HCPCS codes for drugs and biologicals for which we proposed

[141] *https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient.*

packaged payment in CY 2024 but that then have per-day costs greater than the CY 2024 final rule drug packaging threshold, based on the updated ASPs and hospital claims data used for the CY 2024 final rule, would receive separate payment in CY 2024.

We did not receive any public comments on our proposal, and we are finalizing our proposal with modification because of the change in the amount of the drug packaging threshold that was described in section V.B.1.a of this final rule with comment period. We will package items with a per day cost less than or equal to $135 and identify items with a per day cost greater than $135 as separately payable unless they are policy-packaged. In addition, we are finalizing, without modification, our proposal to recalculate the mean unit cost for items that do not currently have an ASP-based payment rate from all of the CY 2022 claims data and updated cost report information available for this CY 2024 final rule with comment period to determine their final per day cost.

We also did not receive any public comments on our proposal to continue to follow the established policies, initially adopted for the CY 2005 OPPS (69 FR 65780), when the packaging status of HCPCS codes for drugs, biologicals, and therapeutic radiopharmaceuticals in the proposed rule is different from the same drug's HCPCS code's packaging status determined based on the data used for the final rule with comment period. For CY 2024, we are finalizing these two proposals without modification. Please refer to Addendum B to this final rule with comment period, which is available on the CMS website, for information on the packaging status of drugs, biologicals, and therapeutic radiopharmaceuticals.

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).

Comment: One commenter recommended that CMS continue to apply radiolabeled product edits to the nuclear medicine procedures to ensure that all packaged costs are included on nuclear medicine claims in order to establish appropriate payment rates in the future. The commenter was concerned that many providers performing nuclear medicine procedures are not including the cost of diagnostic radiopharmaceuticals used for the procedures in their claim submissions. The commenter believes this lack of drug cost reporting could be causing the cost of nuclear medicine procedures to be underreported and therefore requested that the radiolabeled product edits be reinstated.

Response: We appreciate the commenter's feedback; however, we are not reinstating the radiolabeled product edits for nuclear medicine procedures, which required a diagnostic radiopharmaceutical to be present on the same claim as a nuclear medicine procedure for payment to be made under the OPPS. As previously discussed in the CY 2020 OPPS/ASC final rule with comment period (85 FR 86033 and 86034), the edits were in place between CY 2008 and CY 2014 (78 FR 75033). We believe the period of time in which the edits were in place was sufficient for hospitals to gain experience reporting procedures involving radiolabeled products and to become accustomed to ensuring that they code and report charges so that their claims fully and appropriately reflect the costs of those radiolabeled products. As with all other items and services recognized under the OPPS, we expect hospitals to code and report their costs appropriately, regardless of whether there are claims processing edits in place.

We welcome ongoing dialogue and engagement from interested parties regarding suggestions for payment changes for consideration in future rulemaking.

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 and 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 2024.

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 2022 claims data and our pricing information, which is based on the ASP methodology, which is generally ASP plus 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 the CY 2024 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 2022 claims data to make the proposed packaging determinations for them: 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 methodology based payment rate, which is generally ASP plus 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 if the estimated per day cost of each drug or biological is less than or equal to the proposed CY 2024 drug packaging threshold of $140 (in which case all HCPCS codes for the same drug or biological would be packaged) or greater than the proposed CY 2024 drug packaging threshold of $140 (in which case 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 2024 is displayed in Table 93.

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TABLE 93: HCPCS CODES TO WHICH THE CY 2024 DRUG-SPECIFIC PACKAGING DETERMINATION METHODOLOGY APPLIES

CY 2024 HCPCS Code	CY 2024 Long Descriptor	CY 2024 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
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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We did not receive any public comments on our proposal, and we are finalizing our proposal with the only modification being that the final CY 2024 drug packaging threshold will be $135 per day as described in section V.B.1.a. of this final rule with comment period. All other parts of the proposal are finalized without modification.

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 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 plus 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.[142]

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. For CY 2023 and subsequent years, we finalized a policy 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 plus 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 2023.

In the case of a drug or biological during an initial sales period in which data on the prices for sales of 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 are not available. Consistent with section 1847A(c)(4) of the Act, in the CY 2019 PFS final rule (83 FR 59661 through 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 through 59666). Since CY 2020, we have continued to utilize a 3 percent add-on instead of a 6 percent add-on for drugs that are paid based on WAC pursuant to our authority under section 1833(t)(14)(A)(iii)(II) of the Act (84 FR 61318 and 85 FR 86039), 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 apply this provision to non-SCOD separately payable drugs. Because we establish the average price for a drug paid based on WAC under section 1847A of the Act as WAC plus 3 percent instead of WAC plus 6 percent, we believe it is appropriate to price separately payable drugs paid based on WAC at the same amount under the OPPS. Our policy to pay for drugs and biologicals at WAC plus 3 percent, rather than WAC plus 6 percent, applies whenever WAC-based pricing is used for a drug or biological under 1847A(c)(4). We refer readers to the CY 2019 PFS final rule (83 FR 59661 through 59666) for additional background on this policy.

Consistent with our current policy, payments for separately payable drugs and biologicals are included in the budget neutrality adjustments, under the requirements in section 1833(t)(9)(B) of the Act. Also, the budget neutral weight scalar is not 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 the CY 2024 OPPS/ASC proposed rule (available on the CMS website),[143] which illustrate the proposed CY 2024 payment based on the ASP methodology for separately payable nonpass-through drugs and biologicals and the ASP methodology 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, 2023, or WAC, AWP, or mean unit cost from CY 2022 claims data and updated cost report information available for the CY 2024 OPPS/ASC proposed rule. In general, these published payment rates are not the same as the actual January 2024 payment rates. This is because payment rates for drugs and biologicals

[142] Medicare Payment Advisory Committee. June 2005 Report to the Congress. Chapter 6: Payment for pharmacy handling costs in hospital outpatient departments. Available at: *https://www.medpac.gov/wp-content/uploads/import_data/scrape_files/docs/default-source/reports/June05_ch6.pdf.*

[143] *https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient.*

with ASP information for January 2024 will be determined through the standard quarterly process where ASP data submitted by manufacturers for the third quarter of CY 2023 (July 1, 2023, through September 30, 2023) will be used to set the payment rates that are released for the quarter beginning in January 2024 in December 2023. In addition, payment rates for drugs and biologicals in Addenda A and B to the proposed rule, for which there was no ASP, WAC, or AWP information available for April 2023, are based on mean unit cost in the available CY 2022 claims data. If new pricing information becomes available for payment for the quarter beginning in January 2024, we will price payment for these drugs and biologicals based on their newly available information. Finally, there may be drugs and biologicals that have ASP, WAC, or AWP information available for the CY 2024 OPPS/ASC proposed rule (reflecting April 2023 ASP data) that do not have ASP, WAC, or AWP information available for the quarter beginning in January 2024. These drugs and biologicals would then be paid based on mean unit cost data derived from CY 2022 hospital claims. Therefore, the proposed payment rates listed in Addenda A and B to the proposed rule are not for January 2024 payment purposes and are only illustrative of the CY 2024 OPPS payment methodology using the most recently available information at the time of issuance of the CY 2024 OPPS/ASC proposed rule.

For CY 2024, we did not propose any changes to our policies for payment for separately payable drugs and biologicals; and we are continuing our payment policy that has been in effect since CY 2013 to pay for separately payable drugs and biologicals in accordance with section 1833(t)(14)(A)(iii)(II) of the Act (the statutory default).

We did, however, propose to amend the regulation text to reflect our longstanding policies for calculating the Medicare program payment and copayment amounts for separately payable drugs and biologicals by adding a new paragraph (d) to § 419.41.

Comment: A few commenters supported separate payment for specific drugs, biologicals, and radiopharmaceuticals for CY 2023. Commenters also supported CMS paying for all separately payable drugs and biologicals as SCODs. Multiple commenters expressed their approval for our proposal to pay for separately payable drugs and biologicals at ASP plus 6 percent.

Response: We appreciate the commenters' feedback and support.

Comment: One commenter requested that an add-on percentage of greater than 6 percent of ASP be paid for separately payable radiopharmaceuticals to reflect higher overhead and handling costs for these products.

Response: The add-on percentage of 6 percent is generally viewed as reflecting the overhead and handling cost of most drugs, radiopharmaceuticals, and biologicals that are separately payable in the OPPS even though the overhead and handling costs for individual products may be higher or lower than 6 percent of the ASP. We believe that the add-on percentage of 6 percent is appropriate for separately payable radiopharmaceuticals.

Comment: One commenter requested that we exclude radiopharmaceuticals from our proposed policy, explaining that during an initial sales period in which cost data for the drug or biological are not sufficiently available from the manufacturer, payments can be made for drugs using WAC pricing plus a 3 percent price add-on. The commenters believe the cost of preparing radiopharmaceuticals is higher than the cost of preparing other drugs and biologicals and a 6 percent price add-on should be required anytime that we use WAC to price a radiopharmaceutical.

Response: The WAC of a drug or biological is defined in section 1847A(c)(6)(B) of the Act as the manufacturer's list price for the drug or biological to wholesalers or direct purchasers in the United States, not including prompt pay or other discounts, rebates or reductions in price, for the most recent month for which the information is available, as reported in wholesale price guides or other publications of drug or biological pricing data. Because the WAC does not include discounts, it typically exceeds ASP, and the use of a WAC-based payment amount for the same drug results in higher dollar payments than the use of an ASP-based payment amount. Also, MedPAC, in their June 2017 Report to the Congress (*https://www.medpac.gov/wp-content/uploads/import_data/scrape_files/docs/defaultsource/reports/jun17_reporttocongress_sec.pdf*), suggested that greater parity between ASP-based acquisition costs and WAC-based payments for Part B drugs could be achieved and recommended changing the 6 percent add-on for WAC-based payments to 3 percent. Given this evidence that WAC pricing tends to overestimate drug cost, we believe our current policy to pay for drugs at WAC plus 3 percent for drugs, biologicals, and radiopharmaceuticals when ASP is not available more accurately reflects the cost of new products recently entering the market than does WAC plus 6 percent.

For CY 2024, we did not propose any changes to our policies for payment for separately payable drugs and biologicals; and we are continuing our payment policy that has been in effect since CY 2013 to pay for separately payable drugs and biologicals in accordance with section 1833(t)(14)(A)(iii)(II) of the Act (the statutory default).

We did, however, propose to amend the regulation text to reflect our longstanding policies for calculating the Medicare program payment and copayment amounts for separately payable drugs and biologicals by adding a new paragraph (d) to § 419.41. After consideration of the comments received, we are finalizing the proposal without modification.

b. Biosimilar Biological Products

(1) Provisions of the Inflation Reduction Act Relating to Biologicals

The Inflation Reduction Act (Pub. L. 117–169, August 16, 2022) (hereinafter referred to as ''IRA'') contains two provisions that affect payment limits for biosimilar biological products (hereinafter referred to as ''biosimilars''): section 11402 of the IRA amends the payment limit for new biosimilars furnished on or after July 1, 2024, during the initial period when ASP data is not available. Section 11403 of the IRA makes changes to the payment limit for certain biosimilars with an ASP that is not more than the ASP of the reference product for a period of 5 years. We implemented section 11403 of the IRA under program instruction,[144] [145] as permitted under section 1847A(c)(5)(C) of the Act.

Section 11402 of the IRA amended section 1847A(c)(4) of the Act by adding subparagraph (B), which limits the payment amount for biosimilars during the initial period described in section 1847A(c)(4)(A). The provision requires that for new biosimilars furnished on or after July 1, 2024, during the initial period when ASP data are not available, the payment limit for the biosimilar is the lesser of (1) an amount not to exceed 103 percent of the WAC of the biosimilar or the Medicare Part B drug

[144] *https://www.cms.gov/files/document/r11496cp.pdf.*

[145] *https://www.cms.gov/medicare/payment/fee-for-service-providers/part-b-drugs/average-drug-sales-price.*

payment methodology in effect on November 1, 2003, or (2) 106 percent of the lesser of the WAC or ASP of the reference product, or in the case of a selected drug during a price applicability period, 106 percent of the maximum fair price of the reference product. We referred readers to the CY 2024 PFS proposed rule for the discussion of the proposed changes to the regulation at § 414.904 to codify section 11402 of the IRA (88 FR 52384 and 52385).

Section 11403 of the IRA amended section 1847A(b)(8) of the Act by establishing a temporary payment increase for qualifying biosimilar biological products (hereinafter referred to as ''qualifying biosimilars'') furnished during the applicable 5-year period.[146] Section 1847(b)(8)(B)(iii) of the Act defines ''qualifying biosimilar biological product'' as a biosimilar biological product (as described in section 1847A(b)(1)(C) of the Act) with an ASP (as described in section 1847A(b)(8)(A)(i) of the Act) less than the ASP of the reference product for a calendar quarter during the applicable 5-year period. Section 11403 of the IRA requires that a qualifying biosimilar be paid at ASP plus 8 percent of the reference product's ASP rather than 6 percent during the applicable 5-year period. Section 1847A(b)(8)(B)(ii) of the Act defines the applicable 5-year period for a qualifying biosimilar for which payment has been made using ASP (that is, payment under section 1847A(b)(8) of the Act) as of September 30, 2022, as the 5-year period beginning on October 1, 2022. For a qualifying biosimilar for which payment is first made using ASP during the period beginning October 1, 2022, and ending December 31, 2027, the statute defines the applicable 5-year period as the 5-year period beginning on the first day of such calendar quarter of such payment. We referred readers to the CY 2024 PFS proposed rule for the discussion of the proposed changes to the regulations at §§ 414.902 and 414.904 to codify section 11403 of the IRA.

Section 1833(t)(14)(A)(iii) of the Act provides for payment of separately covered outpatient drugs (SCODs), and currently, CMS pays under the OPPS for SCODs consistent with the payment methodology set forth in section 1833(t)(14)(A)(iii)(II) of the Act (the statutory default). Through rulemaking, CMS adopted a policy to apply the statutory default payment methodology to separately payable drugs and biologicals that are not SCODs (70 FR 68715 and 68716). Under this authority, the payment rate for SCODs and applicable separately payable drugs and biologicals is determined in accordance with sections 1842(o) and 1847A of the Act, as calculated and adjusted by the Secretary as necessary for purposes of paragraph (14). Because our current policy is to pay for separately payable drugs and biologicals at payment amounts determined under section 1847A, we proposed that, for a separately payable biosimilar that is new for purposes of section 1847A(c)(4)(A), the OPPS payment amount would be the amount determined under section 1847A, subject to the payment limit in section 1847A(c)(4)(A). We also proposed that, for a separately payable biosimilar that meets the definition of a ''qualifying biosimilar biological product'' for purposes of section 1847A(b)(8)(B)(iii) of the Act, the OPPS payment amount for the biosimilar would be the amount determined under section 1847A, subject to the temporary payment increase under section 1847A(b)(8)(B)(iii). We proposed to codify OPPS payment for biosimilars consistent with sections 1847A(c)(4)(A) and 1847A(b)(8)(B)(iii) by adding new paragraphs (f) and (g) to the regulation at § 419.41. The proposed regulation text cross-references the regulation text included in the PFS proposed rule, which proposed to codify the requirements in sections 1847A(c)(4)(A) and 1847A(b)(8)(B)(iii). We referred readers to the PFS proposed rule for more information about those proposed regulations.

We did not receive any public comments on our proposal and, for CY 2024, we are finalizing as proposed our proposal that the OPPS payment amount for a separately payable biosimilar that meets the definition of a ''qualifying biosimilar biological product'' for purposes of section 1847A(b)(8)(B)(iii) of the Act will be the amount determined under section 1847A, subject to the temporary payment increase under section 1847A(b)(8)(B)(iii). For CY 2024, we are finalizing as proposed our proposal to codify OPPS payment for biosimilars consistent with sections 1847A(c)(4)(A) and 1847A(b)(8)(B)(iii) by adding new paragraphs (f) and (g) to the regulation at § 419.41. The final regulation text cross-references the regulation text included in the PFS final rule, which codifies the requirements in sections 1847A(c)(4)(A) and 1847A(b)(8)(B)(iii). We refer readers to the PFS final rule for more information about those regulations.

(2) Proposal To Except Biosimilars From the OPPS Packaging Threshold When Their Reference Products Are Separately Paid

Medicare Part B spending for biologicals and biosimilars has significantly outpaced the spending for non-biologic drugs for the past 16 years. According to a 2020 report from the Assistant Secretary for Planning and Evaluation (ASPE), the spending for biologicals and biosimilars represented 77 percent of Medicare Part B prescription drug spending in CY 2017.[147] In a 2020 MedPAC report, the top 10 Part B drugs based on spending were all biologicals, and spending on them in the HOPD represented 39 percent of total HOPD drug spending in CY 2019.[148] Although Part B drug spending for biologicals and biosimilars has grown tremendously in the past 16 years, we also recognize that there is evidence that the entry of biosimilars into the market has contributed to lower aggregate spending for the Medicare program.[149]

Congress has made legislative changes related to payment for biosimilars. First, it amended the Social Security Act to provide for payment of biosimilars in the Affordable Care Act (ACA) and more recently, in the IRA, to update payment for certain biosimilars. In particular, section 3139 of the ACA amended section 1847A(b) by adding a new paragraph (8), which provides that the payment amount for a biosimilar biological product is the biosimilar's ASP and 6 percent of the reference product's ASP.[150] And as explained previously, section 11402 of the IRA changed the payment limit for biosimilars during the initial period when ASP data is not available; and section 11403 of the IRA temporarily

[146] *https://www.congress.gov/bill/117th-congress/house-bill/5376/text?q=%7B%22search%22%3A%5B%22inflation+reduction+act%22%2C%22inflation%22%2C%22reduction%22%2C%22act%22%5D%7D&r=1&s=1.*

[147] Assistant Secretary for Planning and Evaluation. ''Medicare Part B Drugs: Trends in Spending and Utilization, 2006–2017.'' November 2020. Available at *https://aspe.hhs.gov/sites/default/files/private/pdf/264416/Part-B-Drugs-Trends-Issue-Brief.pdf.*

[148] Medicare Payment Advisory Commission. July 2021 Data Book: Health Care Spending and the Medicare Program. July 2021. Available at *https://www.medpac.gov/wp-content/uploads/import_data/scrape_files/docs/default-source/data-book/july2021_medpac_databook_sec.pdf.*

[149] Medicare Payment Advisory Commission. July 2022 Data Book: Health Care Spending and the Medicare Program. July 2022. Available at *https://www.medpac.gov/wp-content/uploads/2022/07/July2022_MedPAC_DataBook_Sec10_v2_SEC.pdf.*

[150] *https://www.congress.gov/111/plaws/publ148/PLAW-111publ148.pdf.*

increased the payment limit for certain biosimilars.

Our overarching policy goal is to create incentives for efficiency and selection of the least costly products while still meeting a beneficiary's clinical needs and to protect the long-term solvency of the Part B Trust Fund. When we established a policy to pay for biosimilars, we intended to promote the use of biosimilars as a less expensive alternative to their reference 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 and 70446; and for CY 2017, 81 FR 79674). In the CY 2018 OPPS/ASC final rule with comment period (82 FR 59351), we explained that consistent with our established OPPS drug, biological, and radiopharmaceutical payment policy, HCPCS coding for biosimilar biological products will be based on policy established under the CY 2018 PFS final rule with comment period (82 FR 53182 through 53187), where CMS finalized a policy to implement separate HCPCS codes for biosimilar biological products. We also clarified that all biosimilar biological products will be eligible for pass-through payment and not just the first biosimilar biological product for a reference product.

Our threshold packaging policy's intent is to create incentives for efficiency, but we have concerns that packaging biosimilars when the reference product or other marketed biosimilars are separately paid may create financial incentives for providers to select more expensive, but clinically similar, products. In most cases, a biosimilar either has pass-through status or is separately payable. However, there have been a few instances where biosimilars are packaged. For example, in CY 2021, we noted that HCPCS code Q5105 (Injection, epoetin alfa-epbx, biosimilar, (Retacrit) (for esrd on dialysis), 100 units), was on pass-through status through September 2021. HCPCS code Q5105 is a biosimilar for HCPCS code Q4081 (injection, epoetin alfa, 1000 units (for esrd on dialysis)), and HCPCS code Q4081 is currently packaged under the OPPS. After HCPCS code Q5105's pass-through status expired, payment for HCPCS code Q5105 was packaged because its per day cost fell below our packaging threshold of $130 for CY 2021. In CY 2023, payment for HCPCS code Q5101 (Injection, filgrastim-sndz, biosimilar, (zarxio), 1 microgram) is packaged because its per day cost fell below our packaging threshold of $135 for CY 2023. HCPCS code Q5101 is the biosimilar for HCPCS code J1442 (Injection, filgrastim (g-csf), excludes biosimilars, 1 microgram), which is currently separately payable with a status indicator ''K.''

Packaging payment for both of these biosimilars is consistent with our policy since CY 2018 to subject nonpass-through biosimilars to the OPPS threshold-packaging policy. However, we believe this policy may create incentives to use the more expensive reference product or biosimilars that are separately payable, as hospitals would be paid less for using the threshold-packaged biosimilar. For example, the CY 2023 threshold packaging of the biosimilar described by HCPCS code Q5101 (Injection, filgrastim-sndz, biosimilar, (zarxio), 1 microgram) may have created a financial incentive for providers to select the separately paid reference product or the separately paid filgrastim biosimilar over the packaged filgrastim biosimilar, which is inconsistent with our policy goal of encouraging efficiency and promoting use of biosimilars as lower cost alternatives to their reference products. Accordingly, for CY 2024, we proposed to except biosimilars from the OPPS threshold packaging policy when their reference products are separately paid, meaning we would pay separately for these biosimilars even if their per-day cost is below the threshold packaging policy. We believe the threshold packaging exception for biosimilars when their reference products are separately paid would preserve our policy intent to promote biosimilar use as a lower cost alternative to higher cost reference products.

In addition, if a reference product's per-day cost falls below the threshold packaging policy, we proposed that all the biosimilars related to the reference product would be similarly packaged regardless of whether their per-day costs are above the threshold. This would allow for consistent treatment of similar biological products in the unusual circumstance in which a biosimilar is priced above the reference product. For the purpose of identifying biosimilar(s) related to a reference product, we would rely on the product's FDA approval under section 351(k) of the Public Health Service Act. For example, filgrastimsndz (Zarxio), filgrastim-aafi (Nivestym), and filgrastim-ayow (Releuko-) are biosimilars related to filgrastim (Neupogen).[151]

Comment: Several commenters expressed support for our proposal to except biosimilars from the drug packaging threshold when their reference products are separately paid and not packaged.

Response: We thank the commenters for their support to except biosimilars from the current threshold packaging policies when their reference product is above the threshold and paid separately. As stated earlier, when we established a policy to pay for biosimilars, we intended to promote the use of biosimilars as a less expensive alternative to their reference products. Our threshold packaging policy's intent is to create incentives for efficiency, but we have concerns that packaging biosimilars when the reference product or other marketed biosimilars are separately paid may create financial incentives for providers to select more expensive, but clinically similar, products. We believe the threshold packaging exception for biosimilars when their reference products are separately paid would preserve our policy intent to promote biosimilar use as a lower cost alternative to higher cost reference products.

Comment: Commenters generally opposed our proposal to package payment for biosimilar(s) when its reference product is below the drug packaging threshold and packaged. The commenters contended the current threshold packaging policy imposes inflationary pressure on drug costs by incentivizing manufacturers to maintain the ASP above the packaging threshold to ensure separate payment while providers are incentivized to select the higher cost biologicals for a similar reason.

Response: We thank the commenters for their insights on this subject. The threshold-packaging policy's intent is to create incentives for efficiency. We proposed the threshold-packaging exception for biosimilars when its reference product is separately paid to remove the financial incentives for providers to select a more expensive biological. We believe there are merits to our proposal to package biosimilars when their reference product's per day cost is below the drug packaging threshold and payment for the reference product is packaged. We believe this corresponding policy proposal would also remove the financial incentive to use the more expensive biologic, in this scenario, the biosimilar(s) (the more

[151] *https://purplebooksearch.fda.gov/results?query=filgrastim&title=Zarxio.*

expensive and separately paid product) when its reference product falls below the packaging threshold. At the same time, we acknowledge that the scenario of the per day cost of a reference product falling below the packaging threshold while the per day cost of a biosimilar remains above the packaging threshold has not yet occurred. For this reason, for CY 2024, we are not finalizing our proposal to package biosimilar(s) when their related reference product's per day cost is below the drug packaging threshold and payment for the reference product is packaged. We will continue to monitor Part B drug utilization and spending for biologicals and potentially revisit this issue in future rulemaking.

Comment: We received several comments requesting that the policy of excepting biosimilars from the OPPS drug packaging threshold be applied retroactively beginning with CY 2023. One commenter indicated that making this policy change retroactive to CY 2023 would support the continued use of biosimilars.

Response: Under the statute, retroactive rulemaking authority is reserved for certain special circumstances that do not apply here. We believe it would be inappropriate to apply our retroactive rulemaking authority under section 1871(e)(1)(A) of the Act in this case.

Comment: Some commenters recommended that CMS categorically exempt reference and biosimilar biological products from its threshold packaging policy. The commenters believed the threshold packaging policy imposes inflationary pressures on drug costs by incentivizing manufacturers to price their products above the packaging threshold and, as a result, incentivizing providers to switch to those products above the packaging threshold, which would be paid separately.

Response: We thank the commenters for their comment. We believe our threshold packaging policy encourages efficiency and is an essential component of a prospective payment system. However, we will continue to review new policy ideas that promote the use of biosimilars as a less expensive alternative to their reference products for future rulemaking.

Comment: One commenter stated the best policy is to treat biosimilars and their reference product similarly by either packaging all of them or paying separately for all of them. The commenter stated that if any one of the related products (a biosimilar or reference product) is below the packaging threshold, it would be appropriate to package all of them. Conversely, the commenter believed biosimilars and their reference products should be separately payable only if the per day costs of all of the products exceed the packaging threshold.

Response: We thank the commenter for their feedback. As mentioned above, we believe the threshold packaging exception for biosimilars when their reference products are separately paid is consistent with our broader policy intent to promote biosimilar use as a lower cost alternative to higher cost reference products. However, we will not finalize our proposal to package biosimilar(s) when their related reference product's per day cost is below the drug packaging threshold and payment for the reference product is packaged for CY 2024.

After consideration of the public comments we received, we are finalizing our proposal with modification. Specifically, we are finalizing the exception of biosimilars from the OPPS threshold packaging policy when their reference products are separately paid, meaning for CY 2024, we would pay separately for these biosimilars even if their per-day cost is below the threshold packaging policy. We believe creating a threshold-packaging exception for biosimilars when their reference products are separately paid will remove the financial incentive to use a more expensive separately payable biologic and preserve our policy intent to promote biosimilar use as a lower cost alternative to higher cost reference products. However, we believe our policy proposal to package biosimilar(s) when the reference product's per-day cost falls below the packaging threshold would be unnecessary at this time since this scenario has not yet occurred. We will examine the claims data, monitor Part B drug utilization and spending for biologics, and address this issue in future rulemaking if necessary.

(3) Comment Solicitation on Packaging Policy for Reference Products and Biosimilars

While we proposed to except biosimilars from the threshold packaging policy when their reference products are separately paid, we also solicited comment on the packaging of payment for a reference product *and* its biosimilar(s) into the payment for the associated service or procedure when the per-day cost of the reference product, *or* any of its biosimilar(s), is less than or equal to the applicable OPPS drug packaging threshold. While both our proposed policy and the policy described by this comment solicitation share the goal of consistent treatment of similar biologic products, the method to achieve that goal differs. Our proposed policy would result in biosimilars being paid separately if their reference product is paid separately, whereas here we sought comment on a policy that would result in packaged payment for a biologic if the reference product or any of its biosimilars have per day costs below the drug packaging threshold.

For example, for purposes of this comment solicitation, if a biosimilar's per-day cost is above the threshold and separately paid but its reference product is packaged, the biosimilar (and all its related biosimilar(s)) would be packaged.

Additionally, we sought comment on other ways to structure payment for biologicals and biosimilars that would encourage efficiency while maintaining beneficiary access.

Comment: Commenters generally opposed our comment solicitation to package payment for biosimilar(s) and the reference product when the per-day cost of any of the products fall below the packaging threshold.

Response: At this time, we are only finalizing our proposed policy to except biosimilars from the OPPS threshold-packaging policy when their reference products are separately paid, meaning that CMS will pay separately for these biosimilars even if their per-day cost falls below the cost threshold of the threshold-packaging policy. At this time, we are not implementing a policy that packages payment for reference products and biosimilars if the per-day cost of any product drops below the OPPS drug packaging threshold. It is important to note that we have not yet encountered a situation where the per-day cost of the reference product is below the packaging threshold and the per-day cost of biosimilar products is above the packaging threshold. CMS will continue to monitor payment and utilization patterns as well as overall Part B spending for biosimilars and their reference products and address any problematic pricing trends that may develop in future rulemaking.

Comment: MedPAC stated that if any one of the products (the biosimilar or reference product) is below the packaging threshold, they should all be treated similarly and packaged, and that biosimilar products and their reference product should be separately payable only if the cost of all of the products exceeds the packaging threshold.

Response: We thank MedPAC for their response to this comment solicitation. As mentioned above, we believe our final policy to except biosimilars from the OPPS threshold-packaging policy when their reference products are

separately paid will remove the financial incentive to use a more expensive separately payable biological. We believe this policy is consistent with broader agency goals of promoting biosimilars as a lower cost alternative to higher cost reference products.

Comment: One commenter appreciated that we solicited comments on alternative methods to structure payments for biosimilars. The commenter noted that the current ASP-based payment methodology for biosimilars has resulted in declining provider reimbursement that may disincentivize use of these products.

Response: We thank the commenter for sharing their concerns. We do not have any data to support the assertion that the current ASP-based payment methodology for biosimilars has resulted in declining provider reimbursement that may disincentivize provider use. We reiterate that the ACA requires the ASP add-on for biosimilars to be 6 percent of the reference product's ASP. Additionally, section 11403 of the IRA amended section 1847A(b)(8) of the Act by establishing a temporary payment limit increase for qualifying biosimilar biological products of ASP plus 8 percent of the reference product's ASP rather than 6 percent during the applicable 5-year period. Consistent with these authorities and with the policy we are finalizing to except biosimilars from the threshold packaging policy when their reference products are separately paid, we seek to promote the use of biosimilars as a less expensive alternative to their reference products, to provide more options to patients and physicians, and to encourage competition to provide a robust and comprehensive selection of choices for patients at a fair price.

Comment: One commenter urged CMS to work with stakeholders to develop new payment approaches for Part B biosimilars to ensure sustainability.

Response: We thank the commenter, and we believe in a strong working relationship with the interested parties on Part B issues. We continue to believe that biosimilars are a less expensive alternative to their reference products. For CY 2016 and CY 2017, we finalized a policy to provide for the separate coding and payment for products approved under each individual abbreviated application, rather than grouping all biosimilars with a common reference product into codes (80 FR 70445 and 70446 and 81 FR 79674). Additionally, as required by section 11403, we established a temporary payment limit increase for qualifying biosimilar biological products of ASP plus 8 percent of the reference product's ASP rather than 6 percent during the applicable 5-year period. We believe that these policies together will encourage greater manufacturer participation in the marketplace and the introduction of more biosimilar products, thus driving competition and providing savings in the long term.

Comment: One commenter urged CMS to consider how the Agency can encourage other payers to similarly promote biosimilars.

Response: We thank the commenter, but we note this comment is out of scope for this final rule.

We thank commenters for their valuable feedback, and we will continue to explore policy ideas to increase healthcare efficiency and promote biosimilar use in future rulemaking.

3. Payment Policy for Therapeutic Radiopharmaceuticals

In the CY 2023 OPPS/ASC final rule with comment period, we adopted as final our proposal to continue our longstanding payment policy for therapeutic radiopharmaceuticals for CY 2023 and subsequent years. Accordingly, this payment policy for therapeutic radiopharmaceuticals continues to apply in CY 2024. We pay for separately payable therapeutic radiopharmaceuticals under the ASP methodology adopted for separately payable drugs and biologicals. If ASP methodology (ASP, WAC, and AWP) information is unavailable for a therapeutic radiopharmaceutical, we base therapeutic radiopharmaceutical payment on mean unit cost data derived from hospital claims. The rationale outlined in the CY 2010 OPPS/ASC final rule with comment period (74 FR 60524 and 60525) for applying the principles of separately payable drug pricing to therapeutic radiopharmaceuticals continues to be appropriate for nonpass-through, separately payable therapeutic radiopharmaceuticals. Therefore, we are paying for all nonpass-through, separately payable therapeutic radiopharmaceuticals at ASP plus 6 percent (or applicable WAC or AWP amount) 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 and 60521).

Consistent with the policy we adopted for CY 2023 and subsequent years, for CY 2024, we will rely on the most recently available mean unit cost data derived from hospital claims data for payment rates for therapeutic radiopharmaceuticals for which ASP methodology (ASP, WAC, and AWP) 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 methodology (ASP, WAC, and AWP) 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 2024 payment rates for nonpass-through, separately payable therapeutic radiopharmaceuticals are included in Addenda A and B of the CY 2024 OPPS/ASC proposed rule (which are available on the CMS website).[152]

We did not receive any public comments on our payment policy for therapeutic radiopharmaceuticals or our proposed CY 2024 final payment rates for nonpass-through, separately payable therapeutic radiopharmaceuticals, and we are finalizing our proposed rates without modification.

4. Payment for Blood Clotting Factors

For CY 2023, 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 (87 FR 71969 and 71970). That is, for CY 2023, we provided payment for blood clotting factors under the OPPS at ASP plus 6 percent, plus an additional payment for the furnishing fee. We note that when blood clotting factors are provided in physicians' offices or other settings for which Medicare makes payment under Part B, a furnishing fee is also applied to the payment. The CY 2023 updated furnishing fee was $0.250 per unit.

In the CY 2023 OPPS/ASC final rule with comment period, we adopted as final for CY 2023 and subsequent years a policy to pay for blood clotting factors at ASP plus 6 percent, consistent with our payment policy for other nonpass-through, separately payable drugs and biologicals, and to pay an updated furnishing fee. Our policy to pay a furnishing fee for blood clotting factors under the OPPS is consistent with the methodology applied in the physician's

[152] *https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient.*

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 will 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: *https://www.cms.gov/medicare/payment/fee-for-service-providers/part-b-drugs/average-drug-sales-price.*

We did not receive any public comments on our proposed payment policy for blood clotting factors and are finalizing our proposal without modification. For CY 2024, we will continue to pay for blood clotting factors using the same methodology as other separately payable drugs and biologicals under the OPPS and will continue to pay 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

In the CY 2023 OPPS/ASC final rule with comment period, we adopted as final our proposal to continue our longstanding payment policy for nonpass-through drugs, biologicals, and radiopharmaceuticals with HCPCS codes but without OPPS hospital claims data for CY 2023 and subsequent years. Therefore, for CY 2024, this policy will continue to apply. 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 and 70443). Consistent with our policy, because we have no claims data and must determine if these products exceed the per-day cost threshold, we estimated the average number of units of each product that would typically be furnished to a patient during one day in the hospital outpatient setting and utilized the ASP methodology to determine whether their payment will be packaged as well as their payment status indicators. We refer readers to Table 94 below for the final CY 2024 status indicator for each of the nonpass-through drugs, biologicals, and radiopharmaceuticals with HCPCS codes but without OPPS hospital claims data, which are also listed in Addendum B to this rule on the CMS website.[153]

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[153] *https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient.*

TABLE 94: DRUGS AND BIOLOGICALS WITHOUT OPPS CLAIMS DATA

CY 2024 HCPCS Code	CY 2024 Long Descriptor	Final CY 2024 Status Indicator	Final CY 2024 APC
90378	Respiratory syncytial virus monoclonal antibody, recombinant, for intramuscular use, 50 mg, each	K	9003
A9604	Samarium SM-153 lexidronam, therapeutic, per treatment dose, up to 150 millicuries	K	1295
C9488	Injection, conivaptan hydrochloride, 1 mg	K	9488
J0470	injection, dimercaprol, per 100 mg	K	9039
J0691	Injection, lefamulin, 1 mg	E2	
J0800	injection, corticotropin, up to 40 units	D	
J0879	Injection, difelikefalin, 0.1 microgram, (for esrd on dialysis)	N	
J1426	Injection, casimersen, 10 mg	G	9412
J1427	Injection, viltolarsen, 10 mg	K	9386
J1429	Injection, golodirsen, 10 mg	K	9356
J1458	injection, galsulfase, per 5 mg	K	9224
J1551	Injection, immune globulin (cutaquig), 100 mg	K	9007
J1554	Injection, immune globulin (asceniv), 500 mg	K	9392
J1632	Injection, brexanolone, 1mg	K	9333
J1951	Injection, leuprolide acetate for depot suspension (fensolvi), 1 mg	K	9419
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)	K	9197
J3485	injection, zidovudine, 10 mg	N	
J7181	Factor XIII (antihemophilic factor, recombinant), Tretten, per i.u.	K	1746

J7203	Injection factor ix, (antihemophilic factor, recombinant), glycopegylated, (rebinyn), 1 iu	K	9468
J7332	Hyaluronan or derivative, triluron, for intra-articular injection, 1 mg	K	9338
J8705	Topotecan, oral, 0.25 mg	K	1238
J9019	Injection, asparaginase (erwinaze), 1,000 iu	K	9289
J9210	Injection, emapalumab-lzsg, 1 mg	K	9310
J9348	Injection, naxitamab-gqgk, 1 mg	G	9408
Q0222	Injection, bebtelovimab, 175 mg	K	9401
Q2041	Axicabtagene ciloleucel, up to 200 million autologous anti-cd19 car positive viable t cells, including leukapheresis and dose preparation procedures, per therapeutic dose	K	9035
Q2053	Brexucabtagene autoleucel, up to 200 million autologous anti-cd19 car positive viable t cells, including leukapheresis and dose preparation procedures, per therapeutic dose	K	9391
Q2055	Idecabtagene vicleucel, up to 460 million autologous b-cell maturation antigen (bcma) directed car-positive t cells, including leukapheresis and dose preparation procedures, per therapeutic dose	G	9422

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We did not receive any specific public comments regarding our payment for non-pass-through drugs, biologicals, and radiopharmaceuticals with HCPCS codes but without OPPS hospital claims data. For CY 2024, we will continue to assign drug or biological products status indicator ''K'' and pay for these products separately for the remainder of CY 2024 if pricing information becomes available. The CY 2024 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 final rule with comment period, which is available on the CMS website.

6. OPPS Payment Methodology for 340B Purchased Drugs and Biologicals

a. Overview

Under the OPPS, we generally set payment rates for separately payable drugs and biologicals under section 1833(t)(14)(A) of the Act. Section 1833(t)(14)(A)(iii)(II) of the Act provides that, if hospital acquisition cost data is not available, the payment amount is the average price for the drug in a year established under section 1842(o) of the Act, which cross-references section 1847A of the Act, which generally sets a default rate of ASP plus 6 percent for certain drugs and biologicals. The provision also provides that the average price for the drug or biological in the year as established under section 1847A of the Act is calculated and adjusted by the Secretary as necessary for purposes of paragraph (14). 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 and biologicals, which was based on findings of the GAO [154] and MedPAC [155] that 340B hospitals were acquiring drugs and biologicals at a significant discount under HRSA's 340B Drug Pricing Program. We direct readers to the CY 2018 OPPS/ASC final rule with comment period for a more detailed discussion of the 340B drug payment policy (82 FR 52493 through 52511).

This policy has been the subject of extensive litigation, including before the Supreme Court of the United States. On June 15, 2022, the Supreme Court held in *American Hospital Association* v. *Becerra,* 142 S. Ct. 1896, that if CMS has not conducted a survey of hospitals' acquisition costs, it may not vary the payment rates for outpatient prescription drugs by hospital group. While the Supreme Court's decision addressed payment rates for CYs 2018 and 2019, it had implications for subsequent payment rates. Therefore, for CY 2023, we finalized a policy to revert to the default payment rate, which is generally ASP plus 6 percent, for 340B acquired drugs and biologicals and finalized a policy to pay for 340B

[154] Government Accountability Office. ''Medicare Part B Drugs: ''Action Needed to Reduce Financial Incentives to Prescribe 340B Drugs at Participating Hospitals.'' June 2015. Available at *https://www.gao.gov/assets/gao-15-442.pdf.*

[155] Medicare Payment Advisory Commission. March 2016 Report to the Congress: Medicare Payment Policy. March 2016. Available at Medicare Payment Advisory Commission. March 2016 Report to the Congress: Medicare Payment Policy. March 2016. Available at *https://www.medpac.gov/document/http-www-medpac-gov-docs-default-source-reports-may-2015-report-to-the-congress-overview-of-the-340b-drug-pricing-program-pdf/.*

acquired drugs and biologicals no differently than we pay for drugs and biologicals that are not acquired through the 340B program. We also finalized a budget neutrality adjustment to the CY 2023 OPPS conversion factor of 0.9691 percent rather than the 0.9596 percent adjustment we had proposed. This adjustment offset the prior increase of 3.19 percent that was applied to the conversion factor when we implemented the 340B payment policy in CY 2018 in a budget neutral manner and ensured the CY 2023 conversion factor was equivalent to the conversion factor that would be in place if the 340B drug payment policy had never been implemented.

After the publication of the proposed CY 2023 OPPS rule, on September 28, 2022, the District Court issued a final judgment vacating the 340B reimbursement rate for the remainder of 2022, which the District Court explained would automatically reestablish the default rate for 340B-acquired drugs and biologicals. The agency took the necessary steps, including issuing instructions to Medicare contractors and updating drug payment files, to implement that September 28, 2022, decision and has since paid the default rate, which is generally ASP plus 6 percent, for 340B acquired drugs and biologicals.[156]

Comment: Many commenters supported our proposal to continue to pay a rate of ASP plus 6 percent, or equivalent, for 340B-acquired drugs and biologicals. Several commenters acknowledged the benefit of the 340B program for their particular hospital and reiterated their belief that CMS should maintain the same payment rate for 340B-acquired drugs and those drugs not acquired through the 340B program. When explaining the benefit of the 340B program, one commenter asked CMS to work with HRSA, Congress, and others to protect the 340B program.

Response: We thank commenters for their support. We note that the 340B Drug Pricing Program is a program administered by HRSA and comments regarding its administration are outside the scope of this final rule with comment period.

Comment: Some commenters believed that CMS should not continue the increased ASP plus 6 percent payment rate for 340B-acquired drugs. These commenters believed that this would increase out-of-pocket costs for beneficiaries for these drugs and were concerned about the benefit of the 340B drug pricing program to vulnerable patients. One commenter spoke about the perverse incentive that the significant difference between 340B drug acquisition costs and the Medicare payment rate creates. The commenter was concerned that this incentive could further exacerbate the issue of increased drug spending and drug prices. Several commenters encouraged CMS to take appropriate steps to curtail payments that are significantly greater than the rate at which hospitals acquire 340B drugs and noted that a survey of hospital acquisition costs could help CMS achieve significant drug savings. Similarly, one commenter believed that CMS's proposed policy would be paying hospitals close to 50 percent more than their 340B drug acquisitions costs and that CMS has already determined that a generous reimbursement rate for 340B-acquired drugs would be ASP minus 28.7 percent per a previous drug acquisition cost survey. This commenter was concerned that CMS was ignoring the Supreme Court ruling that, in their view, stated that the CMS could vary reimbursement rates based on survey data and that payment rates based on ASP plus 6 percent were arbitrary. There were also concerns from this commenter that CMS violated the Administrative Procedure Act by not acknowledging and using this survey data to inform payment rates.

Response: We thank the commenters for their viewpoints expressed here and for their suggestions regarding drug cost surveys. For CY 2024, we are continuing our policy to apply to longstanding payment methodologies for 340B-acquired drugs that existed prior to CY 2018. In the CY 2021 OPPS/ASC final rule with comment period, we adopted as final our proposal to continue the Medicare payment policy for 340B drugs in place at that time (that is, the policy to pay a general rate of ASP minus 22.5 percent), rather than finalizing our alternative proposal to pay for 340B drugs at a rate of ASP minus 28.7 percent based on survey data (86 FR 63646 through 63648). We stated that while we believed our methods to conduct the 340B drug acquisition cost survey referenced in that rule, as well as the methodology we used to calculate the proposed average or typical discount received by 340B entities on 340B drugs, were valid, we nonetheless recognized that we received many comments on that survey from stakeholders. We noted that using survey data is complex, and we emphasized that we wished to continue to evaluate how to balance and weigh the use of survey data, the necessary adjustments to the data, and the weighting and incorporation of ceiling prices—all to determine how best to take the relevant factors into account for potentially using the survey to set Medicare OPPS drug payment policy (86 FR 63646). Since the CY 2021 OPPS/ASC final rule with comment period was issued, the Supreme Court held that because CMS had not conducted a survey of hospitals' acquisition costs, it could not vary the payment rates for outpatient prescription drugs by hospital group. *See Am. Hosp. Ass'n* v. *Becerra,* 142 S. Ct. 1896, 1906 (2022). We are concerned that using data from the 2020 survey, which surveyed only 340B hospitals, might not comport with the Supreme Court's decision.

We are also mindful of the burden surveys place on hospitals and CMS, should we decide to conduct an updated survey. The survey we previously conducted was just a survey of 340B hospitals; we did not conduct a survey of additional hospital groups at that time. And while that more limited survey placed a certain burden on 340B providers (a comment we received at the time), a survey of all hospital groups would be a much larger, more complex endeavor. According to the GAO hospitals survey in 2005, surveys may be useful on occasion to validate ratesetting data CMS receives, such as ASP. However, they also create significant work for hospitals and CMS as the data collector. For these reasons, GAO recommended that CMS survey hospitals only occasionally to validate hospital acquisition costs. We are mindful of these concerns but will take the commenters' feedback regarding a survey of hospital drug acquisition costs into consideration as we consider potential future rulemaking.

After a consideration of comments received, for CY 2024, we are finalizing the general payment rate of ASP plus 6 percent as the default payment rate for drugs and biologicals acquired under the 340B program and will pay for these drugs and biologicals no differently than we pay for those drugs and biologicals that are not acquired under the 340B program.

We note that many commenters also referenced the 340B Remedy proposed rule (88 FR 44078) in their comments. We note that these comments were out of scope for purposes of this CY 2024 OPPS/ASC final rule with comment period; however, the 340B Remedy final rule publishes in the **Federal Register** of November 8, 2023 (FR Doc. 2023–24407), and the summaries of and our responses to the public comments can be found on the CMS OPPS website.[157]

[156] Vacating Differential Payment Rate for 340B-Acquired Drugs in 2022 Outpatient Prospective Payment System Final Rule with Comment Period. *https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient.*

b. Payment for 340B Drugs and Biologicals in CYs 2018 Through 2022

For full descriptions of our OPPS payment policy for drugs and biologicals acquired under the 340B program beginning in CY 2018, 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 59015 through 59022); the CY 2021 OPPS/ASC final rule with comment period (85 FR 86042 through 86055); the CY 2022 OPPS/ASC final rule with comment period (86 FR 63640 through 63649); and the CY 2023 OPPS/ASC final rule with comment period (87 FR 71970 through 71976).

In July of 2023, CMS published a proposed rule, referred to as the ''remedy proposed rule'' to address the reduced payment amounts to 340B hospitals under the reimbursement rates in effect for CYs 2018 through 2022 and to comply with the statutory requirement to maintain budget neutrality under the OPPS. The remedy proposed rule does not propose changes to our CY 2024 OPPS drug payment policy or the CY 2024 OPPS conversion factor, but it does propose changes to the calculation of the OPPS conversion factor beginning in CY 2025. We believe our proposed remedy rule is consistent with the Supreme Court's decision in *American Hospital Association* and the District Court's remand order. We refer readers to the 340B Remedy proposed rule (88 FR 44078) for a full description of the proposed remedy policy as well as the 340B Remedy final rule.

c. CY 2024 Proposed 340B Drug Payment Policy

For CY 2024, consistent with our policy finalized for CY 2023, we proposed to continue to pay the statutory default rate, which is generally ASP plus 6 percent, for 340B acquired drugs and biologicals. The payment for 340B acquired drugs and biologicals will not differ from the payment rate for drugs and biologicals not acquired through the 340B program. We believe this policy is appropriate given the Supreme Court decision discussed previously.

In the CY 2023 OPPS/ASC final rule with comment period, we maintained the requirement that 340B hospitals report the ''JG'' (*Drug or biological acquired with 340B drug pricing program discount, reported for informational purposes*) or ''TB'' (*Drug or biological acquired with 340B drug pricing program discount, reported for informational purposes for select entities*) modifiers to identify drugs and biologicals acquired through the 340B Program for informational purposes (87 FR 71974). We explained that we believed maintaining both modifiers would reduce provider burden compared to shifting to a single modifier, as all providers can continue utilizing the modifier (either ''JG'' or ''TB'') that they had been using for the previous five calendar years. On December 20, 2022, we issued ''Part B Inflation Rebate Guidance: Use of 340B Modifiers,'' which, in accordance with section 1847A(i) of the Act, requires all 340B covered entities, including hospital-based and non-hospital-based entities, to report the applicable modifier for separately payable drugs and biologicals acquired through the 340B Program.[158] Section 1847A(i) of the Act, as added by the Inflation Reduction Act, requires the Secretary to establish a Part B inflation rebate by manufacturers of certain single source drugs and biologicals with prices increasing faster than the rate of inflation. Section 1847A(i)(3)(B)(ii)(I) of the Act specifically excludes units of drugs and biologicals for which the manufacturer provides a discount under the 340B program from the units of drugs and biologicals for which a manufacturer otherwise may have a Part B inflation rebate liability. Effective implementation of the Part B inflation rebate requires CMS to identify units of drugs and biologicals acquired through the 340B Program so they can be subtracted from the total number of otherwise rebatable units as applicable. This guidance explained that the ''JG'' and ''TB'' modifiers provide an existing mechanism to identify drugs and biologicals acquired through the 340B Program that is familiar to most 340B covered entities paid under the OPPS, and stated that it did not change the requirements in the CY 2023 OPPS/ASC final rule with comment period (*i.e.,* that 340B covered entity hospitals should continue to use the modifiers they used previously to identify 340B drugs and biologicals). For claims with dates of service beginning no later than January 1, 2024, the guidance instructed all 340B covered entities to report the appropriate modifier, including those not currently reporting the ''JG'' or ''TB'' modifier, such as Ryan White clinics and hemophilia clinics, which should report the ''JG'' modifier on separately payable Part B claim lines for drugs and biologicals acquired through the 340B Program.

Although we stated in the CY 2023 OPPS/ASC final rule with comment period and in the ''Part B Inflation Rebate Guidance: Use of 340B Modifiers'' that hospital-based 340B covered entities should continue to use the modifier they used previously (either the ''JG'' or ''TB'' modifier), we now believe utilizing a single modifier will allow for greater simplicity, especially because both modifiers are used for the same purpose: to identify separately payable drugs and biologicals acquired under the 340B Program. Requiring hospitals to report a single modifier would allow CMS to continue to identify and exclude 340B-acquired drugs and biologicals from the definition of units for the purpose of Part B inflation rebate liability, while eliminating the need to use two modifiers for the same purpose. Additionally, we believed the proposal would lessen the burden on providers as they would only have to report one modifier for all scenarios in which a 340B drug is acquired. Accordingly, we proposed that all 340B covered entity hospitals paid under the OPPS would report the ''TB'' modifier effective January 1, 2025, even if the hospital previously reported the ''JG'' modifier.

The ''JG'' modifier would remain effective through December 31, 2024. Hospitals that currently report the ''JG'' modifier could choose to continue to use it in CY 2024 or choose to transition to use of the ''TB'' modifier during that year. Beginning on January 1, 2025, the ''JG'' modifier would be deleted, and hospitals would be required to report drugs and biologicals acquired through the 340B program using the ''TB'' modifier. Additionally, beginning January 1, 2025, we would revise the ''TB'' modifier descriptor (*Drug or biological acquired with 340B drug pricing program discount, reported for informational purposes for select entities*) to no longer include ''. . .*for select entities*'' as all entities would report this modifier after this date. We noted that the proposal, if finalized, would update the December 20, 2022, guidance titled ''Part B Inflation Rebate Guidance: Use of the 340B Modifiers.''[159] Additionally, CMS plans to further update this guidance to align the modifier requirements for 340B covered entity providers and suppliers not paid under the OPPS with the modifier requirement changes for 340B covered entity hospitals paid under the OPPS.

For more information on the Medicare Part B inflation rebate program, please visit ''Inflation Rebates in Medicare'' at *https://www.cms.gov/inflation-*

[158] *https://www.cms.gov/files/document/part-b-inflation-rebate-guidance340b-modifierfinal.pdf.*

[159] *https://www.cms.gov/files/document/part-b-inflation-rebate-guidance340b-modifierfinal.pdf.*

reduction-act-and-medicare/inflation-rebates-medicare.

Comment: Commenters generally opposed the continued requirement to report the 340B modifiers, citing the administrative burden associated with the required reporting. Commenters believed CMS should abandon the requirement of any 340B modifiers after the Supreme Court decision that the 340B drug payment policy was unlawful.

Response: We thank the commenters for their feedback. We reiterate that the 340B modifier requirement is to identify and exclude 340B-acquired drugs and biologicals from the definition of units for the purpose of Part B inflation rebate liability. We note that the requirement for the 340B modifier(s) was not the subject of the Supreme Court 340B decision. We believe it is appropriate to consolidate the 340B modifier to a single modifier, which will allow for greater operational simplicity to achieve the IRA policy objective.

Comment: A commenter requested that CMS clarify the purpose for the continued requirement of a 340B modifier. The commenter stated the CY 2024 OPPS/ASC proposed rule on this subject is unclear if the only purpose of the modifier is for implementing the Inflation Reduction Act requirements related to Part B inflation rebates.

Response: We thank the commenter for their feedback. We reiterate the purpose of the 340B modifier requirement is to is to identify and exclude 340B-acquired drugs and biologicals from the definition of units for the purpose of Part B inflation rebate liability.

Comment: Commenters stated that the 340B modifier requirement presents a considerable administrative burden for 340B hospitals, demanding substantial staff time and resources. One commenter explained that hospital pharmacists devote significant time to determining if new drug codes require the 340B modifier. Once the drugs have been identified, the pharmacists must then communicate with other departments to ensure the drugs are properly coded and billed. This is in addition to the regular self-audits pharmacists perform. Some commenters stated that reporting only one 340B modifier could eventually be less burdensome (by reducing potential confusion) than the current two modifiers. However, they noted that hospitals currently billing with the ''JG'' modifier will still be required to change their processes and bill using the ''TB'' modifier by January 1, 2025, presenting an additional unnecessary administrative burden. The commenters stated it is not necessary for CMS to collect the information via the 340B modifier(s) in order to comply with the IRA and that CMS could exclude all drug claims with the status indicator ''K'' that are billed by 340B hospitals from the IRA rebate calculations as a less burdensome alternative.

Response: We thank commenters for their feedback. As mentioned above, we note that this continued requirement for the 340B modifier is to identify and exclude 340B-acquired drugs and biologicals from the Part B inflation rebate liability. Many 340B hospitals have been reporting the 340B modifiers since CY 2018, and many hospitals already report a modifier through their State Medicaid program. We believe that the continued requirement for a single 340B modifier on outpatient claims for 340B-acquired drugs would promote consistency between the two programs.

We disagree with commenters that CMS could accurately exclude 340B drugs from the IRA rebate calculation without imposing a burden on 340B providers. Some 340B covered entities provide healthcare services to both 340B and non-340B patients, and the payment status indicator ''K'' does not differentiate between340B and non-340B claims. Therefore, the 340B modifier is needed to identify 340B drugs.

Comment: Some commenters supported the requirement of a single 340B modifier and agreed a single modifier will simplify the identification of 340B drugs or biologicals and help support reducing duplicate discounts and diversion. They also stated that their study showed 340B participating rural referral centers and sole community centers reported only 61 percent of Part B separately payable products with the applicable 340B modifiers. The commenters noted that there is no penalty for 340B providers that choose not to comply with the policy and recommended that CMS establish a robust audit process with appropriate penalties to deter abuses of the 340B program. They also suggested CMS adopt a ''non-340B'' modifier to enhance enforcement of the policy to report the appropriate modifier, thereby reducing duplicate discounts and diversion.

Response: We thank the commenters for their feedback. We are not aware that covered entities are underreporting 340B claims. We note that some 340B covered entities often provide healthcare services to both 340B and non-340B patients, but it is their responsibility to submit accurate claims. Under the False Claims Act 31, U.S.C. 3729–3733, Medicare has the authority to fine providers who knowingly, willfully, and repeatedly bill inaccurately coded claims. Providers are required to maintain current knowledge of Medicare billing policies and to submit accurate claims. Providers are also required to maintain all documentation to support the validity of the services reported on the claim and ensure this information is available upon request.

We noted that we had received a similar suggestion for a ''non-340B'' modifier in the CY 2018 OPPS/ASC final rule with comment period (82 FR 52508 and 52509). We disagree with the commenters and as noted in the 2018 OPPS/ASC final rule with comment period, we believe a consistent application of the modifier being required for a drug that was purchased under the 340B Program instead of a drug not purchased under the 340B Program will help improve program integrity by helping ensure that hospitals are not receiving ''duplicate discounts'' through both the Medicaid rebate program and the 340B Program.

After consideration of the public comments we received, we are finalizing our proposal without modification to require that all 340B covered entity hospitals paid under the OPPS report the ''TB'' modifier effective January 1, 2025, even if the hospital previously reported the ''JG'' modifier, for 340B-acquired drugs and biologicals. We believe the transition to a single 340B modifier ''TB'' will allow for greater simplicity, especially because both modifiers are used for the same purpose to continue to identify and exclude 340B-acquired drugs and biologicals from the definition of units for the purpose of Part B inflation rebate liability. We believe this policy will reduce the burden on providers as they would only have to report one modifier for all scenarios in which a 340B drug is acquired. The ''JG'' modifier will remain effective through December 31, 2024. Hospitals that currently report the ''JG'' modifier may choose to continue to use it in CY 2024 or choose to transition to use of the ''TB'' modifier sooner, provided all hospitals are using the ''TB'' modifier by January 1, 2025.

7. 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, to ensure adequate resource homogeneity among APC assignments for the skin substitute application procedures (78 FR 74933). In the CY 2015 OPPS/ASC final rule with comment period (79 FR 66886), we stated that skin substitutes are best characterized as either surgical supplies or devices because of their required surgical application and because they share significant clinical similarity with other surgical devices and supplies.

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 2023, the payment rate for APC 5053 (Level 3 Skin Procedures) was $580.95, the payment rate for APC 5054 (Level 4 Skin Procedures) was $1,725.86, and the payment rate for APC 5055 (Level 5 Skin Procedures) was $3,253.04. This information is also available in Addenda A and B of the CY 2023 final rule with comment period (87 FR 71748) (Addenda A and B are available on the CMS website: *https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient/regulations-notices*).

We have continued the high-cost/low-cost categories policy since CY 2014, and we proposed to continue it for CY 2024. Under the 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 and 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 did not exceed either the MUC threshold or the PDC threshold to the low-cost group (87 FR 71976).

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 over $1,000 in the payment amount for the same procedure. In addition, these interested parties 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 interested parties requested that CMS consider alternatives to the current methodology used to calculate the MUC and PDC thresholds and 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 plus 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 interested parties 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 did 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). For more detailed information and discussion regarding the goals of this policy and the subsequent comment solicitations in CY 2019 and CY 2020 regarding possible alternative payment methodologies for graft skin substitute products, please refer to the CY 2018 OPPS/ASC final rule with comment period (82 FR 59347); the CY 2019 OPPS/ASC final rule with comment period (83 FR 58967 and 58968); and the CY 2020 OPPS/ASC final rule with comment period (84 FR 61328 through 61331).

b. Proposals for Packaged Skin Substitutes for CY 2024

For CY 2024, consistent with our policy since CY 2016, we proposed to continue to determine the high-cost/low-cost status for each skin substitute product based on either a product's geometric MUC exceeding the geometric MUC threshold or the product's PDC (the total units of a skin substitute multiplied by the MUC and divided by the total number of days) exceeding the PDC threshold. Consistent with the methodology as established in the CY 2014 OPPS/ASC through CY 2018 OPPS/ASC final rules with comment period, we analyzed CY 2022 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 2024 MUC threshold was $47 per cm² (rounded to the nearest $1) and the proposed CY 2024 PDC threshold was $817 (rounded to the nearest $1). Also, the availability of a 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 2024, as we did for CY 2023, we proposed to assign each skin substitute that exceeds either the MUC threshold or the PDC threshold to the high-cost group. In addition, we proposed to assign any skin substitute that does not exceed either the MUC threshold or the PDC threshold to the low-cost group except that we proposed that any skin substitute product that was assigned to the high-cost group in CY 2023 would be assigned to the high-cost group for CY 2024, regardless of whether it exceeds or falls below the CY 2024 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 2024, we proposed to continue to assign skin substitutes with pass-through payment status to the high-cost category. We proposed 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 plus 6 percent payment rate as compared to the MUC threshold. If ASP is not available, we proposed to use WAC plus 3 percent to assign a product to either the high-cost or low-cost category. Finally, if neither ASP nor WAC is available, we proposed to use 95 percent of AWP to assign a skin substitute to either the high-cost or low-cost category. We proposed to continue to use WAC plus 3 percent instead of WAC plus 6 percent to conform to our proposed policy described in section V.B.2.b of the CY 2024 OPPS/ASC proposed rule to establish a payment rate of WAC plus 3 percent for separately payable drugs and biologicals that do not have ASP data available. We proposed that any skin substitute product that is assigned a code in the HCPCS A2XXX series would be assigned to the high-cost skin substitute group including new products without pricing information. New skin substitutes without pricing information that are not assigned a code in the HCPCS A2XXX series would be assigned to the low-cost category until pricing information is available to compare to the CY 2024 MUC and PDC thresholds. For a discussion of our existing policy under which we assign skin substitutes without pricing information that are not assigned a code in the HCPCS A2XXX series 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).

Comment: The HOP Panel recommended, and several commenters supported, ending the packaging of the graft skin substitute administration add-on codes (CPT codes 15272, 15274, 15276, and 15278; HCPCS codes C5272, C5274, C5276, and C5278). The HOP Panel and the commenters requested that these codes be assigned to APCs that reflect the estimated costs of these service codes. Commenters claim that packaging the graft skin substitute administration add-on codes eliminates the variation in payment for wound care treatments based on the size of the wound. They assert that providers are discouraged from treating wounds between 26 and 99 cm² and over 100 cm² in the outpatient hospital setting because of the financial losses they experience to provide such care. Commenters believe that packaging graft skin substitute administration add-on codes disrupts the methodology of how the American Medical Association (AMA), the organization that manages CPT service codes, intended graft skin substitute procedures to be paid. The CPT codes describe the actual amount of the graft skin substitute product that is used for an individual service when the amount of product used is 25 cm² or more. Commenters request that providers receive additive payment for the actual amount of skin substitute product used for the individual service as described by both the procedure code and the associated add-on code.

Response: We do not agree with the HOP Panel or the commenters that we should pay separately for graft skin substitute add-on codes under the OPPS. The OPPS is a prospective payment system and not a fee-for-service payment system. That means that we generally attempt to make one payment for all of the services billed with the primary medical procedure, including add-on procedures such as the ones described by CPT codes 15272, 15274, 15276, and 15278, and HCPCS codes C5272, C5274, C5276, and C5278.

More specifically, we calculate the OPPS payment rate by first calculating the geometric mean cost of the procedure. This calculation includes claims for individual services that used a lower level of resources and claims for individual services that used a higher level of resources. The resulting geometric mean cost will reflect the median service cost for a given medical procedure. Next, we group the medical procedure with other medical procedures with clinical and resource similarity in an APC and calculate the geometric mean of these related procedures to generate a base payment rate for all procedures assigned to the APC. Skin substitutes are surgical supplies and are packaged into the cost of the associated procedure. The application of graft skin substitutes cannot occur unless a graft skin substitute is used. So, the cost of the product will be reflected in the overall cost of the application procedure.

A prospective payment system like the OPPS is designed to pay providers the median cost of the primary service they provide, and such a system encourages efficiencies and cost-savings in the administration of health care. However, a prospective payment system is not intended to discourage providers from rendering medically necessary care to patients. For example, it is possible that a provider could experience a financial loss when they perform a service where a patient receives 85 cm² of a graft skin substitute product, but that same provider could see a financial gain when the next patient receives a skin graft where only 10 cm² of product is used. Paying separately for add-on codes for the administration of graft skin substitutes in a prospective payment system defeats the goals of such a payment system. Therefore, we will continue to package the add-on codes for the administration of graft skin substitutes in the OPPS to encourage cost-savings and efficiencies with wound care treatment. If providers are paid at cost or nearly at cost for each individual service they render, there is no incentive for them to control costs. Add-on codes for the administration of graft skin substitutes should be packaged with the primary medical service to be able to establish a median payment rate that gives providers incentives to keep their costs in line with typical providers throughout the Medicare program. The need for cost efficiencies in the application of graft skin substitutes to treat wounds is no different than need for cost efficiencies in other procedures administered in the outpatient hospital setting. Therefore, we believe that add-on codes, including the add-on codes for the administration

of graft skin substitutes, should remain packaged to maintain the integrity of the OPPS.

Comment: The HOP Panel recommended, and several commenters supported, ensuring that the payment rate for graft skin substitute procedures be the same no matter where on the body the graft skin substitute product is applied to the patient. There are four graft skin substitute application procedures for high-cost skin substitute products (CPT codes 15271, 15273, 15275, and 15277) and a similar four graft skin substitute application procedures for low-cost skin substitute products (HCPCS codes C5271, C5273, C5275, and C5277). Commenters claim that the cost to apply graft skin substitute products does not depend on the location of the wound because the same amount of product is used on the wound and the same clinical resources are used to treat the wound independent of the location of the wound.

Other commenters made a similar request, asking that CPT code 15277 (Application of skin substitute graft to face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet, and/or multiple digits, total wound surface area greater than or equal to 100 sq cm; first 100 sq cm wound surface area, or 1 percent of body area of infants and children) that is currently assigned to APC 5054 (Level 4 Skin Procedures) be reassigned to APC 5055 (Level 5 Skin Procedures). That would mean that the two graft skin substitute application procedures for the application of high-cost skin substitute products for wounds greater than 100 cm^2 (CPT code 15273 and 15277) would be in the same APC.

Response: The reason there are four CPT codes describing graft skin substitute application services is that there are different CPT codes for applying graft skin substitutes for wounds up to 100 cm^2 and for wounds that are greater than 100 cm^2; and there are different CPT codes for applying graft skin substitutes to the trunk, arms, and legs as compared to the face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet, fingers, and toes. We appreciate commenters' concerns and note that current codes describing the application of high-cost graft skin substitutes for wounds less than 100 cm^2 (CPT codes 15271 and 15275) have been assigned to the same APC (5054), and the current codes describing the application of low-cost graft skin substitutes for wounds less than 100 cm^2 (HCPCS codes C5271 and C5275) have been assigned to the same APC (5053). Because they are currently included in the same APC, the OPPS payment for them is the same; and this payment policy is consistent with the recommendation from the HOP Panel and other commenters. This means for the application of graft skin substitute products up to 100 cm^2, the location where the graft skin substitute is applied does not affect the payment rate for the service. We note that the code describing the application of high-cost products for wounds that are greater than 100 cm^2 on the trunk, arms, and legs (CPT code 15273) has been assigned to a higher-paying APC (APC 5055) than the APC assignment for the code describing the application of high-cost graft skin substitute products for wounds greater than 100 cm^2 on the face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hand, feet, fingers, and toes (CPT code 15277), which is assigned to APC 5054. Likewise, the code describing the application of low-cost products for wounds that are greater than 100 cm^2 on the trunk, arms, and legs (HCPCS code C5273) has been assigned to a higher-paying APC (APC 5054) than the code for the application of low-cost graft skin substitute products for wounds greater than 100 cm^2 on the face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hand, feet, fingers, and toes (HCPCS code C5277), which is assigned to APC 5054. The differences in costs that have determined APC assignments for these services for wounds greater than 100 cm^2 have been supported by historical cost data. We also note that none of these service codes are in violation of the 2 times rule, which requires that the geometric mean cost of significant items and services within an APC group to be no more than two-times the geometric mean cost of the lowest geometric mean cost for a significant item or service within the same APC group.

Comment: The HOP Panel recommended, and several commenters supported, having us realign both the high-cost and low-cost application procedure codes to potentially higher-paying APC groups that reflect the current average sales prices of graft skin substitute products as manufacturers now are required to submit average sales prices for graft skin substitute products. Commenters believe combining ASP prices for graft skin substitutes and the cost of the graft skin substitute application procedures would better reflect the costs of those procedures than our current methodology of using cost data from claims to assign application procedures to APCs. Commenters believe that the product cost information that is packaged into the graft skin substitute application procedures is lower than the ASP price for graft skin substitute products and leads to the graft skin substitute application procedures being assigned APCs with lower payment rates than the actual cost of the procedures. Commenters feel that this approach also may provide more cost stability to the APC assignments for the graft skin substitute application procedures.

Response: We disagree with the commenters that using ASP pricing instead of using claims cost data would be a preferrable method for estimating the graft skin substitute product cost of graft skin substitute application procedures. It is unclear from the commenters' suggestion how the product cost of the graft skin substitute would be calculated if not using the charges reported by providers. Presumably, their approach would involve extracting the units of graft skin substitute product used on a particular packaged service and then multiplying by an ASP on file to revise the cost of packaged procedure to reflect the ASP price of the graft skin substitute product units. We do not believe this is a feasible approach for CY 2024, and it appears to be a different approach to pricing one group of packaged supplies as compared to how all other packaged supplies are priced in the OPPS. We normally use a provider's reported charges for supplies and use the appropriate cost-to-charge ratio to estimate the contribution of the supply cost to the overall cost of the procedure. However, we remain open to new payment methodologies. We welcome feedback from interested parties in future rulemaking about how this payment approach could work and why it would improve the pricing of graft skin substitute application procedures.

Comment: Two commenters asked that we eliminate the high-cost and low-cost skin substitute groups for graft skin substitute products. Instead, the commenter requested that we no longer policy package skin substitute products in the OPPS. The commenter suggested we should pay for graft skin substitutes separate from the application procedure based on their ASP plus 6 percent price where available.

Response: A substantial portion of the cost of a skin substitute graft application procedure is the graft skin substitute product itself, and the cost of the skin substitute graft products is reflected in the cost of the overall procedure. Packaging the cost of graft skin substitute products into the affiliated procedures leads to cost savings and efficiencies in the use of graft skin substitute products. Providers have the opportunity to assess the value of products of varying costs. The payment

rates for the application procedures for graft skin substitute products reflect the decisions of providers across the United States between the costs and benefits of all available products and should limit the use of the highest-cost graft skin substitute products over lower-cost products unless the highest-cost products are found to be clinically superior. Packaging of graft skin substitute products helps to reduce costs for graft skin substitute procedures and allows more Medicare resources to be used for other categories of medical services.

Comment: The HOP Panel recommended, and several commenters supported, that all new graft skin substitute products be assigned to the low-cost group whether they have a Q-code or an A-code until cost data become available for the product. Commenters believe it is not appropriate that products assigned Q-codes are assigned to the low-cost group while products assigned A-codes are assigned to the high-cost group. Commenters note that A-codes are being assigned to graft skin substitute products that have FDA 510(k) clearance but are not synthetic products, which conflicts with the expectation that only graft skin substitute products that would have been described by the now-deleted HCPCS code C1849 (Skin substitute, synthetic, resorbable, per square centimeter) be assigned to the high-cost group. More broadly, commenters believed that no category of graft skin substitute products should be assigned to the high-cost group until there is cost data supporting that assignment.

Response: We appreciate the concerns of the commenters. However, we decided on an approach that would ensure that any graft skin substitute product that could potentially have been described by deleted HCPCS code C1849 be included in the high-cost group. As explained in the CY 2023 OPPS final rule (87 FR 71980 and 71981), we wanted to ensure that graft skin substitute products that were described by HCPCS code C1849 or could potentially be described by HCPCS code C1849 would be granted time to develop the cost data necessary to allow us to determine if the product should stay in the high-cost group, which provides stability for the payment of these graft skin substitute products. We wanted to avoid having products with less than two years of claims data that were originally in the high-cost group be reassigned to the low-cost group simply because of a lack of available data.

Also, as discussed in the CY 2023 OPPS final rule (87 FR 71981), the current categorization of skin substitutes as either synthetic or non-synthetic is not mutually exclusive given the expansion of skin substitute products that may contain both biological and synthetic elements. Having products with both biological and synthetic elements leads to difficulty defining which of the products assigned to the A2XXX series would be considered ''synthetic'' and described by HCPCS code C1849. Therefore, for CY 2023, we finalized a policy, which will continue for CY 2024, to assign to the high-cost group any skin substitute product that is assigned a code in the HCPCS A2XXX series including new products without pricing information. This policy gives the broadest definition of products that could have been described by HCPCS code C1849 and ensures that none of those graft skin substitute products would be assigned to the low-cost group until we receive cost data for them.

Comment: The HOP Panel recommended, and several commenters supported, our current policy not to assign graft skin substitute products that are not in sheet form (*e.g.,* gel, powder, ointment, foam, liquid, or injected) to any APC group, because these products cannot be reported with the graft skin substitute application codes of CPT codes 15271 through 15278 (the high-cost group) or with HCPCS codes C5271 through C5278 (the low-cost group). Commenters note that skin substitutes that are not in sheet form are used primarily for clinic visits and the debridement of chronic wounds. Also, according to the commenters, the use of skin substitutes that are not in sheet form does not conform to the AMA's directions for the application of skin substitute products.

Response: We appreciate the HOP Panel's and the commenters' support of our policy.

Comment: One commenter disagreed with the HOP Panel recommendation not to assign graft skin substitute products that are not in sheet form (*e.g.,* gel, powder, ointment, foam, liquid, or injected) to any APC group. The commenter understands that current coding guidelines for CPT codes 15271 through 15278 precludes products that are not in sheet form from being billed with these CPT codes. However, the commenter anticipates that in the future procedure codes for the application of non-sheet products will be created; and the commenter thinks it is best for us to prepare for the establishment of these new procedure codes.

Response: We appreciate the views of the commenter, but we did not make any proposals related to payment for application of non-sheet skin substitute products in this year's OPPS proposed rule. We may consider this topic for future rulemaking if CPT or HCPCS codes are established for the application of non-sheet skin substitute products.

Comment: Several commenters supported our current skin substitute payment policy to assign graft skin substitute products to either a high-cost or a low-cost group based on the product's cost. Likewise, commenters also supported our policy of keeping graft skin substitute products in the high-cost group once the cost of the product exceeds either the MUC or the PDC threshold for at least one year even if in future years the cost of the product is less than either the MUC or PDC threshold.

Response: We appreciate the commenters' support of our policies.

Comment: Manufacturers of two products that are not traditional graft skin substitute products requested that their products be assigned to either of the high-cost skin or low-cost skin substitute groups based on the cost of their products. One product is HCPCS code A2014 (Omeza collagen matrix, per 100 mg) that is an amorphous solid, which, according to its manufacturer, Omeza, is used to treat wounds similar to the wounds treated by graft skin substitute products. The second product is HCPCS code A2025 (Miro3d, per cubic centimeter) that is a dry, thick sheet of uncompressed decellularized porcine liver that has enough thickness for its base unit to be a cubic centimeter. According to its manufacturer, Reprise Biomedical, Miro3d must be rehydrated before being applied.

Response: We do not believe either HCPCS code A2014 (Omeza collagen matrix, per 100 mg) or HCPCS code A2025 (Miro3d, per cubic centimeter) should be assigned to either the high-cost or low-cost group. Regarding Omeza collagen matrix, an amorphous solid is not a graft skin substitute product even if the product forms a sheet-like layer after application. Therefore, we cannot assign the product to either the high-cost skin or the low-cost skin substitute group. For Miro3d, normally a product with a base unit of cubic centimeter is a liquid product. This is the first product with a base unit of a cubic centimeter that we are aware of to be in solid form. We request further information regarding this product to help us to determine whether Miro3d should be assigned to the high-cost or low-cost skin substitute group in a future OPPS quarterly update, including whether the product could be reported with either CPT codes 15271

through 15278 or HCPCS codes C5271 through C5278.

Comment: The manufacturer of the product described by HCPCS code Q4278 (Epieffect, per square centimeter) requested that the product be assigned to the high-cost skin substitute group based on its ASP as reported in a pricing compendium.

Response: We request that the manufacturer provide us with the pricing information that they have cited regarding HCPCS code Q4278. Once we receive this information, we will determine if HCPCS code Q4278 should be assigned to the high-cost group.

Comment: The manufacturer of the products described by HCPCS codes Q4122 (Dermacell, dermacell awm or dermacell awm porous, per square centimeter) and Q4150 (Allowrap dds or dry, per square centimeter) requested that these graft skin substitute products continue to be assigned to the high-cost skin substitute group for CY 2024.

Response: Based on their cost data and our policies, both HCPCS codes Q4122 (Dermacell, dermacell awm or dermacell awm porous, per square centimeter) and Q4150 (Allowrap dds or dry, per square centimeter) will remain in the high-cost group for CY 2024.

After consideration of the public comments we received, we are adopting our proposals without modification. Our final policies are to:

- Continue assign skin substitutes with pass-through payment status to the high-cost category.
- 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 plus 6 percent payment rate as compared to the MUC threshold. If ASP is not available for the product, we will use WAC plus 3 percent to assign a product to either the high-cost or low-cost category. Finally, if neither ASP nor WAC is available, we will use 95 percent of AWP to assign a skin substitute to either the high-cost or low-cost category.
- Continue to use WAC plus 3 percent instead of WAC plus 6 percent to conform to our policy described in section V.B.2.b of this final rule with comment period to establish a payment rate of WAC plus 3 percent for separately payable drugs and biologicals that do not have ASP data available.
- Assign any skin substitute product that is assigned a code in the HCPCS A2XXX series to the high-cost skin substitute group, including new products without pricing information. New skin substitutes without pricing information that are not assigned a code in the HCPCS A2XXX series would be assigned to the low-cost category until pricing information is available to compare to the CY 2024 MUC and PDC thresholds.

Finally, we have updated the MUC and PDC thresholds for CY 2024. The final MUC threshold will be $47 per cm^2 (rounded to the nearest $1) and the final PDC threshold will be $807 (rounded to the nearest $1). Table 95 includes the final CY 2024 cost category assignment for each skin substitute product.

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TABLE 95: SKIN SUBSTITUTE ASSIGNMENTS TO HIGH-COST AND LOW-COST GROUPS FOR CY 2024

CY 2024 HCPCS Code	CY 2024 Short Descriptor	CY 2023 High/Low Cost Assignment	CY 2024 High/Low Cost Assignment
A2001	Innovamatrix ac, per sq cm	High	High
A2002	Mirragen adv wnd mat per sq	High	High
A2005	Microlyte matrix, per sq cm	High	High
A2006	Novosorb synpath per sq cm	High	High
A2007	Restrata, per sq cm	High	High
A2008	Theragenesis, per sq cm	High	High
A2009	Symphony, per sq cm	High	High
A2010	Apis, per square centimeter	High	High
A2011	Supra sdrm, per sq cm	High	High
A2012	Suprathel, per sq cm	High	High
A2013	Innovamatrix fs, per sq cm	High	High
A2015	Phoenix wnd mtrx, per sq cm	High	High
A2016	Permeaderm b, per sq cm	High	High
A2017	Permeaderm glove, each	High	High
A2018	Permeaderm c, per sq cm	High	High
A2019	kerecis marigen shld sq cm	High	High
A2020	ac5 wound system	High	High
A2021	neomatrix per sq cm	High	High
A2022	Innovabrn/innovamatx xl sqcm	High	High
A2024	Resolve matrix per sq cm	High	High
A4100	Skin sub fda clrd as dev nos	Low	Low
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

CY 2024 HCPCS Code	CY 2024 Short Descriptor	CY 2023 High/Low Cost Assignment	CY 2024 High/Low Cost Assignment
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	High	High*
Q4135	Mediskin	Low	High
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
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	High	High
Q4169	Artacent wound, per sq cm	High	High
Q4170	Cygnus, per sq cm	High	High
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*

CY 2024 HCPCS Code	CY 2024 Short Descriptor	CY 2023 High/Low Cost Assignment	CY 2024 High/Low Cost Assignment
Q4180	Revita, per sq cm	High	High
Q4181	Amnio wound, per square cm	High	High
Q4182	Transcyte, per sq centimeter	High	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	High	High*
Q4190	Artacent ac 1 sq cm	High	High
Q4191	Restorigin 1 sq cm	High	High
Q4193	Coll-e-derm 1 sq cm	High	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	High	High
Q4199	Cygnus matrix, per sq cm	High	High
Q4200	Skin te 1 sq cm	High	High
Q4201	Matrion 1 sq cm	High	High
Q4203	Derma-gide, 1 sq cm	High	High
Q4204	Xwrap 1 sq cm	Low	Low
Q4205	Membrane graft or wrap sq cm	High	High
Q4208	Novafix per sq cm	High	High
Q4209	Surgraft per sq cm	High	High*
Q4210	Axolotl graf dualgraf sq cm	High	High
Q4211	Amnion bio or axobio sq cm	High	High
Q4214	Cellesta cord per sq cm	Low	Low
Q4216	Artacent cord per sq cm	Low	Low
Q4217	Woundfix biowound plus xplus	High	High
Q4218	Surgicord per sq cm	Low	High
Q4219	Surgigraft dual per sq cm	High	High*
Q4220	Bellacell HD, Surederm sq cm	Low	Low
Q4221	Amniowrap2 per sq cm	Low	High
Q4222	Progenamatrix, per sq cm	High	High*
Q4224	Hhf10-p per sq cm	Low	Low
Q4225	Amniobind, per sq cm	Low	Low
Q4226	Myown harv prep proc sq cm	High	High*
Q4227	Amniocore per sq cm	High	High
Q4228	Bionextpatch, per sq cm	Low	Low
Q4229	Cogenex amnio memb per sq cm	High	High*
Q4232	Corplex, per sq cm	High	High
Q4234	Xcellerate, per sq cm	High	High
Q4235	Amniorepair or altiply sq cm	High	High
Q4236	Carepatch per sq cm	Low	Low
Q4237	cryo-cord, per sq cm	High	High

CY 2024 HCPCS Code	CY 2024 Short Descriptor	CY 2023 High/Low Cost Assignment	CY 2024 High/Low Cost Assignment
Q4238	Derm-maxx, per sq cm	High	High
Q4239	Amnio-maxx or lite per sq cm	High	High
Q4247	Amniotext patch, per sq cm	Low	Low
Q4248	Dermacyte Amn mem allo sq cm	High	High
Q4249	Amniply, per sq cm	High	High
Q4250	AmnioAMP-MP per sq cm	Low	High
Q4253	Zenith amniotic membrane psc	Low	High
Q4254	Novafix dl per sq cm	High	High*
Q4255	Reguard, topical use per sq	Low	Low
Q4256	Mlg complet, per sq cm	Low	Low
Q4257	Relese, per sq cm	Low	Low
Q4258	Enverse, per sq cm	High	High*
Q4259	Celera per sq cm	Low	Low
Q4260	Signature apatch, per sq cm	Low	Low
Q4261	Tag, per square centimeter	Low	Low
Q4262	Dual layer impax, per sq cm	Low	Low
Q4263	Surgraft tl, per sq cm	Low	Low
Q4264	Cocoon membrane, per sq cm	Low	Low
Q4265	Neostim tl per sq cm	Low	Low
Q4266	Neostim per sq cm	Low	Low
Q4267	Neostim dl per sq cm	Low	Low
Q4268	Surgraft ft per sq cm	Low	Low
Q4269	Surgraft xt per sq cm	Low	Low
Q4270	Complete sl per sq cm	Low	Low
Q4271	Complete ft per sq cm	Low	Low
Q4272	Esano a, per sq cm	Low	Low
Q4273	Esano aaa, per sq cm	Low	Low
Q4274	Esano ac, per sq cm	Low	Low
Q4275	Esano aca, per sq cm	Low	Low
Q4276	Orion, per sq cm	Low	Low
Q4277	Woundplus e-grat, per sq cm	Low	Low
Q4278	Epieffect, per sq cm	Low	Low
Q4279	Vendaje ac, per sq cm	Low	Low
Q4280	Xcell amnio matrix per sq cm	Low	Low
Q4281	Barrera slor dl per sq cm	Low	Low
Q4282	Cygnus dual per sq cm	Low	Low
Q4283	Biovance tri or 3l, sq cm	Low	Low
Q4284	Dermabind sl, per sq cm	Low	Low
Q4285	Nudyn dl or dl mesh pr sq cm	Low	Low
Q4286	Nudyn sl or slw, per sq cm	Low	Low
Q4287	Dermabind dl, per sq cm	Low	Low
Q4288	Dermabind ch, per sq cm	Low	Low
Q4289	Revoshield+ amnio, per sq cm	Low	Low
Q4290	Membrane wrap hydr per sq cm	Low	Low
Q4291	Lamellas xt, per sq cm	Low	Low

CY 2024 HCPCS Code	CY 2024 Short Descriptor	CY 2023 High/Low Cost Assignment	CY 2024 High/Low Cost Assignment
Q4292	Lamellas, per sq cm	Low	Low
Q4293	Acesso dl, per sq cm	Low	Low
Q4294	Amnio quad-core, per sq cm	Low	Low
Q4295	Amnio tri-core, per sq cm	Low	Low
Q4296	Rebound matrix, per sq cm	Low	Low
Q4297	Emerge matrix, per sq cm	Low	Low
Q4298	Amnicore pro, per sq cm	Low	Low
Q4299	Amnicore pro+, per sq cm	Low	Low
Q4300	Acesso tl, per sq cm	Low	Low
Q4301	Activate matrix, per sq cm	Low	Low
Q4302	Complete aca, per sq cm	Low	Low
Q4303	Complete aa, per sq cm	Low	Low

* These products do not exceed either the MUC or PDC threshold for CY 2024 but are assigned to the high-cost group because they were assigned to the high-cost group in CY 2023.

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8. Radioisotopes Derived From Non-Highly Enriched Uranium (non-HEU) Sources

Radioisotopes are widely used in modern medical imaging, particularly for cardiac imaging and predominantly for the Medicare population. Some of the Technetium-99 (Tc-99m), the radioisotope used in the majority of such diagnostic imaging services, has been produced in legacy reactors outside of the United States using highly enriched uranium (HEU).

The United States wanted to eliminate domestic reliance on these reactors and has been promoting the conversion of all medical radioisotope production to non-HEU sources. Alternative methods for producing Tc-99m without HEU are technologically and economically viable, but it was expected that this change in the supply source for the radioisotope used for modern medical imaging would introduce new costs into the payment system that were not accounted for in the historical claims data.

Therefore, beginning in CY 2013, we finalized a policy to provide an additional payment of $10 for the marginal cost for radioisotopes produced by non-HEU sources (77 FR 68323). Under this policy, hospitals report HCPCS code Q9969 (Tc-99m from non-highly enriched uranium source, full cost recovery add-on per study dose) once per dose along with any diagnostic scan or scans furnished using Tc-99m as long as the Tc-99m doses used can be certified by the hospital to be at least 95 percent derived from non-HEU sources (77 FR 68323).

We stated in the CY 2013 OPPS/ASC final rule with comment period (77 FR 68321) that our expectation was that this additional payment would be needed for the duration of the industry's conversion to alternative methods of producing Tc-99m without HEU. We also stated that we would reassess, and propose, if necessary, on an annual basis whether such an adjustment continued to be necessary and whether any changes to the adjustment were warranted (77 FR 68321). A 2016 report from the National Academies of Sciences, Engineering, and Medicine anticipated the conversion of Tc-99m production from non-HEU sources would be completed at the end of 2019.[160] However, the Secretary of Energy issued a certification effective January 2, 2020, stating that there continued to be an insufficient global supply of molybdenum-99 (Mo-99), which is the source of Tc-99m, produced without the use of HEU, available to satisfy the domestic U.S. market (85 FR 3362). The January 2, 2020, certification was to remain in effect for up to 2 years.

The Secretary of Energy issued a new certification regarding the supply of non-HEU- sourced Mo-99 effective January 2, 2022 (86 FR 73270). This certification stated that there was a sufficient global supply of Mo-99 produced without the use of HEU available to meet the needs of patients in the United States. The Department of Energy also expected that the last HEU reactor that produces Mo-99 for medical providers in the United States would finish its conversion to a non-HEU reactor by December 31, 2022. In CY 2019, we stated that we would reassess the non-HEU incentive payment policy once conversion to non-HEU sources is closer to completion or has been completed (83 FR 58979). There is now a sufficient supply of non-HEU-sourced Mo-99 in the United States, and there is no available supply of HEU-sourced Mo-99 in the United States. In the CY 2023 OPPS/ASC final rule with comment period, we stated that we believed the conversion to non-HEU sources of Tc-99m had reached a point where it was necessary to reassess our policy of providing an additional payment of $10 for the marginal cost for radioisotopes produced by non-HEU sources (87 FR 71987).

In the OPPS, diagnostic radiopharmaceuticals are packaged into the cost of the associated diagnostic imaging procedure no matter the per day cost of the radiopharmaceutical. The cost of the radiopharmaceutical is included as a part of the cost of the diagnostic imaging procedure and is reported through Medicare claims data. Medicare claims data used to set payment rates under the OPPS generally is from 2 years prior to the payment year.

As we explained in the CY 2023 OPPS/ASC final rule with comment period (87 FR 71987), the claims data we would use to set payment rates for

[160] National Academies of Sciences, Engineering, and Medicine. 2016. Molybdenum-99 for Medical Imaging. Washington, DC: The National Academies Press. Available at: *https://doi.org/10.17226/23563.*

CY 2024 (likely CY 2022 claims data) contain claims for diagnostic radiopharmaceuticals that reflect both HEU-sourced Tc-99m and non-HEU-sourced Tc99m, rather than radiopharmaceuticals sourced solely from non-HEU Tc-99m. The cost of HEU-sourced Tc-99m is substantially lower than the cost of non-HEU-sourced Tc-99m. Therefore, we explained that providers who use radiopharmaceuticals in CY 2024 that contain only non-HEU-sourced Tc-99m might not receive a payment that is reflective of the radiopharmaceutical's current cost without the add-on payment. We believed that extending the additional $10 add-on payment described by HCPCS code Q9969 for non-HEU-sourced Tc-99m through the end of CY 2024 would ensure adequate payment for non-HEU-sourced Tc-99m. Starting in CY 2025, we believed the Medicare claims data utilized to set payment rates (likely CY 2023 claims data) would only include claims for diagnostic radiopharmaceuticals that utilized non-HEU-sourced Tc-99m, meaning the data would reflect the full cost of the Tc-99m diagnostic radiopharmaceuticals that would be used by providers in CY 2025. As a result, we believed there would no longer be a need for the additional $10 add-on payment for CY 2025 or future years.

This policy was based on the Secretary of Energy's certification that the last HEU reactor that produces Mo-99 for medical providers in the United States would finish its conversion to a non-HEU reactor by December 31, 2022, and that all Tc-99m used for radiopharmaceuticals in 2023 would be produced from non-HEU sources. However, we understand that the conversion of the last HEU reactor that produces Tc-99m to a non-HEU reactor did not occur until March 2023, so it is possible that some claims for diagnostic radiopharmaceuticals in CY 2023 would report the cost of HEU-sourced Tc-99m. This means that in CY 2025, as in CY 2024, there is the possibility that the payment rate for procedures using diagnostic radiopharmaceuticals could be lower than the costs providers will face for these procedures because providers will only have access to non-HEU-sourced Tc-99m.

We believe that extending the additional $10 add-on payment described by HCPCS code Q9969 for non-HEU-sourced Tc-99m through the end of CY 2025 rather than the end of CY 2024, as we previously finalized, would ensure adequate payment for non-HEU-sourced Tc-99m now that the conversion from HEU-sourced Tc-99m to non-HEU-sourced Tc-99m is complete. Starting in CY 2026, the Medicare claims data utilized to set payment rates (likely CY 2024 claims data) will only include claims for diagnostic radiopharmaceuticals that utilized non-HEU-sourced Tc-99m, which means the data will more closely reflect the cost of the Tc-99m diagnostic radiopharmaceuticals that will be used by providers in CY 2026. As a result, there will no longer be a need for the additional $10 add-on payment for CY 2026 or future years.

We proposed to continue the additional $10 payment through December 31, 2025, as, beginning in CY 2026, the Medicare claims data used to set payment rates will reflect the full cost of non-HEU-sourced Tc-99m.

Comment: Multiple commenters supported making the additional $10 payment permanent rather than ending it after December 31, 2025. Some of the commenters wanted a permanent $10 payment to help encourage the domestic production of Tc-99m starting in CY 2026. One of the commenters suggested adding a new claim edit to require providers to identify whether the Tc-99m radiopharmaceutical product they use is sourced from non-HEU or HEU reactors to confirm the transition from HEU-sourced to non-HEU-sourced Tc-99m products has been completed. Multiple commenters also requested that the $10 additional payment be increased to an amount that reflects what the payment would have been if it was adjusted annually by the hospital market basket since it was implemented in 2013. The commenters also requested that the copayment amount for HCPCS code Q9969 be eliminated because they are concerned that the administrative burden of handling the beneficiary copayment is discouraging providers from reporting the $10 additional payment.

Response: As stated in the CY 2023 OPPS final rule, the purpose of the $10 additional payment is limited to mitigating any adverse impact of transitioning to non-HEU sources (87 FR 71986). As the transition is now complete, we do not think it is necessary to increase the amount of the adjustment for its final two years. Once the transition is complete and payment rates reported for Tc-99m radiopharmaceuticals no longer include costs from HEU-sourced Tc-99m, the original purpose of the $10 additional payment to encourage the use of non-HEU-sourced Tc-99m will be achieved. We will take the comments regarding using the $10 additional payment to encourage the domestic production of Tc-99m into consideration for future rulemaking.

We also disagree with the request to waive the copayment for HCPCS code Q9969 as we do not believe the administrative burden associated with collecting copayments in this situation is unique or significant to justify such an action. Providers regularly collect copayments for services paid under the OPPS, and we do not believe that collecting a copayment for the additional $10 payment is a significant added burden for providers. Likewise, we do not agree with the suggestion to require a claim edit to identify a radiopharmaceutical as non-HEU or HEU sourced. We believe such a requirement would likely increase the administrative burden on providers unnecessarily, because the adjustment will only be in place for two more years and very few claims will report Tc-99m radiopharmaceuticals that are HEU sourced.

Comment: Multiple commenters supported the portion of our proposal that would continue the $10 additional payment for non-HEU sourced Tc-99m radiopharmaceuticals through December 31, 2025.

Response: We appreciate the support of the commenters.

After consideration of the public comments we received, we are finalizing without modification our proposal to continue the additional $10 payment for CYs 2024 and 2025 to ensure providers receive sufficient payment for diagnostic radiopharmaceuticals containing Tc99m until such time as the full cost of non-HEU-sourced Tc-99m is reflected in the Medicare claims data. We also are finalizing without modification our proposal that the additional $10 payment will end after December 31, 2025, as, beginning with CY 2026, the Medicare claims data used to set payment rates will reflect the full cost of non-HEU-sourced Tc-99m.

C. Requirement in the Physician Fee Schedule CY 2024 Proposed Rule for HOPDs and ASCs To Report Discarded Amounts of Certain Single-Dose or Single-Use Package Drugs

Section 90004 of the Infrastructure Investment and Jobs Act (Pub. L. 117–9, November 15, 2021) (''the Infrastructure Act'') amended section 1847A of the Act to redesignate subsection (h) as subsection (i) and insert a new subsection (h), which requires manufacturers to provide a refund to CMS for certain discarded amounts from a refundable single-dose container or single-use package drug. The CY 2024 PFS proposed rule

includes proposals to operationalize section 90004 of the Infrastructure Act, including a proposal that impacts hospital outpatient departments (HOPDs) and ambulatory surgical centers (ASCs). Similar to our CY 2023 notice in the OPPS/ASC proposed rule (87 FR 71988), we wanted to ensure interested parties were aware of these proposals and knew to refer to the Physician Fee Schedule (PFS) proposed rule for a full description of the proposed policy. Interested parties were asked to submit comments on any proposals related to implementation of section 90004 of the Infrastructure Act on the CY 2024 PFS proposed rule. We stated that public comments on these proposals would be addressed in the CY 2024 PFS final rule with comment period. We note that this same notice appeared in section XIII.D.3 of the proposed rule.

As explained in the CY 2024 OPPS/ASC proposed rule (88 FR 49759), because the CY 2024 PFS proposed rule discussed and proposed to codify certain billing requirements for HOPDs and ASCs, we wanted to ensure interested parties were aware of them and knew to refer to that rule for a full description of the proposed policy. Interested parties were asked to submit comments on this and any other proposals to implement section 90004 of the Infrastructure Act in response to the CY 2024 PFS proposed rule. We stated public comments on these proposals would be addressed in the CY 2024 PFS final rule.

We thank commenters for their feedback on the proposal. For final details on this policy, we refer readers to the CY 2024 PFS final rule.

VI. Estimate of OPPS Transitional Pass-Through Spending for Drugs, Biologicals, Radiopharmaceuticals, and Devices

A. Amount of Additional Payment and Limit on Aggregate Annual Adjustment

Section 1833(t)(6)(E) of the Act limits the total projected amount of transitional pass-through payment for drugs, biologicals, 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 pro rata 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 2024 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 2024. 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 devices that we know are newly eligible, or project may be newly eligible, for device pass-through payment in the remaining quarters of CY 2023 or beginning in CY 2024. The sum of the proposed CY 2024 pass-through spending estimates for these two groups of device categories equals the proposed total CY 2024 pass-through spending estimate for device categories with pass-through payment status. We determined the device pass-through estimated payments for each device category based on the amount of payment as required by 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 2024, 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. Consistent with current policy, we proposed to apply a rate of ASP plus 6 percent to most drugs and biologicals for CY 2024, and therefore our estimate of drug and biological pass-through payment for CY 2024 for this group of items was $100 million.

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 are not separately paid. In addition, we policy-package all non-pass-through drugs, biologicals, and radiopharmaceuticals that function as supplies when used in a diagnostic test or procedure, drugs and biologicals that function as supplies when used in a surgical procedure, drugs and biologicals used for anesthesia, and other categories of drugs and biologicals, as discussed in section V.B.1.c of the CY 2024 OPPS/ASC proposed rule (88 FR 49678). Consistent with current policy, we proposed that all of these policy-packaged drugs and biologicals with pass-through payment status will be paid at ASP+6 percent, like other pass-through drugs and biologicals, for CY 2024, less the policy-packaged drug APC offset amount described below. Our estimate of pass-through payment for policy-packaged drugs and biologicals with pass-through payment status approved prior to CY 2024 is not $0. This is because the pass-through payment amount and the fee schedule amount associated with the drug or biological will not be the same, unlike for separately payable drugs and biologicals. In section V.A.6 of the CY

2024 OPPS/ASC proposed rule (88 FR 49675 and 49676), 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 proposed to offset the amount of pass-through 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. Consistent with current policy, if we determine that an offset is appropriate for a specific policy-packaged drug or biological receiving pass-through payment, we proposed to reduce our estimate of pass-through payments for these drugs or biologicals by the APC offset 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 2024. 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 2023 or beginning in CY 2024. The sum of the CY 2024 pass-through spending estimates for these two groups of drugs and biologicals equals the total CY 2024 pass-through spending estimate for drugs and biologicals with pass-through payment status.

B. Estimate of Pass-Through Spending for CY 2024

For CY 2024, we proposed to set the applicable pass-through payment percentage limit at 2.0 percent of the total projected OPPS payments for CY 2024, consistent with section 1833(t)(6)(E)(ii)(II) of the Act and our OPPS policy from CY 2004 through CY 2023 (87 FR 71989). The pass-through payment percentage limit is calculated using pass-through spending estimates for devices and for drugs and biologicals.

For the first group of devices, consisting of device categories that are currently eligible for pass-through payment and will continue to be eligible for pass-through payment in CY 2024, there are 7 active categories for CY 2024. The active categories are described by HCPCS codes C1747, C1761, C1826, C1827, C1831, C1832, and C1833. Based on the information from the device manufacturers, we estimated that HCPCS code C1747 will cost $37.5 million in pass-through expenditures in CY 2024, HCPCS code C1761 will cost $19.6 million in pass-through expenditures in CY 2024, HCPCS code C1826 will cost $7.4 million in pass-through expenditures in CY 2024, HCPCS code C1827 will cost $28.8 million in pass-through expenditures in CY 2024, HCPCS code C1831 will cost $163,436 in pass-through expenditures in CY 2024, HCPCS code C1832 will cost $37,603 in pass-through expenditures in CY 2024, and HCPCS code C1833 will cost $281,238 in pass-through expenditures in CY 2024. Therefore, we proposed an estimate for the first group of devices of $93.7 million.

We did not receive any public comments on our proposal. Using our methodology for this final rule with comment period, we estimate that HCPCS code C1747 will cost $37.5 million in pass-through expenditures in CY 2024, HCPCS code C1761 will cost $19.4 million in pass-through expenditures in CY 2024, HCPCS code C1826 will cost $7.4 million in pass-through expenditures in CY 2024, HCPCS code C1827 will cost $28.8 million in pass-through expenditures in CY 2024, HCPCS code C1831 will cost $266,665 in pass-through expenditures in CY 2024, HCPCS code C1832 will cost $44,830 in pass-through expenditures in CY 2024, and HCPCS code C1833 will cost $278,751 in pass-through expenditures in CY 2024. Therefore, we have finalized the CY 2024 spending estimate for this first group of devices of approximately $93.7 million.

In estimating our proposed CY 2024 pass-through spending for device categories in the second group, we included the following: (1) device categories that we assumed at the time of the development of the proposed rule would be newly eligible for pass-through payment in CY 2024; (2) additional device categories that we estimated could be approved for pass-through status after the development of the CY 2024 OPPS/ASC proposed rule (88 FR 49696) and before January 1, 2024; and (3) contingent projections for new device categories established in the second through fourth quarters of CY 2024. For CY 2024, we proposed 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. For the CY 2024 OPPS/ASC proposed rule (88 FR 49696), the proposed estimate of CY 2024 pass-through spending for this second group of device categories was $40.4 million.

We did not receive any public comments on the proposal. As stated earlier in this final rule with comment period, we are approving four devices for pass-through payment status in the CY 2024 rulemaking cycle: Ambu® aScope™ 5 Broncho HD; FLEX Vessel Prep™ System; CavaClear Inferior Vena Cava (IVC) Filter Removal Laser Sheath; and CERAMENT® G. The manufacturers of these systems provided utilization and cost data that indicate the amount of spending for the devices would be approximately $14.4 million for Ambu® aScope™ 5 Broncho HD; $6.0 million for FLEX Vessel Prep™ System; $5.2 million for CavaClear Inferior Vena Cava (IVC) Filter Removal Laser Sheath; and $8.2 million for CERAMENT® G. Therefore, we are finalizing an estimate of $33.8 million for this second group of devices for CY 2024.

To estimate proposed CY 2024 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 2024, we proposed to use the CY 2022 Medicare hospital outpatient claims data regarding their utilization, information provided in their respective pass-through applications, other historical hospital claims data, pharmaceutical industry information, and clinical information regarding these drugs and biologicals to project the CY 2024 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 2024, we estimated the pass-through payment amount as the difference between the general payment rate of ASP+6 percent and the payment rate for non pass-through drugs and biologicals that would be separately paid. Because we proposed to utilize a payment rate of ASP plus 6 percent for most separately payable drugs and biologicals in the proposed rule, the proposed payment rate difference between the pass-through payment

amount and the non pass-through payment amount was $0 for this group of drugs.

We did not receive any comments on our proposal. Because payment for policy-packaged drugs and biologicals is packaged if the product is not paid separately due to its pass-through payment status, we proposed to include in the CY 2024 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. For this first group of policy-packaged drugs and biologicals, we estimated a pass-through for CY 2024 spending of $90 million.

We did not receive any public comments on our proposal. Using our methodology for this final rule with comment period, we calculated the CY 2024 spending estimate for this first group of drugs and biologicals of approximately $90 million using a rate of ASP+6 percent, which remained unchanged from the proposed rule.

To estimate proposed CY 2024 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 CY 2024 OPPS/ASC proposed rule (88 FR 49696) were newly eligible or recently became eligible for pass-through payment in CY 2024, additional drugs and biologicals that we estimated could be approved for pass-through status subsequent to the development of the CY 2024 OPPS/ASC proposed rule (88 FR 49696) and before January 1, 2024, and projections for new drugs and biologicals that could be initially eligible for pass-through payment in the second through fourth quarters of CY 2024), we proposed 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 2024 pass-through payment estimate. We also proposed to consider the most recent OPPS experience in approving new pass-through drugs and biologicals. Using our proposed methodology for estimating CY 2024 pass-through payments for this second group of drugs, we calculated a proposed spending estimate for this second group of drugs and biologicals of approximately $10 million.

We did not receive any public comments on our proposal. Since the release of the CY 2024 OPPS/ASC proposed rule, we have identified two additional policy-packaged drugs in addition to the two policy-packaged drugs that had pass-through status when the proposed rule was released. Therefore, we have identified a total of four policy-packaged drugs that have pass-through status. Our original proposed estimate of $10 million of additional pass-through payments for the second group of drugs and biologicals did anticipate the approval of some of the additional policy-packaged drugs and biologicals with pass-through status, but not all of them. Therefore, for this final rule with comment period, we are revising our estimate of pass-through spending for the second group of drugs and biologicals to be $18.5 million.

We estimated for the CY 2024 OPPS/ASC proposed rule (88 FR 49696) that the amount of pass-through spending for the device categories and the drugs and biologicals that are continuing to receive pass-through payment in CY 2024 and those device categories, drugs, and biologicals that first become eligible for pass-through payment during CY 2024 would be approximately $234.1 million (approximately $134.1 million for device categories and approximately $100 million for drugs and biologicals) which represented 0.26 percent of total projected OPPS payments for CY 2024 (approximately $88.6 billion). Therefore, we estimated for the proposed rule that pass-through spending in CY 2024 would not amount to 2.0 percent of total projected OPPS CY 2024 program spending.

We estimate for this final rule with comment period that the amount of pass-through spending for the device categories and the drugs and biologicals that are continuing to receive pass-through payment in CY 2024 and the amount of pass-through spending for those device categories, drugs, and biologicals that first become eligible for pass-through payment during CY 2024 would be approximately $236 million (approximately $127.5 million for device categories and approximately $108.5 million for drugs and biologicals), which represents only 0.27 percent of total projected OPPS payments for CY 2024 (approximately $88.9 billion). Therefore, we estimate that pass-through spending in CY 2024 will not exceed the 2.0 percent of total projected OPPS CY 2024 program spending limit provided for in section 1833(t)(6)(E) of the Act.

VII. OPPS Payment for Hospital Outpatient Visits and Critical Care Services

For CY 2024, we proposed to continue our current clinic and emergency department (ED) hospital outpatient visits payment policies. For a description of these policies, we refer readers to the CY 2016 OPPS/ASC final rule with comment period (80 FR 70448). We also proposed to continue our payment policy for critical care services for CY 2024. For a description of this policy, we refer readers to the CY 2016 OPPS/ASC final rule with comment period (80 FR 70449), and for the history of this payment policy, we refer readers to the CY 2014 OPPS/ASC final rule with comment period (78 FR 75043).

We did not receive any comments on our proposals to continue our current ED outpatient visits and critical care payment policies for CY 2024 and are finalizing our proposals without modification.

As we stated in the CY 2022 OPPS/ASC final rule with comment period (86 FR 63663), the volume control method for clinic visits furnished by non-excepted off-campus provider-based departments (PBDs) applies for CY 2022 and subsequent years. More specifically, we finalized a policy to continue to utilize a PFS-equivalent payment rate for the hospital outpatient clinic visit service described by HCPCS code G0463 when it is furnished by these departments for CY 2022 and beyond. The PFS-equivalent rate for CY 2024 is 40 percent of the proposed OPPS payment. Under this policy, these departments will be paid approximately 40 percent of the OPPS rate for the clinic visit service in CY 2024.

The following is a summary of the comments we received and our responses to those comments.

Comment: We received several comments on our overall clinic visit payment policy. Many commenters continued to express the belief that this policy undermines Congressional intent and exceeds the agency's legal authority. As they have in previous years, commenters stated that the policy is based on flawed assumptions and urged CMS to eliminate it altogether. One of these commenters additionally requested that CMS immediately restore the higher payment rates for clinic visits furnished by excepted off-campus PBDs that existed before implementation of the clinic visit payment policy and promptly repay hospitals the difference between the amounts they would have received under those higher rates and

the amounts they were paid under the policy.

Response: We continue to believe that section 1833(t)(2)(F) of the Act gives the Secretary authority to develop a method for controlling unnecessary increases in the volume of covered OPD services, including a method that controls unnecessary volume increases by removing a payment differential that is driving a site-of-service decision, and as a result, is unnecessarily increasing service volume.[161] As we noted in the CY 2019 OPPS/ASC proposed rule (83 FR 37138 through 37143), ''[a] large source of growth in spending on services furnished in hospital outpatient departments (HOPDs) appears to be the result of the shift of services from (lower cost) physician offices to (higher cost) HOPDs.'' We continue to believe that these shifts in the sites of service are unnecessary if the beneficiary can safely receive the same services in a lower cost setting but instead receives care in a higher cost setting due to payment incentives. In most cases, the difference in payment is leading to unnecessary increases in the volume of covered outpatient department services, and we remain concerned that this shift in care setting increases beneficiary cost-sharing liability because Medicare payment rates for the same or similar services are generally higher in hospital outpatient departments than in physician offices. We continue to believe that our method addresses the concerns described in the CY 2019 OPPS/ASC final rule with comment period (83 FR 59005).

Additionally, we note that this policy has been litigated. On July 17, 2020, the United States Court of Appeals for the District of Columbia Circuit (D.C. Circuit) ruled in our favor, 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. The appellees petitioned the United States Supreme Court for a writ of certiorari. On June 29, 2021, the Supreme Court denied the petition.

Comment: We received comments supporting CMS's efforts to continue implementing its method to control for unnecessary increases in the volume of outpatient services. These commenters asked that CMS continue to consider ways to expand the current site-neutral payment policies to other services and settings. Some of these commenters suggested that CMS apply the site-neutral payment policy to a list of 57 APCs for which MedPAC determined it would be reasonable and appropriate to align the OPPS and ASC payment rates with those set in the physician fee schedule (PFS).[162] Other commenters recommended that CMS consider expanding the site-neutral payment policy to all services provided by excepted, off-campus PBDs. Others suggested that the site-neutral policy be extended to on-campus PBDs, ASCs, and emergency departments.

Response: We appreciate the commenters' support and we will continue to monitor this policy and take commenters' suggestions into consideration for potential future rulemaking.

After consideration of the public comments, we are continuing the volume control method under which we utilize a PFS-equivalent payment rate for the hospital outpatient clinic visit service described by HCPCS code G0463 when it is furnished by excepted off-campus PBDs in CY 2024.

In the CY 2023 OPPS/ASC final rule with comment period (87 FR 71748), we finalized a policy that excepted off-campus provider-based departments (PBDs) (departments that bill the modifier ''PO'' on claim lines) of rural Sole Community Hospitals (SCHs), as described under 42 CFR 412.92 and designated as rural for Medicare payment purposes, are exempt from the clinic visit payment policy that applies a Physician Fee Schedule-equivalent payment rate for the clinic visit service, as described by HCPCS code G0463, when provided at an off-campus PBD excepted from section 1833(t)(21) of the Act. For the full discussion of this policy, we refer readers to the CY 2023 OPPS/ASC final rule with comment period (87 FR 72047 through 72051). For CY 2024, we proposed to continue to exempt excepted off-campus PBDs of rural SCHs from the clinic visit payment policy. We stated that we will continue to monitor the effect of this change in Medicare payment policy, including on the volume of these types of OPD services.

The following is a summary of the comments we received and our responses to those comments.

Comment: All commenters supported our proposal to continue to exempt excepted off-campus PBDs of rural SCHs from the clinic visit payment policy for CY 2024. One commenter stated that the continuation of the exemption is an important step in maintaining access to care for a segment of the population that is underserved. This commenter additionally stated that the continuation will not only improve patient outcomes by allowing easily treatable conditions to be addressed in a timely manner but will also reduce total Medicare spending as these conditions will be treated in the most appropriate setting. Another commenter praised the continuation of the exemption as a recognition on CMS's part of the important role rural providers play in the delivery of care and the financial pressures they face.

Response: We thank the commenters for their support.

Comment: Several of these commenters requested that CMS consider expanding the exemption to excepted off-campus PBDs of rural hospitals with fewer than 100 beds, Medicare Dependent Hospitals (MDHs), and Low Volume Hospitals in a future rulemaking cycle, arguing that the same reasoning that led CMS to propose to exempt SCHs also applies to these hospitals. One commenter noted that MDHs have a larger percentage of inpatient days or discharges for Medicare patients and that they are therefore more vulnerable to inadequate Medicare payments than other hospitals because they are less able to cross-subsidize inadequate Medicare payments with more generous payments from private payers. The commenter expressed that this greater dependence on Medicare may make certain hospitals more financially vulnerable and thus, more worthy of being exempt from the clinic visit policy. This commenter also suggested that it would be appropriate to extend the exemption to urban SCHs and provided specific examples of instances where an SCH is designated urban by CMS, but the hospital is actually a considerable distance from the nearest urban area. This commenter expressed that there are many factors that underscore why urban SCHs and MDHs should also receive the payment exemption, including below-average patient care margins at these types of hospitals. The commenter also argued that extending this exemption to MDHs and urban SCHs would only add nominally to the cost of the proposed policy.

Response: In the CY 2006 OPPS final rule with comment period (70 FR 68556 through 68561) we uniquely identified rural SCHs as providers with demonstrated additional resource costs. We found that rural SCHs have significantly higher costs per unit than urban hospitals. We have continued to adjust payments for rural SCHs by 7.1 percent each year since 2006. Building upon that foundation, for CY 2018 we

[161] Available at: *https://www.ssa.gov/OP_Home/ssact/title18/1833.htm.*

[162] Found at *https://www.medpac.gov/wp-content/uploads/2022/06/Jun22_MedPAC_Report_to_Congress_v4_SEC.pdf.*

finalized a policy to exclude rural SCHs from our 340B drug payment policy and continued to do so until September 27, 2023, when the 340B drug payment policy ended and we resumed paying for 340B drugs and biologicals under the OPPS at the same rates we pay for non-340B drugs and biologicals (generally, ASP plus 6 percent)). We believe exempting rural SCHs, which have demonstrated additional resource costs, is appropriate to ensure these hospitals can remain open to serve the beneficiaries who rely on them for their care. We share commenters' concerns about the financial difficulties associated with maintaining access to care in medically vulnerable communities. However, in each of these cases, the Congress did not determine that any of these hospital types required additional payments for outpatient services. Section 1833(t)(13)(B) of the Act authorizes an appropriate adjustment for hospitals located in rural areas where the Secretary determines, based on a study, that the costs incurred by these hospitals by APC group exceed costs incurred by hospitals in urban areas. In the CY 2006 OPPS final rule with comment period (70 FR 68556 through 68561), we summarized our study of the cost of covered outpatient department services to hospitals in rural areas and found that rural SCHs were the only rural hospital type that had higher resource costs for covered outpatient department services. Rural SCHs demonstrated significantly higher cost per unit than urban hospitals after controlling for labor input prices, service-mix complexity, volume, facility size, and type of hospital. In the CY 2006 OPPS final rule with comment period (70 FR 68556 through 68561) we stated that we found no significant difference in cost between all small rural hospitals with 100 or fewer beds and urban hospitals. We found that there was insufficient evidence to conclude that rural hospitals with 100 or fewer beds have higher costs than urban hospitals. We proposed a narrow exception to our clinic visit policy largely based upon the historical treatment and documented additional resource costs of rural SCHs under the OPPS. We are only excepting rural SCHs because we continue to believe that the underlying principles of the clinic visit policy continue to justify application of the volume control method for clinic visits to the remaining hospital types, including most rural and safety-net providers. Where the difference in payment is leading to unnecessary increases in the volume of covered outpatient department services, we remain concerned that this shift in care setting increases beneficiary cost-sharing liability because Medicare payment rates for the same or similar services are generally higher in hospital outpatient departments than in physician offices. Further, we do not believe that commenters provided sufficient reasoning or data to show that the other provider types suggested (Medicare Dependent Hospitals, Urban Sole Community Hospitals, and Low-Volume Adjustment Hospitals) demonstrate the additional resource costs that rural SCHs do and should therefore also be exempted from this OPPS payment policy. We share commenters' concerns about maintaining access to care in urban and rural settings and enhancing access to care in medically vulnerable communities. We also share commenters' concerns about profit margins. However, we must balance the concerns of providers with the concerns of beneficiaries regarding the affordability of their care. For hospitals subject to the clinic visit policy, the proposed PFS-equivalent rate for a clinic visit brings the approximate average copayment down from $26 to $10. We will continue to study access and cost to see if further exemptions to the clinic visit policy are appropriate.

Comment: One commenter noted that, while it is necessary to distinguish between urban and rural hospitals for a number of payment and policy mechanisms, they believe the Metropolitan Statistical Areas (MSAs) CMS uses to delineate between these areas are not the most precise tool. This commenter argued that CMS should extend this exemption to urban SCHs because using MSAs to determine urban and rural areas is imprecise and unfairly disadvantages urban SCHs that may be the sole source of hospital services in their communities.

Response: We acknowledge the commenters' points about the important role that urban SCHs serve in their communities. However, we have not found that urban SCHs have the additional resource costs for covered outpatient department services that rural SCHs have, and as such, we are only applying the clinic visit policy exemption to rural SCHs.

Comment: A few commenters suggested extending the exemption to hospitals that provide a disproportionate share of the nation's uncompensated care, and serve high proportions of Medicaid, Medicare, and uninsured patients. The commenters argued that PBDs of these hospitals are disproportionately impacted by site-neutral payment policies and shielding these PBDs from the impact of these policies would ensure they can continue to cover the costs associated with providing comprehensive, coordinated care to complex patient populations in underserved areas. The commenters did acknowledge that CMS has not defined hospitals that meet these criteria and would need to do so in order to exempt associated PBDs from the clinic visit policy. They further recognized that rural SCHs are easily identified because there is an existing definition to capture the hospitals that fall into this group. They recommended that CMS first define a group of hospitals that meet these criteria and then exclude those hospitals' excepted PBDs from the clinic visit policy to ensure continued access for marginalized communities without other reliable sources of care.

Response: As the commenter stated, we have not created a definition for the group of hospitals the commenter cited and would need to do so in order use this definition to exempt associated PBDs from the clinic visit policy. We will continue to monitor this issue and revisit any additional exemptions in future rulemaking as appropriate.

Comment: One commenter presented data showing that 56 percent of rural SCHs, 73 percent of urban SCHs, and 60 percent of Medicare Dependent Hospitals (MDHs) are located in at least one type of medically underserved area (MUA) as designated by the Health Resources & Services Administration.

Response: We do not currently utilize MUA designations to determine payment for covered outpatient department services under the OPPS. We believe our policy to exempt rural SCHs is consistent with our other policies that target this hospital type, which we have determined have higher resource costs for covered outpatient department services, and therefore, that our policy to exempt them is appropriate from an OPPS perspective.

Comment: One commenter recommended that CMS broaden the scope of exempted hospitals to support patient access to care and encouraged CMS to work with interested parties to identify the additional types of hospitals that would be eligible to receive an exemption.

Response: We appreciate the commenter's suggestion and will consider it for future rulemaking.

After consideration of the public comments we received, we are finalizing our proposal to continue to exempt excepted off-campus PBDs of rural SCHs from the clinic visit payment policy in CY 2024.

VIII. Payment for Partial Hospitalization and Intensive Outpatient Services

This section discusses payment for partial hospitalization services as well as intensive outpatient services. Since CY 2000, Medicare has paid for partial hospitalization services under the OPPS. Beginning in CY 2024, as authorized by section 4124 of the Consolidated Appropriations Act (CAA), 2023 (Pub. L. 117–328), Medicare will begin paying for intensive outpatient services furnished by hospital outpatient departments, community mental health centers, federally qualified health centers, and rural health clinics. Additional background on the partial hospitalization and intensive outpatient benefits is included in the following paragraphs.

A. Partial Hospitalization

1. 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 (SUD). 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 information regarding PHP.

Partial hospitalization program policies and payment have been addressed under OPPS since CY 2000. 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 with comment period (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 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 and 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, respectively).

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).

In the CY 2020 OPPS/ASC final rule with comment period (84 FR 61339 through 61350), we finalized a 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 30, 2020 interim final rule with comment (85 FR 27562 through 27566), effective as of March 1, 2020, and for the duration of the COVID–19 Public Health Emergency (PHE), hospital and CMHC staff were

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. In the CY 2023 OPPS/ASC final rule (87 FR 72247), we confirmed these provisions as final, including that they apply only for the duration of the COVID–19 PHE. On May 11, 2023, the COVID–19 PHE ended, and accordingly, these flexibilities ended as well.

In the CY 2021 OPPS/ASC final rule with comment period (85 FR 86073 through 86080), we continued our current methodology to utilize cost floors, as needed. Since the final calculated geometric mean per diem costs for both CMHCs and hospital-based PHPs were significantly higher than each proposed cost floor, a floor was not necessary at the time, and we did not finalize the proposed cost floors in the CY 2021 OPPS/ASC final rule with comment period.

In the CY 2022 OPPS/ASC final rule with comment period (86 FR 63665 and 63666), we explained that we observed a number of changes, likely as a result of the COVID–19 PHE, in the CY 2020 OPPS claims that we would have ordinarily used for CY 2022 ratesetting, and this included changes in the claims for partial hospitalization. We explained that significant decreases in utilization and in the number of hospital-based PHP providers who submitted CY 2020 claims led us to believe that CY 2020 data were not the best overall approximation of expected PHP services in CY 2022. Therefore, we finalized our proposal to calculate the PHP per diem costs using the year of claims consistent with the calculations that would be used for other OPPS services, by using the CY 2019 claims and the cost reports that were used for CY 2021 final rulemaking to calculate the CY 2022 PHP per diem costs. In addition, for CY 2022 and subsequent years, we finalized our proposal to use cost and charge data from the Hospital Cost Report Information System (HCRIS) as the source for the CMHC cost-to-charge ratios (CCRs), instead of using the Outpatient Provider Specific File (OPSF) (86 FR 63666).

In the CY 2023 OPPS/ASC final rule with comment period (87 FR 71995), we explained that we continued to observe a decrease in the number of hospital-based and CMHC PHP days in our trimmed dataset due to the continued effects of COVID–19, however, the Medicare outpatient service volumes appeared to be returning to more normal, pre-pandemic levels. Therefore, we finalized our proposal to use the latest available CY 2021 claims, but use the cost information from prior to the COVID–19 PHE for calculating the CY 2023 CMHC and hospital-based PHP APC per diem costs. The application of the OPPS standard methodology, including the effect of budget neutralizing all other OPPS policy changes unique to CY 2023, resulted in the final calculated CMHC PHP APC payment rate being unexpectedly lower than the CY 2022 final CMHC PHP APC rate. Therefore, in the interest of accurately paying for CMHC PHP services, under the unique circumstances of budget neutralizing all other OPPS policy changes for CY 2023, and in keeping with our longstanding goal of protecting continued access to PHP services provided by CMHCs by ensuring that CMHCs remain a viable option as providers of mental health care in the beneficiary's own community, we finalized utilizing the equitable adjustment authority of section 1833(t)(2)(E) of the Act to appropriately pay for CMHC PHP services at the same payment rate as for CY 2022, that is, $142.70. In addition, we clarified the payment under the OPPS for new HCPCS codes that designate non-PHP services provided for the purposes of diagnosis, evaluation, or treatment of a mental health disorder and are furnished to beneficiaries in their homes by clinical staff of the hospital would not be recognized as PHP services, however, none of the PHP regulations would preclude a patient that is under a PHP plan of care from receiving other reasonable and medically necessary non-PHP services from a hospital (87 FR 72001 and 72002).

Section 4124(a) of Division FF of the CAA, 2023 amends section 1861(ff)(1) of the Act to modify the definition of partial hospitalization services furnished on or after January 1, 2024. Specifically, section 4124(a) of the CAA, 2023 amends section 1861(ff)(1) of the Act by adding to the current definition that partial hospitalization services are ''for an individual determined (not less frequently than monthly) by a physician to have a need for such services for a minimum of 20 hours per week.'' We discuss these revisions to the definition of partial hospitalization services in section VIII.A.2 of this CY 2024 OPPS/ASC final rule.

2. Revisions to PHP Physician Certification Requirements

As amended by section 4124(a) of the CAA, 2023, section 1861(ff)(1) requires that a physician determine that each patient needs a minimum of 20 hours of PHP services per week, and this determination must occur no less frequently than monthly. We proposed to codify this requirement in regulation as an additional requirement for the physician certification applicable for PHP services that we would add to § 424.24(e)(1)(i). We did not propose any changes to the existing physician certification requirements for PHP, including that the patient would require inpatient hospitalization if they did not receive PHP services, which will remain at § 424.24(e)(1)(i).

Existing regulations at § 410.43 set forth conditions and exclusions that apply for partial hospitalization services. Under § 410.43(a)(3), partial hospitalization services are services that are furnished in accordance with a physician certification and plan of care as specified under § 424.24(e). Additionally, current patient eligibility criteria at § 410.43(c)(1) state that partial hospitalization programs are intended for patients who require a minimum of 20 hours per week of therapeutic services as evidenced in their plan of care. Because partial hospitalization services are already required to be furnished in accordance with a physician certification and plan of care, we stated in the proposed rule that we believe it is appropriate to include this 20-hour minimum weekly requirement as a physician certification requirement at § 424.24(e)(1)(i). We noted that we do not believe the proposed change to the regulation would create a new requirement for PHPs from a practical perspective, as the change to the definition of partial hospitalization services made by the CAA, 2023 is consistent with the longstanding 20-hour minimum weekly regulatory requirement at § 410.43(c)(1) that Medicare has applied to PHP.

We proposed to modify the regulation at § 424.24(e)(1)(i) to require the physician certification for PHP services include a certification that the patient requires such services for a minimum of 20 hours per week. Current regulations at § 424.24(e)(3)(ii) require an initial recertification after 18 days, with subsequent recertifications of PHP services no less frequently than every 30 days. We stated that we believe this interval is consistent with the CAA, 2023 requirement that the physician's

determination of the need for PHP services at least 20 hours per week must occur no less frequently than monthly.

Comment: Overall, commenters agreed that the proposed modification to the regulation at § 424.24(e)(1)(i) is consistent with the CAA, 2023 requirement that the physician certifies the need for PHP services for at least 20 hours per week. One commenter recommended CMS consider allowing any addiction treatment professional operating within their scope of practice under state regulation to certify the need for PHP for SUD treatment.

Response: We appreciate the commenters' support. Section 4124(a) of the CAA, 2023 specifically states that the certification must be determined by a physician. Section 1861(r) of the Act defines ''physician'' as a doctor of medicine or osteopathy legally authorized to practice medicine and surgery by the State in which he performs such function or action. Therefore, we do not believe we are able to expand the certification of the need for PHP services to any addiction treatment professional.

Comment: Commenters recommended that CMS reconsider the timing associated with the initial PHP recertification requirement. Commenters noted section 1861(ff)(1) of the Act, as amended by section 4124(a) of the CAA, 2023, specifies that recertification should occur ''not less frequently than monthly''. The commenters further noted that the current regulation at § 424.24(e)(3)(ii) requires the initial PHP recertification as of the 18th day of partial hospitalization services, which is significantly earlier than one month after the patient begins receiving PHP services. The commenters stated it may be clinically beneficial for the PHP to have more days of furnishing partial hospitalization before determining whether recertification is warranted for the person.

Response: We appreciate the commenter's concerns regarding the timing of the first recertification of PHP services. We did not propose to modify the regulation at § 424.24(e)(3)(ii) which requires the first recertification of PHP services occur as of the 18th day of partial hospitalization services. As discussed in the April 2000 OPPS final rule with comment period (65 FR 18454), because partial hospitalization is the outpatient substitute for inpatient psychiatric care, we stated that we believed it was appropriate to adopt the standard used for inpatient psychiatric care at that time. The requirement for initial recertification by the 18th day of an inpatient psychiatric *stay* was codified in regulation at § 424.14(d)(2) in the March 1988 final rule with comment period (53 FR 6636 and 6637). We later modified the initial recertification interval from 18 days to 12 days. As we explained in the RY 2007 IPF PPS final rule (71 FR 27076 and 27077), the standard for IPF initial recertification was determined by the average length of stay (LOS) for inpatient psychiatric hospitalization in the 1980s, which was 18 days. For RY 2007, we amended the regulation at § 424.14(d)(2) to require the initial recertification for IPF patients as of the 12th day of hospitalization. This change was based on analysis of the MedPAR 2002 claims data for IPF services. Although the timing requirement for inpatient psychiatric hospitalization was shortened, we continue to believe that the current timing requirements for PHP initial recertification—that is, as of the 18th day of PHP services—is appropriate. We note that our analysis shows that 18 days generally corresponds to the median length of stay for PHP patients.

Final Decision: After consideration of the public comments we received, we are finalizing our proposed revision to the regulation at § 424.24(e)(1)(i) to require the physician certification for PHP services include a certification that the patient requires such services for a minimum of 20 hours per week.

B. Intensive Outpatient Program Services

1. Establishment of Intensive Outpatient Services Benefit by Section 4124 of the CAA, 2023

Section 4124(b) of the CAA, 2023 established Medicare coverage for intensive outpatient services effective for items and services furnished on or after January 1, 2024. Section 4124(b)(1)(A) of the CAA, 2023 amended section 1832(a)(2)(J) of the Act to add intensive outpatient services to the scope of covered benefits provided by CMHCs, and section 4124(b)(1)(B) amended section 1861(s)(2)(B) to add intensive outpatient services to the definition of ''medical and other health services'', specifically, as a service furnished ''incident to a physicians' services.''

Intensive outpatient services are furnished under an intensive outpatient program (IOP). Similar to PHP, an IOP is a distinct and organized outpatient program of psychiatric services provided for individuals who have an acute mental illness, which includes, but is not limited to, conditions such as depression, schizophrenia, and SUD. Generally speaking, an IOP is thought to be less intensive than a PHP, and the statutory definition of IOP services reflects this difference in intensity. Specifically, section 4124(b)(2)(B) of the CAA, 2023 amended section 1861(ff) of the Act to add a new paragraph (4) to define the term ''intensive outpatient services'' as having the same meaning as ''partial hospitalization services'' in paragraph (1). In particular, intensive outpatient services are the items and services described in paragraph (2) prescribed by a physician for an individual determined (not less frequently than once every other month) by a physician to have a need for such services for a minimum of 9 hours per week 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. For patients of an IOP, section 1835(a)(2)(F)(i) of the Act does not apply, that is, individuals receiving IOP would not require inpatient psychiatric care in the absence of such services. Lastly, section 4124(b)(2)(B) of the CAA, 2023 further added to section 1861(ff)(4)(C), which cross-references paragraph (3), that an IOP is a program furnished by a hospital to its outpatients, or by a community mental health center (CMHC), a Federally qualified health center (FQHC), or a rural health clinic (RHC), 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 4124(c) of the CAA, 2023 amends section 1834 of the Act by adding a new paragraph (5) to subsection (o) and a new paragraph (3) to subsection (y), which include special payment rules for intensive outpatient services furnished in FQHCs and RHCs, which are discussed in greater detail in section VIII.F of this final rule with comment period.

This final rule establishes payment and program requirements for the IOP benefit in all of the above-described settings. Section VIII.B.2 of this final rule with comment period discusses the scope of benefits for IOP services, and section VIII.B.3 of this final rule with comment period discusses physician certification requirements. Section VIII.C of this final rule with comment period discusses coding and billing for

both PHP and IOP services under the OPPS beginning in CY 2024. Section VIII.D of this final rule with comment period discusses the payment methodology. Section VIII.E of this final rule with comment period discusses the outlier policy for CMHCs. Section VIII.F of this final rule with comment period discusses payment for IOP services in FQHCs and RHCs, and section VIII.G of this final rule with comment period discusses payment for IOP services in Opioid Treatment Programs (OTPs).

2. IOP Scope of Benefits

Section 1861(ff)(2) of the Act describes the items and services available under the IOP benefit. These items and services include: individual and group therapy with physicians or psychologists (or other mental health professionals to the extent authorized under State law); occupational therapy requiring the skills of a qualified occupational therapist; services of social workers, trained psychiatric nurses, and other staff trained to work with psychiatric patients; drugs and biologicals furnished for therapeutic purposes (which cannot, as determined in accordance with regulations, be self-administered); individualized activity therapies that are not primarily recreational or diversionary; family counseling (the primary purpose of which is treatment of the individual's condition); patient training and education (to the extent that training and educational activities are closely and clearly related to individual's care and treatment); diagnostic services; and such other items and services as the Secretary may provide (excluding meals and transportation) that are reasonable and necessary for the diagnosis or active treatment of the individual's condition, reasonably expected to improve or maintain the individual's condition and functional level and to prevent relapse or hospitalization, and furnished pursuant to such guidelines relating to frequency and duration of services as the Secretary shall by regulation establish, taking into account accepted norms of medical practice and the reasonable expectation of patient improvement.

Consistent with the statutory definition of intensive outpatient services under section 1861(ff)(2) of the Act, we proposed to add regulations at 42 CFR 410.44 to set forth the conditions and exclusions that would apply for intensive outpatient services. Consistent with the existing regulations for partial hospitalization services, we proposed to require that intensive outpatient services must be furnished in accordance with a physician certification and plan of care. However, where partial hospitalization requires the physician to certify that the services are instead of inpatient hospitalization, intensive outpatient program services are not intended for those who otherwise need an inpatient level of care. That is, section 1861(ff)(4)(A) of the Act, as added by section 4124 of the CAA, 2023, states that for intensive outpatient services, section 1835(a)(2)(F)(i) of the Act shall not apply. As further discussed in section VIII.B.3 of this final rule with comment period, we proposed to add language to the regulation at § 424.24(d), which is currently reserved, that would set forth the physician certification and plan of care requirements for intensive outpatient services.

Additionally, we proposed to revise certain existing regulations at §§ 410.2, 410.3, 410.10, 410.27, 410.150, and 419.21 to add a regulatory definition of intensive outpatient services and to include intensive outpatient services in the regulations for medical and other health services paid for under Medicare Part B, and in the case of § 419.21, under the OPPS. We proposed to create regulations at § 410.111 to establish the requirements for coverage of IOP services furnished in CMHCs, and at § 410.173 to establish conditions of payment for IOP services furnished in CMHCs. Lastly, we proposed to revise § 410.155 to exclude IOP services from the outpatient mental health treatment limitation, consistent with the statutory requirement of section 1833(c)(2) of the Act, as amended by section 4124(b)(3) of the CAA, 2023. We discuss our proposals and the comments we received in the following paragraphs.

a. Definition of Intensive Outpatient Services

We proposed the following definition at § 410.2 for intensive outpatient services: *Intensive outpatient services* means a distinct and organized intensive ambulatory treatment program that offers less than 24-hour daily care other than in an individual's home or in an inpatient or residential setting and furnishes the services as described in § 410.44. Intensive outpatient services are not required to be provided in lieu of inpatient hospitalization. We noted that the proposed definition for intensive outpatient services is consistent with the statutory requirements of section 1861(ff)(3)(A), which apply to both IOP and PHP services. Accordingly, the proposed definition is largely consistent with the existing regulatory definition of partial hospitalization services. However, in accordance with section 1861(ff)(4)(A) of the Act, as added by the CAA, 2023, we included a clarification in the regulatory definition of ''intensive outpatient services'' that they are not required to be provided in lieu of inpatient hospitalization. We stated that we included this clarification in order to more clearly differentiate between the definitions of partial hospitalization and intensive outpatient at § 410.2.

Comment: Commenters were generally supportive of the proposed definition at § 410.2 for intensive outpatient services. However, commenters recommended that language specifying IOP represents a less intensive service than partial hospitalization be included in the definition. The commenters stated this addition could avoid any misconception that IOP is substantively different from PHP.

Response: We thank commenters for their suggestions. We proposed the regulations for IOP to be similar to PHP due to the similarities of both programs as enacted by section 4124(b) of the CAA, 2023. The key distinctions between IOP and PHP can be found in the proposed regulations at § 424.24(d). The proposed regulations at § 424.24(d) outline the content of certification and plan of treatment requirements for IOP, which differ from PHP requirements. Specifically, proposed regulations at § 424.24(d)(1) do not include a requirement that individuals receiving IOP would require inpatient psychiatric care in the absence of such services, which is required under PHP at § 424.24(e)(1)(i). Additionally, the proposed modification to the PHP regulation at § 424.24(e)(1)(i) requires individuals receiving PHP be certified by a physician to need a minimum of 20 hours per week of such services; while the proposed IOP regulation at § 424.24(d)(1)(i) requires individuals receiving IOP be certified by a physician to need a minimum of 9 hours per week of such services. Therefore, we believe the proposed definition at § 410.2 for intensive outpatient services sufficiently defines an intensive outpatient program.

Comment: A few commenters were concerned CMS did not propose to include IOP services furnished remotely. Commenters noted how the availability of remote PHP services during the COVID–19 public health emergency (PHE) has increased access to these services, especially in rural areas. The commenters stated remote IOP services would also be beneficial to increase access to the benefit.

Response: We appreciate the comments on how the availability of remote services increased access during the COVID–19 PHE. Section

1861(ff)(3)(A) of the Act does not allow Medicare to pay for partial hospitalization services furnished to beneficiaries in a home or residential setting. As discussed in the CY 2023 OPPS/ASC final rule with comment period (87 FR 72000 through 72002), we did not propose to recognize OPPS remote services, as described in section X.A.5 of the CY 2023 OPPS/ASC final rule with comment period (87 FR 72014 through 72017), as PHP services, because we do not have statutory authority to pay for services furnished in a home or residential setting as partial hospitalization services. However, we clarified that none of the PHP regulations would preclude a patient that is under a PHP plan of care from receiving other reasonable and medically necessary non-PHP services from a hospital. This means that patients in a PHP are not precluded from receiving remote mental health services provided outside of the PHP by the same or another hospital, when such services are reasonable and medically necessary. In response to IOP services being furnished remotely to beneficiaries in their homes, we note that section 1861(ff) of the Act, as amended by section 4124(b)(2)(B) of the CAA, 2023 adopts much of the statutory definition for PHP and applies it to IOP. Specifically, section 1861(ff)(3)(A) prohibits both PHP and IOP services from being furnished other than in an individual's home or in an inpatient or residential setting. However, as we discussed in the CY 2023 OPPS/ASC final rule with comment period for PHP, we are clarifying in this final rule that none of the proposed IOP regulations would preclude a patient that is under an IOP plan of care from receiving other reasonable and medically necessary non-IOP services from a hospital.

Additionally, we are reiterating and clarifying in this final rule that we would expect that a physician would update the patient's PHP or IOP plan of care to appropriately reflect any change to the type, amount, duration, or frequency of the therapeutic services planned for that patient in circumstances when a PHP or IOP patient receives non-PHP/IOP remote mental health services from a hospital outpatient department. We also note that the medical documentation should continue to support the patient's eligibility for participation in a PHP or IOP.

Final Decision: After consideration of the public comments we received, we are finalizing the proposed definition at § 410.2 for intensive outpatient services: *Intensive outpatient services* means a distinct and organized intensive ambulatory treatment program that offers less than 24-hour daily care other than in an individual's home or in an inpatient or residential setting and furnishes the services as described in § 410.44.

The conditions and exclusions for partial hospitalization services are included in the regulation at § 410.43. We proposed that the conditions and exclusions for intensive outpatient services would be included in new regulations at § 410.44.

At new § 410.44, we proposed to establish regulatory language for intensive outpatient services that is consistent with the existing language for partial hospitalization conditions and exclusions and the statutory definition of intensive outpatient services. Specifically, under § 410.44(a) we proposed that IOP services are services that: (1) are reasonable and necessary for the diagnosis or active treatment of the individual's condition; (2) are reasonably expected to improve or maintain the individual's condition and functional level and to prevent relapse or hospitalization; (3) are furnished in accordance with a physician certification and plan of care as specified under new regulations at § 424.24(d); and include any of the services listed in § 410.44(a)(4). Under § 410.44(a)(4), we include a list of the types of services that we proposed would be covered as intensive outpatient services:

- Individual and group therapy with physicians or psychologists or other mental health professionals to the extent authorized under State law.
- Occupational therapy requiring the skills of a qualified occupational therapist, provided by an occupational therapist, or under appropriate supervision of a qualified occupational therapist by an occupational therapy assistant as specified in part 484.
- Services of social workers, trained psychiatric nurses, and other staff trained to work with psychiatric patients.
- Drugs and biologicals furnished for therapeutic purposes, subject to the limitations specified in § 410.29.
- Individualized activity therapies that are not primarily recreational or diversionary.
- Family counseling, the primary purpose of which is treatment of the individual's condition.
- Patient training and education, to the extent the training and educational activities are closely and clearly related to the individual's care and treatment.
- Diagnostic services.

The proposed list at § 410.44(a)(4) is based on the list of items and services described in section 1861(ff)(2) of the Act. We note that 1861(ff)(2) of the Act also provides that intensive outpatient services may include such other items and services as the Secretary may provide (but in no event to include meals and transportation). As discussed in section VIII.C of this final rule with comment period, we solicited comments on whether additional codes should be added to the list of services recognized as appropriate for PHP and IOP. We discuss the comments we received and provide our responses in that section of this final rule with comment period, and we note that none of the codes we are adopting in that section of this final rule with comment period necessitate changes to the proposed list at § 410.44(a)(4).

In the proposed rule, we further noted that both the statute at section 1861(ff)(2)(C) of the Act and our proposed regulation at § 410.44(a)(4)(iii) refer to ''trained psychiatric nurses, and other staff trained to work with psychiatric patients.'' We explained that under our longstanding policy for partial hospitalization services, we have considered nurses and other staff trained to work with patients within their state scope of practice who are receiving treatment for SUD to be included under this statutory definition and the regulatory definition of PHP at § 410.43(a)(4). We stated that we have heard from interested parties that there could be a misconception that Medicare does not cover PHP for the treatment of SUD. We are clarifying that, in general, notwithstanding the requirement that PHP services are provided in lieu of inpatient hospitalization, Medicare covers PHP for the treatment of SUD, and we consider services that are for the treatment of SUD and behavioral health generally to be consistent with the statutory and regulatory definition of PHP. We clarified in the proposed rule that the terms ''trained psychiatric nurses, and other staff trained to work with psychiatric patients,'' as used in §§ 410.43(a)(4) and 410.44(a)(4) would include trained SUD nurses and other staff trained to work with SUD patients. Under § 410.44(b), we proposed that the following services are separately covered and not paid as intensive outpatient services: (1) physician services; (2) physician assistant services; (3) nurse practitioner and clinical nurse specialist services; (4) qualified psychologist services; and (5) services furnished to residents of a skilled nursing facility (SNF). We note that these proposed exclusions are consistent with the services excluded from payment as partial hospitalization

program services at § 410.43(b). The services listed under §§ 410.43(b) and 410.44(b) would be paid under the applicable systems for such services.

Lastly, under § 410.44(c), we proposed to establish patient eligibility criteria for intensive outpatient services. Specifically, we proposed that intensive outpatient services are intended for patients who: (1) require a minimum of 9 hours per week of therapeutic services as evidenced in their plan of care; (2) are likely to benefit from a coordinated program of services and require more than isolated sessions of outpatient treatment; (3) do not require 24-hour care; (4) have an adequate support system while not actively engaged in the program; (5) have a mental health diagnosis; (6) are not judged to be dangerous to self or others; and (7) have the cognitive and emotional ability to participate in the active treatment process and can tolerate the intensity of the intensive outpatient program.

We noted that these proposed patient eligibility criteria at § 410.44(c) are consistent with the existing partial hospitalization patient eligibility criteria at § 410.43(c). With respect to the proposed criterion of a ''mental health diagnosis'', we clarified that a mental health diagnosis would include SUD and behavioral health diagnoses generally under both the existing partial hospitalization regulation at § 410.43(c)(5) and the proposed intensive outpatient services regulation at § 410.44(c)(5). As discussed earlier in this section, this inclusion of SUD and behavioral health diagnoses as among the patient eligibility criteria for PHP services is consistent with our longstanding policy. However, we noted that interested parties have raised concerns that this policy may not be clear. Therefore, we clarified that the term ''mental health diagnosis'' as used at both §§ 410.43(c)(5) and 410.44(c)(5) would include SUD and behavioral health diagnoses.

Comment: Commenters suggested the proposed regulation at § 410.44(a)(2) codifying the condition that IOP services ''are reasonably expected to improve or maintain the individual's condition and functional level and to prevent relapse or hospitalization'' be modified. Specifically, commenters suggested the regulation at § 410.44(a)(2) be modified to read as follows: ''Are reasonably expected to improve or maintain the individual's condition and functional level and to prevent relapse or worsening of the individual's condition.'' The commenters stated that as IOP is not provided in lieu of hospitalization, more expansive language may be appropriate.

Response: We appreciate the concern that commenters raised that more expansive language may be appropriate for patients of an IOP. As discussed above, at new § 410.44, we proposed to establish regulatory language for intensive outpatient services that is consistent with the existing language for partial hospitalization conditions and exclusions and the statutory definition of intensive outpatient services. The regulatory language for IOP and PHP is derived from the language of section 1861(ff)(2) of the Act. We do not believe it is appropriate to revise the language for IOP.

Comment: A majority of commenters appreciated the clarification that the terms ''trained psychiatric nurses, and other staff trained to work with psychiatric patients,'' as referenced in § 410.43(a)(4) and proposed § 410.44(a)(4) would include trained SUD nurses and other staff trained to work with SUD patients; however, they requested CMS codify this interpretation in the regulations. Specifically, commenters requested that CMS amend the regulations at § 410.43(a)(4)(i) and (iii), proposed § 410.44(a)(4)(i) and (iii) for PHP and IOP, respectively, to include services furnished by SUD counselors, and reference individuals with mental health or SUD diagnoses. In addition, commenters requested CMS amend § 410.43(c)(5) and proposed § 410.44(c)(5) to reference ''mental health or SUD diagnosis'' as acceptable for both the PHP and IOP benefits.

Response: As discussed in the CY 2024 OPPS/ASC proposed rule (88 FR 49700 and 49701) under our longstanding policy for partial hospitalization services, we have considered nurses and other staff trained to work with patients within their state scope of practice who are receiving treatment for SUD to be included under this statutory definition and the regulatory definition of PHP at § 410.43(a)(4). After consideration of the public comments received, and the misconception we have heard that Medicare does not cover PHP for the treatment of SUD, we are finalizing an amendment the PHP regulations at § 410.43(a)(4)(i) and (iii) to include references to SUD professionals and patients with SUD, respectively. Additionally, we are finalizing a modification to the proposed IOP regulations at §§ 410.44 (a)(4)(i) and 410.43(a)(4)(iii) to include references to SUD professionals and patients with SUD, respectively. Furthermore, we are finalizing a modification to the PHP regulation at § 410.43(c)(5), as well as the proposed IOP regulation at § 410.44(c)(5), to include references to SUD diagnoses.

We remind readers that the inclusion of SUD in these regulations does not change the applicability of any other existing PHP regulations or proposed IOP regulations. In all cases, these services must be reasonable and necessary, furnished in accordance with a physician certification and plan of treatment, and provided by an individual working within his or her scope of practice. Further, in the case of PHP services for the treatment of SUD, such services must be provided in lieu of inpatient hospitalization.

Comment: Some commenters requested that CMS amend the regulation at § 410.43(a)(4)(iii) to specifically reference that the services of marriage and family therapists (MFTs) and mental health counselors (MHCs) comprise a portion of partial hospitalization services; while other commenters requested CMS amend the regulatory exclusions at § 410.43(b) and proposed § 410.44(b) of PHP and IOP, respectively, to encompass the professional services of MFTs and MHCs.

Response: As we discussed in the 2000 OPPS final rule (65 FR 18452), payment for partial hospitalization services under the OPPS represents the provider's overhead costs, support staff, and the services of clinical social workers (CSWs) and occupational therapists (OTs), whose professional services are considered to be partial hospitalization services for which payment is made to the provider. These same components of cost discussed in that 2000 OPPS final rule were used to determine the per diem costs for both PHP and IOP for this CY 2024 OPPS/ASC final rule. Although we did not propose to name MHCs or MFTs in the regulatory language of § 410.43(a) or § 410.44(a), the services of these providers, when furnished to PHP or IOP patients, would constitute services of ''other mental health professionals'' under §§ 410.43(a)(4)(i) and 410.44(a)(4)(i). We did not propose to exclude MHCs or MFTs under § 410.43(b) or § 410.44(b), and in accordance with our longstanding policy, to maintain the historical patterns of treatment billed during the base year, we are clarifying that the services of MFTs and MHCs are considered to be partial hospitalization and intensive outpatient services. The services of MFTs and MHCs should not be billed separately when provided to PHP or IOP patients, because they are included within the overhead costs and costs for support staff which are made

to the provider through the per diem PHP or IOP payment.

Comment: Commenters requested CMS remove the proposed regulation at § 410.44(c)(4) which states an IOP is intended for patients who have an adequate support system while not actively engaged in the program. Commenters noted that while mental health outcomes are enhanced by a patient's support system, many IOP patients have housing insecurities or are at risk of being housing insecure. The commenters stated conditioning treatment on a patient's support system may prohibit patients from enrolling in an IOP.

Response: As discussed in the CY 2009 OPPS/ASC final rule with comment period (73 FR 68695) our goal is to improve the level of service furnished in a PHP day, while also ensuring that the partial hospitalization benefit is being utilized by the appropriate population. In addition, for the program to be fully beneficial, a PHP participant should have a strong support system outside of the PHP program to help to ensure success. We also believe having a strong support system outside of the IOP program to help ensure success will further our goal to improve the level of service across the mental health continuum of care.

Final Decision: After consideration of the public comments we received, we are finalizing the proposed regulations at § 410.44 with modifications to include references to SUD. In addition, we are modifying the parallel existing regulations for PHP at § 410.43 to include the same references to SUD.

b. Coverage of IOP as Medical and Other Health Services Paid under Part B

We proposed to amend the regulation at § 410.10(c) to add a reference to ''intensive outpatient services'' to the list of services that are covered as medical and other health services under Part B, when furnished as hospital or CAH services incident to a physician's professional services. We believe this is consistent with section 1861(s)(2)(B) of the Act, as amended by section 4124(b)(1)(B) of the CAA, 2023 to include ''intensive outpatient services'' under the definition of medical and other health services; specifically, hospital services incident to a physicians' services. We note that the services described at § 410.10(c) are furnished by a hospital or CAH. Accordingly, we proposed conforming changes to the regulations at § 410.27(a)(2) and (e) introductory text to include references to intensive outpatient services.

We did not receive any public comments on our proposal, and we are finalizing our proposal without modification to amend the regulation at § 410.10(c) to add a reference to ''intensive outpatient services'' to the list of services that are covered as medical and other health services under Part B, when furnished as hospital or CAH services incident to a physician's professional services. Additionally, we are finalizing our proposal to codify conforming changes to the regulations at § 410.27(a)(2) and (e) introductory text to include references to intensive outpatient services.

c. Technical Changes to Codify Requirements for IOP at CMHCs

We proposed technical changes to the regulations at 42 CFR parts 488 and 489.

First, we proposed to add the statutory basis for IOP at CMHCs at § 488.2. The proposed technical revision would add section 1832(a)(2)(J) of the Act, which sets forth the statutory basis of intensive outpatient services provided by CMHCs at § 488.2.

We also proposed to revise the provision at 42 CFR 489.2(c)(2) so that CMHCs may enter into provider agreements to furnish intensive outpatient services. We proposed to revise the current requirement that allows for CMHCs to enter into provider agreements only for the provision of partial hospitalization services. The proposed revisions to this provision would allow CMHCs to enter into provider agreements only to furnish partial hospitalization services and intensive outpatient services.

Comment: Commenters expressed concern that there may be a mistaken impression that 42 CFR 489.2 means that the only clinical activities for which an entity enrolled as a CMHC may bill Medicare are PHP and IOP services. The commenters requested CMS clarify that nothing in the CMHC conditions for participation prevents or discourages entities enrolled as CMHCs from also being enrolled in Medicare as Part B suppliers (physician groups) furnishing outpatient behavioral health services covered under the Physician Fee Schedule (PFS).

Response: We thank the commenters for raising concerns about a potential misinterpretation of § 489.2 to mean that an entity enrolled as a CMHC may only bill Medicare for PHP and IOP services. In response to these concerns, we are clarifying that nothing in regulation, including the CMHC conditions of participation, prohibits an entity from enrolling as a CMHC and also enrolling in Medicare as a physician group to provide and bill for outpatient behavioral health services under Medicare Part B. In fact, CMHC conditions of participation at § 485.918(b) require CMHCs to provide a broad array of outpatient behavioral health services to the individuals they serve. When billing for PHP or IOP, the CMHC would submit a facility bill for payment under the OPPS at the applicable PHP or IOP per diem rate. When billing for other outpatient behavioral health services under Medicare Part B, including services for PHP and IOP patients that are excluded under §§ 410.43(b) and 410.44(b) and paid separately, the billing practitioner would bill for the services provided, subject to all applicable billing requirements under the PFS. We also note that CMHC conditions of participation under part 485, subpart J, apply to all patients of the CMHC, so if a patient is discharged from a PHP or IOP and begins receiving behavioral health services billed under Medicare Part B, the CMHC conditions of participation would continue to apply.

Final Decision: After consideration of the public comments we received, we are finalizing our proposals without modification to add the statutory basis for IOP at CMHCs at § 488.2 and to revise the provision at 42 CFR 489.2(c)(2) so that CMHCs may enter into provider agreements to furnish IOP services.

d. Technical Changes to Codify Coverage of IOP at CMHCs

We proposed several technical changes and additions to the regulations at §§ 410.2, 410.3, 410.111, 410.150, and 410.173.

First, we proposed to revise the definition of ''Community Mental Health Center (CMHC)'' at § 410.2 to refer to intensive outpatient services. Specifically, we proposed to revise the regulation to state that a CMHC is an entity that provides day treatment or other partial hospitalization services or intensive outpatient services, or psychosocial rehabilitation services. Second, we proposed to revise the definition of ''Participating'' at § 410.2 to refer to intensive outpatient services as services that CMHCs can provide. Specifically, we proposed that ''Participating'' refers to a CMHC that has in effect an agreement to participate in Medicare, but only for the purposes of providing partial hospitalization services and intensive outpatient services. We clarified that the proposed definition would allow a CMHC to be considered a participating provider of both partial hospitalization services and intensive outpatient services, but would not require a CMHC to provide both

types of services in order to be considered participating.

Comment: Commenters appreciated the clarification that organizations need not furnish both PHP and IOP in order to qualify as a CMHCs and were generally supportive of the proposed regulation at § 410.2 to refer to intensive outpatient services as part of the definition of ''Community Mental Health Center (CMHC)''. However, commenters requested clarification on why the reference to psychosocial rehabilitation is included in the definition of CMHC. The commenters stated their understanding that PHP and IOP are the only two discrete Medicare services for which CMHCs may bill the program under the CMHC enrollment.

Response: We appreciate commenters' support of the proposed definition of CMHC at regulation § 410.2. In response to the comments regarding CMHCs providing psychosocial rehabilitation, as discussed in the 1994 interim final rule with comment period (59 FR 6571) section 1916(c)(4) of the Public Health Service (PHS) Act (42 U.S.C. 300x-4(c)(4)) requires a CMHC to provide specialized outpatient services; 24-hour-a-day emergency care services; day treatment, other partial hospitalization services, or psychosocial rehabilitation services; screenings to determine appropriateness of admission to State mental health facilities; and consultation and education services. Accordingly, in that same interim final rule with comment period (59 FR 6577) CMS (formerly known as Health Care Financing Administration (HCFA)) finalized the definition of CMHC in regulation at § 410.2 to include an entity that provides psychosocial rehabilitation services.

In addition, we proposed to revise the scope of benefits provision at § 410.3(a)(2) to provide that the covered services for which the Medicare Part B supplementary medical insurance (SMI) program helps pay include partial hospitalization services and intensive outpatient services provided by CMHCs. We believe these proposed changes are consistent with the scope of benefits provision at section 1832(a)(2)(J) of the Act, as amended by section 4124(b)(1)(A) of the CAA, 2023 to include intensive outpatient services, as well as the proposed CMHC conditions of participation at § 485.918(b)(1)(iii). We refer readers to section XVII.B.5 of this final rule with comment period for discussion on the proposed amendments to regulations at § 485.918(b)(1)(iii).

We did not receive any public comments on our proposal and are finalizing a revision to the scope of benefits provision at § 410.3(a)(2) to provide that the covered services for which the Medicare Part B supplementary medical insurance (SMI) program helps pay include partial hospitalization services and intensive outpatient services provided by CMHCs.

In addition, subpart E of part 410 includes requirements for Community Mental Health Centers (CMHCs) Providing Partial Hospitalization Services. We proposed to modify the subpart E heading to include a reference to intensive outpatient services as well. Under subpart E, we proposed to add a new § 410.111 to set forth Requirements for coverage of intensive outpatient services furnished in CMHCs. We proposed that Medicare Part B would cover IOP services furnished by or under arrangements made by a CMHC if the CMHC has in effect a provider agreement and the services are prescribed by a physician and furnished under the general supervision of a physician, and subject to the proposed physician certification and plan of care requirements under § 424.24(d).

We did not receive any public comments on our proposals and are finalizing a modification to the subpart E heading to include a reference to intensive outpatient services, and the addition of a new § 410.111 to set forth Requirements for coverage of intensive outpatient services furnished in CMHCs.

Additionally, we proposed to revise § 410.150(b)(13) to include a reference to intensive outpatient services. Specifically, we proposed that payment would be made to a CMHC on an individual's behalf for partial hospitalization services or intensive outpatient services furnished by or under arrangements made by the CMHC.

We did not receive any public comments on our proposal and are finalizing a revision to § 410.150(b)(13) to include a reference to intensive outpatient services.

We also proposed to add a new § 410.173 to establish conditions of payment for IOP services furnished in CMHCs. We proposed to state that Medicare Part B pays for intensive outpatient services furnished in a CMHC on behalf of an individual only if the following conditions are met: (a) The CMHC files a written request for payment on the CMS form 1450 and in the manner prescribed by CMS; and (b) The services are furnished in accordance with the requirements described in § 410.111.

We did not receive any public comments on our proposal and are finalizing the addition of § 410.173 as proposed.

Lastly, we proposed to amend § 419.21(c) to refer to intensive outpatient services provided by CMHCs as services for which payment is made under the OPPS. The proposed amendment would be consistent with current regulations at § 419.21(c), which include partial hospitalization services provided by CMHCs. We note that further discussion of the payment methodology under the OPPS for intensive outpatient services is found in section VIII.D of this final rule with comment period.

Final Decision: After consideration of the public comments we received, we are finalizing the proposed technical changes and additions to the regulations at §§ 410.2, 410.3, 410.111, 410.150, and 419.21 as proposed.

e. Exclusion of Intensive Outpatient Services From the Outpatient Mental Health Treatment Limitation

Section 1833(c)(2) of the Act, as amended by section 4124(b)(3) of the CAA, 2023, excludes intensive outpatient services that are not directly provided by a physician from the term ''treatment'' for the purposes of the outpatient mental health treatment limitation under section 1833(c)(1) of the Act, similar to partial hospitalization services. Accordingly, we proposed to amend the regulations at § 410.155(b)(2)(iii) to state that intensive outpatient services not directly provided by a physician are not subject to the outpatient mental health treatment limitation.

Comment: Commenters were supportive of the proposal to amend the regulations at § 410.155(b)(2)(iii) to state that intensive outpatient services not directly provided by a physician are not subject to the outpatient mental health treatment limitation. However, commenters requested clarification whether the proposed regulation at 42 CFR 410.155(b)(2)(iii) means that the mental health treatment limitation does not apply to the professional services furnished to PHP or IOP participants, under the PHP or IOP plan of care, by clinicians other than physicians even though those services are billed under the Part B PFS rather than the OPPS.

Response: Under § 410.155(b)(1), services furnished by physicians and other practitioners, whether furnished directly or incident to those practitioners' services, are subject to the limitation if they are furnished in connection with the treatment of a mental, psychoneurotic, or personality disorder and are furnished to an individual who is not an inpatient of a hospital. This includes services furnished directly by physicians to PHP

and IOP patients. However, we are clarifying that since CY 2014, under current regulation at § 410.155(a)(5), 100 percent of the expenses incurred for such services during a calendar year are considered incurred expenses under Medicare Part B when determining the amount of payment and deductible.

Final Decision: After consideration of the public comments we received, we are finalizing without modification our proposed regulations at § 410.155(b)(2)(iii) to state that intensive outpatient services not directly provided by a physician are not subject to the outpatient mental health treatment limitation.

3. IOP Certification and Plan of Care Requirements

Section 4124(b)(2)(B) of the CAA, 2023 amended section 1861(ff) of the Act by adding a new paragraph (4) to define intensive outpatient services as the items and services prescribed by a physician for an individual determined (not less frequently than once every other month) by a physician to have a need for such services for a minimum of 9 hours per week. This certification must occur no less frequently than once every other month, and there is no requirement to certify that IOP patients would need inpatient hospitalization if they did not receive such services, which is required for PHP patients.

We proposed to codify the content of the certification and plan of treatment requirements for intensive outpatient services at § 424.24(d). Specifically, we proposed to mirror the PHP content of certification and plan of care treatment requirements at § 424.24(e), with the following exceptions: require the content of certification to include documentation that the individual requires such services for a minimum of 9 hours per week (with no requirement for the patient to need inpatient psychiatric care if the IOP services were not provided). The physician's certification of the patient's need for either IOP or PHP services should be based on the physician's determination of the patient's needs and whether the patient meets the IOP or PHP patient eligibility criteria under § 410.44(c) or § 410.43(c), respectively. We noted that the physician's certification should certify the patient's need for either IOP or PHP, and that patients participating in an IOP or PHP should not be under any other IOP or PHP plan of care for the same date of service. The patient's individualized plan of treatment should address all of the conditions that are being treated by the IOP or PHP.

Comment: Commenters disagreed that the certification for IOP services should be limited to a physician. Commenters requested that CMS explicitly allow psychiatric nurse practitioners to certify the need for IOP services and plan of care.

Response: We understand the commenter's request to expand the certification of IOP services to non-physician mental health professionals. However, section 1861(ff) of the Act, as amended by section 4124(b)(2)(B) of the CAA, 2023, specifically states the certification must be determined by a physician. Section 1861(r) of the Act defines ''physician'' as a doctor of medicine or osteopathy legally authorized to practice medicine and surgery by the State in which he performs such function or action. Therefore, we do not believe we have the ability to expand the certification of the need for IOP services to psychiatric nurse practitioners or other mental health professionals.

Comment: A few commenters requested that CMS revise the minimum hours per week for the IOP program from 9 hours per week to 6 hours per week. The commenters stated that IOPs should be highly flexible and reducing the number of required hours would allow a patient to ''step down'' within the confines of IOP treatment, without immediately jumping to individual mental health services.

Response: We appreciate the commenter's suggestions to provide greater flexibility within the mental health continuum of care. However, section 1861(ff) of the Act, as amended by section 4124(b)(2)(B) of the CAA, 2023 specifically states that a patient must require a minimum of 9 hours of IOP services per week. As discussed in section VIII.D.3 of this final rule with comment period, we proposed to apply the three-service payment rate (that is, payment for PHP APCs 5853 for CMHCs and 5863 for hospitals, and IOP APCs 5851 for CMHCs and 5861 for hospitals) for days with three or fewer services while we monitor the initial utilization of IOP services. In addition, patients who do not meet the requirement of needing at least 9 hours per week of IOP services may still receive individual mental health services under the OPPS.

Additionally, we proposed to require in the regulation at § 424.24(d)(3)(ii) that the recertification of IOP services occur no less frequently than every 60 days. We stated that we believe the IOP recertification timing of no less frequently than every 60 days is consistent with the requirement in the statute that an individual be determined by a physician to have a need for IOP services ''not less frequently than once every other month'' because the minimum number of days for two consecutive months is 59 days. We stated that we believe that a consistent 60-day interval would be the most appropriate way to implement the statutory recertification requirement for IOP.

We solicited public comments on whether it would be appropriate to consider finalizing a shorter interval for the first recertification and for subsequent recertification for IOP patients. For example, we requested comments on whether we should consider requiring an initial recertification by the 30th day of IOP services, and no less frequently than every 60 days thereafter. We requested that commenters provide as much detail as possible about the rationale for a shorter recertification interval, if appropriate.

Lastly, we proposed to make conforming changes to § 424.24(b) to add a reference to paragraph (d)(1) in the list of paragraphs that specify the content for which physician certification is required for medical and other health services furnished by providers (and not exempted under § 424.24(a)) which are paid for under Medicare Part B.

Comment: Most commenters supported the proposal to require in the regulation at § 424.24(d)(3)(ii) that the recertification of IOP services occur no less frequently than every 60 days. These commenters agreed that the proposal is consistent with the CAA, 2023 requirements and that a shorter than 60-day recertification interval for IOP patients would not be beneficial.

A few other commenters stated the recertification interval should be no less frequently than every 30 days. The commenters advocating for a 30-day recertification interval argued that patients at the IOP level of care should be in a significantly more stable condition than at the PHP level of care, and after 30 days of service, should continue to improve their stability. Further, the commenters stated a 60-day recertification interval may encourage a longer length of stay and go against the preference for always keeping the patient at the least restrictive level of care.

Response: We appreciate the input from commenters. As we stated in the CY 2024 OPPS/ASC proposed rule (88 FR 49702) we believe that a consistent 60-day interval would be the most appropriate way to implement the statutory recertification requirement for IOP. We intend to monitor the provision of services and lengths of stay in the IOP program, and may consider changes to

the IOP recertification interval, if necessary, in future rulemaking.

Final Decision: After consideration of the public comments we received, we are finalizing, without modification, our proposal to codify the content of the certification and plan of treatment requirements for intensive outpatient services at § 424.24(d).

C. Coding and Billing for PHP and IOP Services Under the OPPS

1. Condition Code 41 and 92

In the CY 2024 OPPS/ASC proposed rule, we explained that we considered the similarities between the types of items and services covered by both PHP and IOP, and the larger continuum of care, when developing the proposed list of services that we believe would appropriately identify the range of services that IOPs provide to Medicare beneficiaries. Since the statutory definitions of both IOP and PHP generally include the same types of items and services covered, we stated that we believe it is appropriate to align the programs using a consistent list of services, so that level of intensity would be the only differentiating factor between partial hospitalization services and intensive outpatient services.

We noted that currently, hospital outpatient departments use condition code 41 to indicate that a claim is for partial hospitalization services. CMHCs do not currently use a condition code on the bill type used—that is, 76X—to indicate that a claim is for partial hospitalization services, because they are only considered a provider of services for partial hospitalization; and therefore, partial hospitalization services are identified by the 76X bill type. We explained that in order to differentiate between IOP and PHP for billing purposes, the National Uniform Billing Committee (NUBC) has approved a new condition code, condition code 92, to identify intensive outpatient claims. Therefore, we proposed to require hospitals and CMHCs to report condition code 92 on claims to indicate that a claim is for intensive outpatient services. We proposed to continue to require hospitals to report condition code 41 for partial hospitalization claims. Additionally, because CMHCs would be permitted to provide both PHP and IOP beginning January 1, 2024, we also proposed to require CMHCs to report condition code 41 for partial hospitalization claims. We stated that we believe this requirement would better allow us to identify which claims are for PHP and which are for IOP. We solicited comment on these proposed reporting requirements for PHP and IOP.

Comment: Commenters supported the proposal that hospitals and CMHCs report condition code 41 to identify partial hospitalization claims, and condition code 92 to identify intensive outpatient claims. The commenters agreed with the importance of distinguishing between PHP and IOP claims.

Response: We appreciate the commenters' support. Beginning January 1, 2024, we will require the use of condition code 41 on all PHP claims from hospitals and CMHCs and require the use of condition code 92 on all IOP claims from hospitals and CMHCs. We will issue operational guidance explaining the use of these condition codes in further detail.

2. Proposed HCPCS Coding for CY 2024

Under current policy, PHPs submit claims with HCPCS codes to identify the services provided during each PHP day. Therefore, we worked in conjunction with physicians to develop a consolidated list of all HCPCS codes that we believe would appropriately identify the full range of services that both IOPs and PHPs provide to Medicare beneficiaries. For reference, Table 42 includes the current list of HCPCS codes that are recognized for PHP payment. For CY 2024, we proposed to add certain codes to the list, change the descriptions of other codes, and remove one code from the list. The list of proposed consolidated HCPCS codes is included in Table 96.

We recognize that the level of intensity of mental health services a patient requires may vary over time; therefore, we believe utilizing a consolidated list of HCPCS codes to identify services under both the IOP and PHP benefits would ensure a smooth transition for patients when a change in the intensity or their services is necessary to best meet their needs. For example, a patient receiving IOP services may experience an acute mental health need that necessitates more intense services through a PHP. Alternatively, an IOP patient that no longer requires the level of intensity provided by the IOP can access less intense mental health services, such as individual mental health services. Therefore, we proposed to add several HCPCS codes that are currently recognized as mental health codes under the OPPS, but are not recognized as PHP codes, to the list of codes that would be recognized for PHP payment. We proposed to maintain all of the existing PHP codes, except for one. We proposed to remove 90865 Narcosynthesis, because we stated that we do not believe this code is widely used in the provision of PHP, and we do not anticipate it would be widely used in the provision of IOP in the future. We proposed that the HCPCS codes listed in Table 43 of the CY 2024 OPPS/ASC proposed rule (88 FR 49704 and 49705) would be payable when furnished by PHPs or IOPs. For reference, this list of codes is reproduced in Table 96 of this final rule with comment period.

BILLING CODE 4150–28–P

TABLE 96: PROPOSED HCPCS APPLICABLE FOR PHP AND IOP

HCPCS/CPT	Short Descriptor	Proposed Action
90785	Psytx complex interactive	
90791	Psych diagnostic evaluation	
90792	Psych diag eval w/med srvcs	
90832	Psytx pt&/family 30 minutes	
90833	Psytx pt&/fam w/e&m 30 min	
90834	Psytx pt&/family 45 minutes	
90836	Psytx pt&/fam w/e&m 45 min	
90837	Psytx pt&/family 60 minutes	
90838	Psytx pt&/fam w/e&m 60 min	
90839	Psytx crisis initial 60 min	Add
90845	Psychoanalysis	
90846	Family psytx w/o patient	
90847	Family psytx w/patient	
90849	Multiple family group psytx	Add
90853	Group psychotherapy	Add
90865	Narcosynthesis	Remove
90880	Hypnotherapy	
90899	Psychiatric service/therapy	Add
96112	Devel tst phys/qhp 1st hr	Add
96116	Neurobehavioral status exam	
96130	Psychological testing evaluation by physician/qualified health care professional; first hour	
96131	Psychological testing evaluation by physician/qualified health care professional; each additional hour	
96132	Neuropsychological testing evaluation by physician/qualified health care professional; first hour	
96133	Neuropsychological testing evaluation by physician/qualified health care professional; each additional hour	
96136	Psychological/neuropsychological testing by physician/qualified health care professional; first 30 minutes	

HCPCS/CPT	Short Descriptor	Proposed Action
96137	Psychological/neuropsychological testing by physician/qualified health care professional; each additional 30 minutes	
96138	Psychological/neuropsychological testing by technician; first 30 minutes	
96139	Psychological/neuropsychological testing by technician; each additional 30 minutes	
96146	Psychological/neuropsychological testing; automated result only	
96156	Hlth bhv assmt/reassessment	Add
96158	Hlth bhv ivntj indiv 1st 30	Add
96164	Hlth bhv ivntj grp 1st 30	Add
96167	Hlth bhv ivntj fam 1st 30	Add
97151	Bhv id assmt by phys/qhp	Add
97152	Bhv id suprt assmt by 1 tech	Add
97153	Adaptive behavior tx by tech	Add
97154	Grp adapt bhv tx by tech	Add
97155	Adapt behavior tx phys/qhp	Add
97156	Fam adapt bhv tx gdn phy/qhp	Add
97157	Mult fam adapt bhv tx gdn	Add
97158	Grp adapt bhv tx by phy/qhp	Add
G0129	PHP/IOP OT service	Update
G0176	Opps/php/IOP; activity thrpy	Update
G0177	Opps/php/IOP; train & educ	Update
G0410	Grp psych PHP/IOP 45-50	Update
G0411	Interactive grp psyc PHP/IOP	Update
G0451	Development test interpt&rep	Add

We proposed to add 18 codes to the list of recognized PHP/IOP codes, as shown in Table 96 of this final rule with comment period. These codes are currently recognized as mental health codes under the OPPS, and we stated we believe it would be appropriate to recognize them for PHP and IOP as well. Additionally, we proposed to update the descriptions of five existing Level II HCPCS codes that are currently recognized for PHP to also refer to IOP.

As shown in Table 96, we proposed to add CPT code 90853 Group psychotherapy to the list of service codes recognized for PHP and IOP. We stated we believe there could be overlap between 90853 and two existing Level II HCPCS codes for PHP group psychotherapy, specifically G0410 and G0411. We stated that we considered whether it would be appropriate to remove G0410 and G0411 from the list of recognized service codes for PHP and IOP, and retain only CPT code 90853. We solicited comments on this topic, and were interested in hearing specific reasons commenters believe support either keeping G0410 and G0411 on the list or removing them. We stated that we were particularly interested in understanding whether it would be appropriate to maintain these codes on a temporary basis to provide a transition for existing PHPs that are using these codes.

We proposed to use the list of HCPCS codes in Table 96 to determine the number of services per PHP or IOP day, and therefore to determine the APC per diem payment amount for each day, as discussed in section VIII.D of this final rule with comment period. In addition, as discussed in section VIII.D of this final rule with comment period, we proposed to calculate the costs for 3-service and 4-service days based on the list of HCPCS codes in Table 96. We reminded readers that currently, to qualify for payment at the applicable PHP APC (5853 or 5863) one service must be from the Partial Hospitalization Primary list, and we identified the services that are currently included in the Partial Hospitalization Primary list along with those which we proposed to add based on our analysis of the services included on days with three and four services from the proposed list shown in Table 96 of this final rule with comment period. We proposed to maintain this requirement for CY 2024 and subsequent years to qualify for payment at the PHP or IOP APC. Thus, we proposed that to qualify for payment for an IOP APC, at least one service must be from the Partial Hospitalization and Intensive Outpatient Primary list. Specifically, we proposed that to qualify for payment for the IOP APC (5851, 5852, 5861 or 5862) or the PHP APC (5853, 5854, 5863, or 5864) one service must be from the Partial Hospitalization and Intensive Outpatient Primary list, which is reproduced in Table 97 of this final rule with comment period for reference.

TABLE 97: PROPOSED PARTIAL HOSPITALIZATION AND INTENSIVE OUTPATIENT PRIMARY SERVICES

HCPCS/CPT	Short Descriptor	Proposed Action
90832	Psytx pt&/family 30 minutes	
90834	Psytx pt&/family 45 minutes	
90837	Psytx pt&/family 60 minutes	
90845	Psychoanalysis	Add
90846	Family psytx w/o patient	
90847	Family psytx w/patient	
90853	Group psychotherapy	Add
90865	Narcosynthesis	Remove
90880	Hypnotherapy	
96112	Devel tst phys/qhp 1st hr	Add
96116	Neurobehavioral status exam	Add
96130	Psychological testing evaluation by physician/qualified health care professional; first hour	Add
96132	Neuropsychological testing evaluation by physician/qualified health care professional; first hour	Add
96136	Psychological/neuropsychological testing by physician/qualified health care professional; first 30 minutes	Add
96138	Psychological/neuropsychological testing by technician; first 30 minutes	Add
G0410	Grp psych partial hosp/IOP 45-50	Update
G0411	Inter active grp psych PHP/IOP	Update

BILLING CODE 4150–28–C

Lastly, we proposed that in the future, in the event there are new codes that represent the PHP and IOP services described under §§ 410.43(a)(4) and 410.44(a)(4), respectively, we would add such codes to Table 96 through sub-regulatory guidance, and that these codes would be payable when furnished by a PHP or IOP. We note that coding updates frequently occur outside of the standard rulemaking timeline. We proposed this sub-regulatory process in order to pay expeditiously when new codes are created that describe any of the services enumerated at §§ 410.43(a)(4) and 410.44(a)(4), which PHPs and IOPs, respectively, would provide. We would identify codes to be added sub-regulatorily if a new code is cross-walked to a previously included code, or if the code descriptor is substantially similar to a descriptor for a code on the list or describes a service on the list. We proposed that any additional services not described at § 410.43(a)(4) or § 410.44(a)(4) would be added to the lists in regulation through notice and comment rulemaking.

We invited public comment on the proposed consolidated list of HCPCS codes that would be payable when furnished in a PHP and IOP. As discussed in the following section of this CY 2024 OPPS/ASC final rule, we also solicited comment on any additional codes that we should consider adding. Specifically, we stated that we were interested in hearing from commenters if there are any other existing codes that CMS should consider adding to the list, or new codes that CMS should consider creating, to describe specific services not appropriately described by the codes shown in Table 96 of this final rule with comment period.

Comment: Commenters supported the removal of 90865 Narcosynthesis and agreed this code is not widely used in the provision of PHP. The commenters also supported a consolidated list of HCPCS codes that would align both the PHP and IOP benefits.

Response: We appreciate the commenters' support. After consideration of the public comments we received, we are finalizing the removal of 90865 Narcosynthesis from the list of HCPCS codes applicable for PHP and IOP.

Comment: One commenter expressed support for adding 90839 (Psytx crisis initial 60 min) to the PHP and IOP code list, but also requested that CMS include 90840 (Psytx crisis ea addl 30 min) to recognize the time associated with additional crisis psychotherapy services.

Response: We appreciate the commenter's suggestion, and we agree that this code would be appropriate to recognize for PHP and IOP. We have

included 90840 (Psytx crisis ea addl 30 min) in Table 98 of this final rule with comment period.

Comment: Commenters supported adding 90853 (Group psychotherapy) as well as maintaining G0410 (Grp psych partial hosp/IOP 45–50) and G0411 (Inter active grp psych PHP/IOP) on the list of HCPCS codes applicable to PHP and IOP. The commenters stated there are differences in the application and descriptions between these codes. Accordingly, commenters stated including codes G0410, G0411, and 90853 on the list would avoid unintentional billing errors.

Response: We appreciate the commenters' input. After consideration of the public comments we received, we are finalizing adding code 90853 Group psychotherapy and maintaining G0410 and G0411 on the list of HCPCS codes applicable to PHP and IOP. We intend to monitor the utilization of these codes and may consider changes in future rulemaking, if necessary.

Comment: Commenters supported adding codes to the list of HCPCS applicable for PHP and IOP through a sub-regulatory process when the codes added describe a service already enumerated at § 410.43(a)(4) or § 410.44(a)(4).

Response: We appreciate the commenters' support. After consideration of the public comments we received, we are finalizing our proposal to add codes to the list of HCPCS applicable for PHP and IOP through a sub-regulatory process when the codes to be added describe a service already enumerated at § 410.43(a)(4) or § 410.44(a)(4).

Comment: Commenters did not support the proposal requiring that to qualify for payment for the IOP APC (5851, 5852, 5861 or 5862) one service must be from the Partial Hospitalization and Intensive Outpatient Primary list. The commenters stated that the requirement of a primary service may undermine the flexibility to provide the full scope of services within IOP. Commenters suggested CMS review utilization data to determine which services should be added or removed from the Partial Hospitalization and Intensive Outpatient Primary Services list.

Response: While we appreciate commenters' input, we disagree that requiring one service from the Partial Hospitalization and Intensive Outpatient Primary list in order to qualify for payment for under IOP may undermine the flexibility to provide the full scope of services. To ensure program integrity, we expect that at least one of the services on the Partial Hospitalization and Intensive Outpatient Primary list will be indicated per day for patients who need the level of care offered by a PHP or IOP program.

Final Decision: After consideration of the public comments we received, we are finalizing our proposal to add code 90853 Group psychotherapy, as well as to maintain G0410 and G0411 on the list of HCPCS codes applicable to PHP and IOP, as well as to add additional codes describing a service already enumerated at § 410.43(a)(4) or § 410.44(a)(4) through a sub-regulatory process.

Further, we are finalizing that at least one service must be from the Partial Hospitalization and Intensive Outpatient Primary Services list to qualify for payment for the PHP or IOP APC. The final list of Partial Hospitalization and Intensive Outpatient Primary Services is found in table 99 of this final rule with comment period.

3. Additional HCPCS Codes Considered for CY 2024 in Response to Comments

As we noted in the prior section, we solicited comment in the CY 2024 OPPS/ASC proposed rule on any additional codes that we should consider adding to the list of HCPCS Applicable for PHP and IOP. Specifically, we stated that we were interested in hearing from commenters if there are any other existing codes that CMS should consider adding to the list, or new codes that CMS should consider creating, to describe specific services not appropriately described by the codes shown in Table 96 of this final rule with comment period.

We provided some examples of such services for public consideration and comment, including caregiver-focused services, services of peer support specialists, and services related to discharge planning and care coordination. In addition, commenters suggested additional services for consideration, as discussed in the following sections.

a. Caregiver-Focused Services

In the proposed rule, we explained that we were particularly interested in whether it would be appropriate to include caregiver-focused services in the list of recognized services for PHP and IOP. We identified and solicited comment on including the following HCPCS codes describing services related to caregivers:

- 96202 multiple -family group behavior management/modification training for parents(s) guardians(s) caregivers(s) with a mental or physical health diagnosis, administered by a physician or other QHP without the patient present, face to face up to 60 minutes.
- 96203 each additional 15 minutes.
- 96161 administration of caregiver-focused health risk assessment instrument (that is, depression inventory) for the benefit of the patient, with scoring and documentation, per standardized instrument.
- 9X015 CAREGIVER TRAINING 1ST 30 MIN
- 9X016 CAREGIVER TRAINING EA ADDL 15
- 9X017 GROUP CAREGIVER TRAINING

We noted that the CMHC conditions of participation at § 485.916(b) and (c) already include references to the role of caregivers in the development and implementation of the individualized treatment plan for PHP patients, and we referred readers to section XVII.B.4 of the CY 2024 OPPS/ASC proposed rule for discussion of proposed amendments to the regulations at § 485.916(d). We solicited comments on whether it would be appropriate to include costs for such services in the calculation of PHP and IOP per diem payment rates. We noted that if we were to include such services, we believe it would be appropriate to exclude them from the determination of the number of services provided per day, but we could include such services in the calculation of cost per day for determining the PHP and IOP payment rates.

Comment: Many commenters supported the inclusion of caregiver-focused services, such as codes 96202, 96203, 96161, 9X015, 9X016, and 9X017, in the list of recognized services for PHP and IOP. A majority of commenters advocated for both including caregiver-focused services in the cost per day and in the determination of the number of services provided per day. One commenter supported including caregiver-focused services in the cost per day but excluding them from the determination of number of services provided per day.

Response: In light of commenters' input, we are adopting the identified codes for caregiver-focused services in the final consolidated list of HCPCs codes recognized for PHP and IOP. We note that placeholder codes 9X015, 9X016, and 9X017 have been replaced with CPT codes 97550, 97551, and 97552 respectively. We believe that including caregiver services as covered under the PHP and IOP benefits supports the directive to consider family caregivers across policies and programs under the Executive Order on Increasing

Access to High-Quality Care and Supporting Caregivers.[163]

We believe that these services can be appropriately considered patient training and education services under §§ 410.43(a)(4)(vii) and 410.44(a)(4)(vii), and therefore we are not making any changes to the conditions and exclusions for PHP or IOP in adopting these codes. When these codes are reported, they will not count toward payment for a 3-service or 4-service day; however, we will include the costs associated with providing such services when calculating the PHP and IOP payment rates in future years.

b. Discharge and Transition Planning

In addition, we solicited comments on whether it would be appropriate to add services related to coordinating a patient's discharge from a PHP or IOP, or their transition from one level of care to another. We note that current regulations require physicians, hospitals, and CMHCs to address discharge planning for PHP patients, and we proposed the same requirements for IOP patients. Specifically, physician recertification requirements for PHP at § 424.24(e)(3)(iii)(C) state that the physician's recertification must address treatment goals for coordination of services to facilitate discharge from the partial hospitalization program. We noted that we proposed the same requirement for IOP at § 424.24(d)(3)(iii)(C), which we are finalizing in this final rule. Additionally, hospital CoPs at § 482.43, which apply to hospital outpatient departments providing PHP and IOP, and CMHC CoPs at § 485.914(e), require appropriate discharge planning to meet each patient's needs. We solicited comments on whether the proposed codes shown in Table 96 of this final rule with comment period represent the services that PHPs and IOPs provide to support transition and discharge planning for their patients, or whether we should consider additional codes. We asked commenters to provide as much detail as possible about the nature of any additional services, and whether there are any existing codes that could describe such services.

Comment: Commenters supported the inclusion of services related to discharge and transition between one level of care to another. Specifically, commenters suggested codes for discharge-related services, care coordination, and case management services, such as 99484 (Coordinated care services/care coordination). One commenter suggested codes 99424–99427 (Principal care management services), 99437 and 99439 (Chronic care management services), and 99489–99491 (Complex chronic care management services). Commenters stated these services are especially important for patients with co-occurring conditions that are being treated in multiple settings simultaneously. Several commenters recommended that CMS recognize proposed coding for Principal Illness Navigation (PIN), social determinants of health (SDOH) risk assessment, and community health integration (CHI) under the Physician Fee Schedule as PHP and IOP codes.

Response: We thank commenters for their suggestions to consider adopting PIN, CHI, and SDOH risk assessment codes, which are described in the CY 2024 Physician Fee Schedule proposed rule (88 FR 52325 through 52336), for inclusion in the list of PHP and IOP codes. As discussed in the CY 2024 PFS proposed rule (88 FR 52325), the proposed PIN, CHI, and SDOH risk assessment codes are intended to better identify and value practitioners' work when they incur additional time and resources helping patients with serious illnesses navigate the healthcare system or removing health-related social barriers that are interfering with the practitioner's ability to execute a medically necessary plan of care.

CMS proposed the following descriptions for CHI codes:

GXXX1 Community health integration services performed by certified or trained auxiliary personnel, including a community health worker, under the direction of a physician or other practitioner; 60 minutes per calendar month, in the following activities to address social determinants of health (SDOH) need(s) that are significantly limiting ability to diagnose or treat problem(s) addressed in an initiating E/M visit:

- *Person-centered assessment, performed to better understand the individualized context of the intersection between the SDOH need(s) and the problem(s) addressed in the initiating E/M visit.*

++ *Conducting a person-centered assessment to understand patient's life story, strengths, needs, goals, preferences and desired outcomes, including understanding cultural and linguistic factors.*

++ *Facilitating patient-driven goalsetting and establishing an action plan.*

++ *Providing tailored support to the patient as needed to accomplish the practitioner's treatment plan.*

- *Practitioner, Home-, and Community-Based Care Coordination.*

++ *Coordinating receipt of needed services from healthcare practitioners, providers, and facilities; and from home- and community-based service providers, social service providers, and caregiver (if applicable).*

++ *Communication with practitioners, home- and community-based service providers, hospitals, and skilled nursing facilities (or other health care facilities) regarding the patient's psychosocial strengths and needs, functional deficits, goals, preferences, and desired outcomes, including cultural and linguistic factors.*

++ *Coordination of care transitions between and among health care practitioners and settings, including transitions involving referral to other clinicians; follow-up after an emergency department visit; or follow-up after discharges from hospitals, skilled nursing facilities or other health care facilities.*

++ *Facilitating access to community-based social services (e.g., housing, utilities, transportation, food assistance) to address the SDOH need(s).*

- *Health education—Helping the patient contextualize health education provided by the patient's treatment team with the patient's individual needs, goals, and preferences, in the context of the SDOH need(s), and educating the patient on how to best participate in medical decision-making.*

- *Building patient self-advocacy skills, so that the patient can interact with members of the health care team and related community-based services addressing the SDOH need(s), in ways that are more likely to promote personalized and effective diagnosis or treatment.*

- *Health care access/health system navigation*

++ *Helping the patient access healthcare, including identifying appropriate practitioners or providers for clinical care and helping secure appointments with them.*

- *Facilitating behavioral change as necessary for meeting diagnosis and treatment goals, including promoting patient motivation to participate in care and reach person-centered diagnosis or treatment goals.*

- *Facilitating and providing social and emotional support to help the patient cope with the problem(s) addressed in the initiating visit, the SDOH need(s), and adjust daily routines to better meet diagnosis and treatment goals.*

[163] *https://www.whitehouse.gov/briefing-room/presidential-actions/2023/04/18/executive-order-on-increasing-access-to-high-quality-care-and-supporting-caregivers/.*

• *Leveraging lived experience when applicable to provide support, mentorship, or inspiration to meet treatment goals.*

GXXX2—Community health integration services, each additional 30 minutes per calendar month (List separately in addition to GXXX1).

CMS proposed the following description for PIN codes:

GXXX3 Principal Illness Navigation services by certified or trained auxiliary personnel under the direction of a physician or other practitioner, including a patient navigator or certified peer specialist; 60 minutes per calendar month, in the following activities:

• *Person-centered assessment, performed to better understand the individual context of the serious, high-risk condition.*

++ *Conducting a person-centered assessment to understand the patient's life story, strengths, needs, goals, preferences, and desired outcomes, including understanding cultural and linguistic factors.*

++ *Facilitating patient-driven goal setting and establishing an action plan.*

++ *Providing tailored support as needed to accomplish the practitioner's treatment plan.*

• *Identifying or referring patient (and caregiver or family, if applicable) to appropriate supportive services.*

• *Practitioner, Home, and Community-Based Care Coordination*

++ *Coordinating receipt of needed services from healthcare practitioners, providers, and facilities; home- and community-based service providers; and caregiver (if applicable).*

++ *Communication with practitioners, home-, and community-based service providers, hospitals, and skilled nursing facilities (or other health care facilities) regarding the patient's psychosocial strengths and needs, functional deficits, goals, preferences, and desired outcomes, including cultural and linguistic factors.*

++ *Coordination of care transitions between and among health care practitioners and settings, including transitions involving referral to other clinicians; follow-up after an emergency department visit; or follow-up after discharges from hospitals, skilled nursing facilities or other health care facilities.*

++ *Facilitating access to community-based social services (e.g., housing, utilities, transportation, food assistance) as needed to address SDOH need(s).*

• *Health education—Helping the patient contextualize health education provided by the patient's treatment team with the patient's individual needs, goals, preferences, and SDOH need(s), and educating the patient (and caregiver if applicable) on how to best participate in medical decision-making.*

• *Building patient self-advocacy skills, so that the patient can interact with members of the health care team and related community-based services (as needed), in ways that are more likely to promote personalized and effective treatment of their condition.*

• *Health care access/health system navigation.*

++ *Helping the patient access healthcare, including identifying appropriate practitioners or providers for clinical care, and helping secure appointments with them.*

++ *Providing the patient with information/resources to consider participation in clinical trials or clinical research as applicable.*

• *Facilitating behavioral change as necessary for meeting diagnosis and treatment goals, including promoting patient motivation to participate in care and reach person-centered diagnosis or treatment goals.*

• *Facilitating and providing social and emotional support to help the patient cope with the condition, SDOH need(s), and adjust daily routines to better meet diagnosis and treatment goals.*

• *Leverage knowledge of the serious, high-risk condition and/or lived experience when applicable to provide support, mentorship, or inspiration to meet treatment goals.*

GXXX4—Principal Illness Navigation services, additional 30 minutes per calendar month (List separately in addition to GXXX3).

CMS proposed the following description for SDOH risk assessment:

GXXX5, Administration of a standardized, evidence-based Social Determinants of Health Risk Assessment, 5–15 minutes, not more often than every 6 months

We note that placeholder codes GXXX1 and GXXX2 have been replaced with GCPCS codes G0019 and G0022, respectively; placeholder codes GXXX3 and GXXX4 have been replaced with HCPCS codes G0023 and G0024 respectively; and placeholder code GXXX5 has been replaced with HCPCS code G0136.

As described above, all of these proposed codes include activities related to addressing social needs. Both PIN and CHI include certain care coordination activities and care transitions for the patient. However, there are distinct differences in the primary focus of PIN and CHI codes. As discussed in the CY 2024 PFS proposed rule (88 FR 52334), CMS proposed that in order to bill for PIN, time spent providing such services must be documented in the medical record in its relationship to the serious, high-risk illness. On the other hand, in the case of CHI services, CMS proposed that time spent providing such services must be documented in the patient's medical record in its relationship to the SDOH need(s) they are intended to address and the clinical problem(s) they are intended to help resolve (88 FR 52329).

As discussed in the CY 2024 Physician Fee Schedule proposed rule (88 FR 52335), CMS proposed that a practitioner could bill separately for other care management services during the same month as PIN or CHI, if time and effort are not counted more than once, requirements to bill the other care management services are met, and the services are medically reasonable and necessary. However, in the case of a patient participating in a PHP or IOP, we anticipate that the time and effort of facility staff in addressing the components of PIN services would generally be duplicative of the time and effort of providing CHI services. Furthermore, because PIN also includes an assessment of and activities related to addressing social needs, we believe that for PHP and IOP patients, the time and effort of facility staff associated with PIN services would generally be duplicative of the time and effort of providing SDOH risk assessment services.

We believe PIN would generally be the most appropriate code for patients participating in a PHP or IOP, because a patient's participation in one of these programs indicates the presence of a serious, high-risk mental health condition (inclusive of SUD). In addition, participation in a PHP or IOP requires certification and periodic recertification of the need for such services by a physician, which we believe is analogous to an initiating visit that is required for PIN services billed under the PFS. Therefore, after consideration of the public comments we received, we are adopting PIN services as applicable for PHP and IOP. We believe the PIN services described by codes G0023, G0024 appropriately describe the broad range of services that PHP and IOP staff provide to program participants each patient month, which include discharge and transition planning, care coordination, and case management services within PHPs and IOPs. We note that as discussed in the CY 2024 PFS final rule, CMS is removing references to peer support specialists from the final descriptions for G0023 and G0024, and is finalizing separate codes that better represent the

scope of practice for peer support specialists.

In addition, we note that these PIN services are reported monthly and represent time spent throughout the month; therefore, we will not count PIN services in the evaluation of whether a PHP or IOP day receives the 3-service or 4-service day for payment; however, we intend to analyze utilization and cost data for these services and consider any payment changes in future rulemaking to better recognize such costs.

We are not adopting SDOH risk assessment or CHI services described by G0136, G0019, and G0022 because we believe the inclusion of these codes would likely be duplicative of PIN services for a patient participating in a PHP or IOP. With respect to the principal care management, chronic care management, and complex chronic care management services that commenters suggested, we discussed these recommendations with CMS medical officers and have determined these services are more appropriate for the primary care setting, rather than a defined program of services like a PHP or IOP.

c. Peer Support Specialists

Additionally, we solicited comments in the proposed rule on peer services, and whether these would be appropriate to include for PHPs and IOPs. Peer support workers are people who have been successful in the recovery process who help others experiencing similar situations. Through shared understanding, respect, and mutual empowerment, peer support workers help people become and stay engaged in the recovery process and reduce the likelihood of relapse. Peer support services can effectively extend the reach of treatment beyond the clinical setting into the everyday environment of those seeking a successful, sustained recovery process. Peer support workers typically engage in a wide range of activities, including: advocating for people in recovery; sharing resources and building skills; building community and relationships; leading recovery groups; and mentoring and setting goals.[164] We stated in the CY 2024 OPPS/ASC proposed rule that we were interested in information about any available codes that would appropriately describe such services.

Comment: Commenters strongly supported the inclusion of peer support services in the list of codes recognized for PHP and IOP.

Response: As discussed above, we are adopting coding for PIN services. Additionally, as discussed in the CY 2024 PFS final rule, CMS is finalizing additional PIN codes which describe the set of services that are within the scope of practice of peer support specialists. As shown in Table 98 of this final rule with comment period, we are adopting these codes as applicable for PHP and IOP. We believe it is appropriate to recognize the services of peer support specialists working within the scope of practice for which they are licensed or certified under applicable State law, or meeting the requirements set forth in the CY 2024 PFS final rule if no applicable State requirements exist, as the services of staff trained to work with psychiatric patients, which is included under section 1861(ff)(2)(c) and which we have codified under the PHP benefit at § 410.43(a)(4)(iii) and are finalizing under the IOP benefit at § 410.44(a)(4)(iii) in this final rule.

As we noted above for PIN services, these peer support PIN service codes are reported monthly and represent time spent throughout the month; therefore, we will not count them in the evaluation of whether a PHP or IOP day receives the 3-service or 4-service day for payment; however, we intend to analyze utilization and cost data for these services and consider any payment changes in future rulemaking to better recognize such costs.

d. Testing and Diagnostic Services

We noted in the proposed rule that our analysis of PHP claims showed that the provision of testing and diagnostic services is very low among PHPs, although such services are covered under the PHP benefit. We included testing and diagnostic services in the proposed list of codes shown in Table 96 of this final rule with comment period, and we proposed to cover such services under the IOP benefit as well. We noted that our analysis of non-PHP days with 3 and 4 services, which we believe could represent IOP days in the future, shows a higher provision of testing and diagnostic services than is found among PHP days. We stated that we believe testing and diagnostic services would be included as component services of PHPs and IOPs, and we are interested in information from the public about why PHPs are not more frequently billing for these services. In particular, we welcomed information from commenters about whether there are specific challenges that PHPs face in providing these services, as well as whether there are different codes, other than those shown in Table 96 of this final rule with comment period, that could better describe the testing and diagnostic services that are provided to PHP patients. In addition, we stated that we are interested in understanding whether these services are typically provided by an entity other than the PHP, such as by a referring provider.

Comment: Commenters provided useful information about why PHPs are not more frequently billing for testing and diagnostic services. Specifically, the commenters stated that the vast majority of PHPs and IOPs are generally designed to treat common types of behavioral health issues and typically focus on depression, anxiety, bipolar disorder, and self-harm. Commenters stated that testing and diagnostic services are usually more common in specialty programs such as eating disorders, obsessive-compulsive disorders, anger management, and child/adolescent programs. Additionally, commenters stated that while diagnostic services are covered under the PHP benefit, since PHP is intended for patients who have a mental health diagnosis, patients that are admitted to a PHP typically have a mental health diagnosis from a referring provider.

Response: We appreciate the information that commenters provided regarding testing and diagnostic services. While we recognize that these may not be used in most programs, we note that section 1861(ff)(2)(H) specifically includes diagnostic services in the definition of partial hospitalization and intensive outpatient services. We continue to believe it is appropriate to include these codes in the available PHP and IOP code set for those programs that do provide these services. We intend to monitor the provision of these services for PHP and IOP patients and may consider coding changes in the future.

e. Other Categories of Services

Comment: One commenter suggested including a variety of codes commonly billed for occupational therapy. For example, codes 97165–97167 for low, moderate, and high complexity occupational therapy evaluations; and code 97168 Occupational therapy re-evaluation.

Response: We appreciate the commenter's recommendation to adopt more detailed coding for occupational therapy. We note that occupational therapy services are an important part of PHPs, specifically listed under 1861(ff)(2)(B) and § 410.43(a)(4)(ii). We also proposed to include occupational therapy services under § 410.44(a)(4). We proposed to include G0129, which is the currently recognized code for

[164] *https://www.samhsa.gov/brss-tacs/recovery-support-tools/peers.*

occupational therapy services provided for PHP patients, and we proposed to recognize this code for IOP patients beginning in CY 2024 as well. We are not including the more detailed list of CPT codes that the commenter recommended; however, we will take this comment into consideration to potentially inform future rulemaking.

Comment: Commenters suggested adding SUD screening and diagnostic evaluations (including G0396 and G0397), GXXX5 Social determinants of health assessment, and individual and group SUD counseling. Additionally, commenters suggested including codes 99446–99449 Interprofessional phone/internet/electronic health record consultation services, as well as withdrawal management, medication management, and psychoeducation services. One commenter advocated the creation of a new add-on code for psychoeducation services.

Response: After consideration of the public comments received, we do not believe SUD screening and diagnostic evaluations, social determinants of health assessment, individual and group SUD counseling, withdrawal management, medication management, or psychoeducation services are appropriate for the PHP or IOP benefits. We consulted with physicians and have determined these services are typically provided by a primary care provider for screening purposes.

Comment: A few commenters suggested including transportation and meals.

Response: While we appreciate the commenters' input, we remind readers that section 1861(ff)(2)(I) of the Act excludes transportation and meals from the items and services that may be offered provided under the PHP and IOP benefits.

Final Decision: After consideration of the public comments we received, we are adopting as final the following list of PHP and IOP codes for CY 2024, which is presented in Table 98.

BILLING CODE 4150–28–P

TABLE 98: FINAL HCPCS APPLICABLE FOR PHP AND IOP

HCPCS/CPT	Short Descriptor	Final Action
90785	Psytx complex interactive	
90791	Psych diagnostic evaluation	
90792	Psych diag eval w/med srvcs	
90832	Psytx pt&/family 30 minutes	
90833	Psytx pt&/fam w/e&m 30 min	
90834	Psytx pt&/family 45 minutes	
90836	Psytx pt&/fam w/e&m 45 min	
90837	Psytx pt&/family 60 minutes	
90838	Psytx pt&/fam w/e&m 60 min	
90839	Psytx crisis initial 60 min	Add
90840	Psytx crisis ea addl 30 min	Add
90845	Psychoanalysis	
90846	Family psytx w/o patient	
90847	Family psytx w/patient	
90849	Multiple family group psytx	Add
90853	Group psychotherapy	Add
90865	Narcosynthesis	Remove
90880	Hypnotherapy	
90899	Psychiatric service/therapy	Add
96112	Devel tst phys/qhp 1st hr	Add
96116	Neurobehavioral status exam	
96130	Psychological testing evaluation by physician/qualified health care professional; first hour	
96131	Psychological testing evaluation by physician/qualified health care professional; each additional hour	
96132	Neuropsychological testing evaluation by physician/qualified health care professional; first hour	
96133	Neuropsychological testing evaluation by physician/qualified health care professional; each additional hour	
96136	Psychological/neuropsychological testing by physician/qualified health care professional; first 30 minutes	
96137	Psychological/neuropsychological testing by physician/qualified health care professional; each additional 30 minutes	
96138	Psychological/neuropsychological testing by technician; first 30 minutes	
96139	Psychological/neuropsychological testing by technician; each additional 30 minutes	
96146	Psychological/neuropsychological testing; automated result only	
96156	Hlth bhv assmt/reassessment	Add
96158	Hlth bhv ivntj indiv 1st 30	Add
96161	Admin of caregiver-focused hlth risk assmt for ben of patient	Add
96164	Hlth bhv ivntj grp 1st 30	Add
96167	Hlth bhv ivntj fam 1st 30	Add

96202	Multiple-family group behavior management/modification training for parent(s) guardian(s) caregiver(s) with a mental or physical health diagnosis up to 60 minutes	Add
96203	Multiple-family group behavior management/modification training for parent(s) guardian(s) caregiver(s) with a mental or physical health diagnosis each addtl 15 minutes	Add
97151	Bhv id assmt by phys/qhp	Add
97152	Bhv id suprt assmt by 1 tech	Add
97153	Adaptive behavior tx by tech	Add
97154	Grp adapt bhv tx by tech	Add
97155	Adapt behavior tx phys/qhp	Add
97156	Fam adapt bhv tx gdn phy/qhp	Add
97157	Mult fam adapt bhv tx gdn	Add
97158	Grp adapt bhv tx by phy/qhp	Add
97550	Caregiver training 1st 30 min	Add
97551	Caregiver training ea addl 15	Add
97552	Grp caregiver training	Add
G0023	Navigate srv 60 min per m	Add
G0024	Navigate srv add 30 min per m	Add
G0129	PHP/IOP OT service	Update
G0140	Nav srv peer sup 60 min pr m	Add
G0146	Nav srv peer sup add 30 pr m	Add
G0176	Opps/php/IOP; activity thrpy	Update
G0177	Opps/php/IOP; train & educ	Update
G0410	Grp psych PHP/IOP 45-50	Update
G0411	Interactive grp psyc PHP/IOP	Update
G0451	Development test interpt&rep	Add

TABLE 99: FINAL PARTIAL HOSPITALIZATION AND INTENSIVE OUTPATIENT PRIMARY SERVICES

HCPCS/CPT	Short Descriptor	Final Action
90832	Psytx pt&/family 30 minutes	
90834	Psytx pt&/family 45 minutes	
90837	Psytx pt&/family 60 minutes	
90845	Psychoanalysis	Add
90846	Family psytx w/o patient	
90847	Family psytx w/patient	
90853	Group psychotherapy	Add
90865	Narcosynthesis	Remove
90880	Hypnotherapy	
96112	Devel tst phys/qhp 1st hr	Add
96116	Neurobehavioral status exam	Add
96130	Psychological testing evaluation by physician/qualified health care professional; first hour	Add
96132	Neuropsychological testing evaluation by physician/qualified health care professional; first hour	Add
96136	Psychological/neuropsychological testing by physician/qualified health care professional; first 30 minutes	Add
96138	Psychological/neuropsychological testing by technician; first 30 minutes	Add
G0410	Grp psych partial hosp/IOP 45-50	Update
G0411	Inter active grp psych PHP/IOP	Update

BILLING CODE 4150–28–P

D. Payment Rate Methodology for PHP and IOP

In summary, we proposed for CY 2024 to revise our methodology for calculating PHP payment rates. We proposed to establish four separate PHP APC per diem payment rates: one for CMHCs for 3-service days and another for CMHCs for 4-service days (APC 5853 and APC 5854, respectively), and one for hospital-based PHPs for 3-service days and another for hospital-based PHPs for 4-service days (APC 5863 and APC 5864, respectively). In addition, for hospital-based PHPs, we proposed to calculate payment rates using the broader OPPS data set, instead of hospital-based PHP data only, because we believe using the broader OPPS data set would allow CMS to capture data from claims not identified as PHP, but that also include the service codes and intensity required for a PHP day. Because we proposed to establish consistent coding and payment between the PHP and IOP benefits, we proposed to consider all OPPS data for PHP days and non-PHP days that include 3 or more of the same service codes. We proposed to establish four separate IOP APC per diem payment rates at the same rates we proposed for PHP APCs: one for CMHCs for 3-service days and another for CMHCs for 4-service days (APC 5851 and APC 5852, respectively), and one for hospital-based IOPs for 3-service days and another for hospital-based IOPs for 4-service days (APC 5861 and APC 5862, respectively). We received public comments on these proposals, which we discuss and provide responses to in the following sections of this CY 2024 OPPS/ASC final rule.

1. Background

The standard PHP day is typically four services or more per day. We currently provide payment for three services a day for extenuating circumstances when a beneficiary would be unable to complete a full day of PHP treatment. As we stated in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66672), it was never our intention that days with only three units of service should represent the number of services provided in a typical PHP day. Our intention was to cover days that consisted of three units of service only in certain limited circumstances. For example, as we noted in the CY 2009 OPPS/ASC proposed rule (73 FR 41513), we believe 3-service days may be appropriate when a patient is transitioning towards discharge (or days when a patient who is transitioning at the beginning of his or her PHP stay). Another example of when it may be appropriate for a program to provide only three units of service in a day is when a patient is

required to leave the PHP early for the day due to an unexpected medical appointment.

2. Current Payment Rate Methodology for PHP

Since CY 2017, our longstanding policy has been to pay PHP on a per diem basis for days that include three or more PHP services, which are identified using a defined list of codes in the Healthcare Common Procedure Coding System (HCPCS). We currently (for CY 2023) utilize two separate PHP APC per diem payment rates: CMHC PHP APC 5853 (Partial Hospitalization (three or More Services Per Day)) using only CMHC data, and hospital-based PHP APC 8563 (Partial Hospitalization (three or More Services Per Day)) using only hospital-based PHP data.

Under longstanding OPPS policy, the hospital-based PHP APC per diem payment amount is also applied as a daily mental health cap, which serves as an upper limit on payment per day for individual OPPS mental health services. Under the current methodology, for CY 2023, hospital-based PHPs are paid a per diem rate of $268.22 for three or more PHP services per day, and CMHCs are paid a per diem rate of $142.70 for three or more PHP services per day. We refer readers to 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) for information on the current calculation of geometric mean per diem costs and payment rates for PHP APCs 5853 and 5863, and the CY 2017 OPPS/ASC final rule with comment period (81 FR 79680 through 79687) and the CY 2022 OPPS/ASC final rule with comment period (86 FR 63665 and 63666) for information on modifications incorporated into the PHP ratesetting methodology.

We note that under our current methodology, we have historically prepared the data by first applying PHP-specific trims and data exclusions and assessing CCRs. We direct the reader to the CY 2016 OPPS/ASC final rule with comment period (80 FR 70463 through 70465) for a more complete discussion of these trims, data exclusions, and CCR adjustments. In prior rules, we have typically included a discussion of PHP-specific data trims, exclusions, and CCR adjustments; we are not including that discussion in this rule. These PHP-specific data trims and exclusions addressed limitations as well as anomalies in the PHP data. However, as discussed in the following section, we proposed for CY 2024 to calculate hospital-based PHP payment rates for 3 services per day and 4 services per day based on cost per day using the broader OPPS data set. Accordingly, we proposed not to apply PHP-specific trims and data exclusions, but rather to apply the same trims and data exclusions consistent with the OPPS.

We did not receive any public comments regarding the proposal, and we are finalizing it as proposed. Additional information about the data trims, data exclusions, and CCR adjustments applicable to the data used for this final rule can be found online at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html*).[165]

3. CY 2024 Payment Rate Methodology for PHP and IOP

As we noted in the proposed rule, the CAA, 2023 established IOP within the continuum of care, and the statute makes reference to weekly hour requirements. Specifically, IOP patients are required to be certified by a physician as needing at least 9 hours of services per week; while PHP patients are required to be certified by a physician as needing at least 20 hours of services per week.

We stated in the proposed rule that while no IOP benefit existed prior to the CAA, 2023, the types of items and services included in IOP have been, and are, paid for by Medicare either as part of the PHP benefit or under the OPPS more generally. Additionally, we stated that prior to the CAA, 2023, CMS had begun gathering information from interested parties on IOP under Medicare. In the CY 2023 OPPS/ASC proposed rule (87 FR 44679), we issued a comment solicitation on intensive outpatient mental health treatment, including SUD treatment furnished by IOPs, to collect information regarding whether there are any gaps in coding that may be limiting access to needed levels of care for treatment of mental health disorders or SUDs for Medicare beneficiaries, and specific information about IOP services, such as the settings of care in which these programs typically furnish services, the range of services typically offered, and the range of practitioner types that typically furnish these services.

We explained that along with the requirements for IOP mandated by the CAA, 2023, we took into consideration information we received from the comment solicitation to construct an appropriate data set to develop proposed rates for IOP. Since IOPs furnish the same types of services as PHP, just at a lower intensity, we stated that we believe it is appropriate to use the same data and methodology for calculating payment rates for both PHP and IOP for CY 2024. We explained that although PHP claims can be specifically identified, there is no specific identifier or billing code to indicate IOP services. However, we noted that hospitals are permitted to furnish and bill for many of these services as outpatient services under the OPPS. Thus, we analyzed a broader set of data that includes both PHP and non-PHP days with 3 or more services in order to calculate proposed payment for PHP services. In order to establish consistent payment between PHP and IOP, we proposed to set IOP payment rates at the same rates as PHP. We stated that the primary goal in developing the proposed payment rate methodology for IOP and PHP services was to pay providers an appropriate amount relative to the patients' needs, and to avoid cost inversion in future years.

For CY 2024, we proposed to calculate hospital-based PHP payment rates for 3 services per day and 4 services per day based on cost per day using the broader OPPS data set, a change from the current methodology of using only PHP data. We stated that we believe using the broader OPPS data set would allow us to capture data from claims that are not identified as PHP, but that include the service codes and intensity required for a PHP day. We stated that the larger data set would expand the sample size to allow for more precise rate calculations. In addition, we proposed to calculate the 3 services per day and 4 services per day PHP rates for CMHCs and hospital-based programs separately.

We also proposed to set payment rates for IOP APCs at amounts equal to the payment rates for PHP APCs. We stated that setting the IOP payment rates equal to the PHP payments would be appropriate because IOP is a newly established benefit, and we do not have definitive data on utilization. However, we explained that both programs utilize the same services, but furnish them at different levels of intensity, with different numbers of services furnished per day and per week, depending on the program. Therefore, we stated that we expect it would be appropriate to pay the same per diem rates for IOP and PHP services unless future data analysis supports calculating rates independently. Table 100 below shows the proposed APCs and the calculated

[165] Click on the link labeled ''CY 2024 OPPS/ASC Notice of Final Rulemaking'', which can be found under the heading ''Hospital Outpatient Prospective Payment System Rulemaking'' and open the claims accounting document link at the bottom of the page, which is labeled ''2024 NFRM OPPS Claims Accounting (PDF)''.

geometric mean per diem costs for the CY 2024 OPPS/ASC proposed rule.

TABLE 100: PROPOSED CY 2024 PHP AND IOP APC GEOMETRIC MEAN PER DIEM COSTS

CY 2024 APC	Group Title	Proposed PHP and IOP APC Geometric Mean Per Diem Costs
5851	Intensive Outpatient (3 services per day) for CMHCs	$97.59
5852	Intensive Outpatient (4 or more services per day) for CMHCs	$153.09
5853	Partial Hospitalization (3 services per day) for CMHCs	$97.59
5854	Partial Hospitalization (4 or more services per day) for CMHCs	$153.09
5861	Intensive Outpatient (3 services per day) for hospital-based IOPs	$284.00
5862	Intensive Outpatient (4 or more services per day) for hospital-based IOPs	$368.18
5863	Partial Hospitalization (3 services per day) for hospital-based PHPs	$284.00
5864	Partial Hospitalization (4 or more services per day) for hospital-based PHPs	$368.18

For beneficiaries in a PHP or IOP, we proposed applying the four-service payment rate (that is, payment for PHP APCs 5854 for CMHCs and 5864 for hospitals, and IOP APCs 5852 for CMHCs and 5862 for hospitals) for days with 4 or more services. For days with three or fewer services, we proposed to apply the three-service payment rate (that is, payment for PHP APCs 5853 for CMHCs and 5863 for hospitals, and IOP APCs 5851 for CMHCs and 5861 for hospitals), which we noted would be a departure from our current policy. We explained that under our current policy, we do not make payment for any PHP days with fewer than three services. We stated that we have heard from interested parties that this policy could discourage treatment of PHP patients when, due to extenuating circumstances, they cannot complete a full day. We stated that we believe paying for a day with three or fewer services would allow us to more easily monitor the actual utilization of services, particularly IOP. Specifically, we stated that we believe utilizing the three-service payment rate (that is, payment for PHP APCs 5853 for CMHCs and 5863 for hospitals, and IOP APCs 5851 for CMHCs and 5861 for hospitals) for days with three or fewer service would accommodate occasional instances when a patient is unable to complete a full day of PHP or IOP. We stated that we expect days with fewer than three services would be very infrequent, and that we intend to monitor the provision of these days among providers and individual patients.

Additionally, we proposed that the 3 service per day hospital-based PHP APC per diem payment amount for APC 5863 would also be applied as the daily mental health cap, which serves as the upper limit on payment per day for individual OPPS mental health services. We explained that setting the 3 service per day hospital-based PHP APC per diem payment amount as the daily mental health cap would be appropriate because currently the daily mental health cap is equal to the payment amount for hospital-based PHP APC 5863, which is payment for 3 or more services per day. Therefore, we noted that consistency with the current daily mental health cap would be maintained. Additionally, we stated that PHP is meant to be the most intensive mental health services program, requiring inpatient care if PHP is not received, and the daily mental health cap is not expected to reach such level of intensity. We stated that we believe applying the 3 service per day hospital-based PHP APC per diem payment amount for APC 5863 as the daily mental health cap would preserve the difference of intensity between PHP and individual OPPS mental health services to not incentivize one over the other. We noted that the proposed CY 2024 payment amount for APC 5863 would be comparable to the CY 2023 payment amount for APC 5863, which is currently applied as the daily mental health cap.

Lastly, we noted that section 4124(c) of the CAA, 2023 requires that the payment amount for intensive outpatient services furnished in FQHCs and RHCs be equal to the payment amount that would have been paid for the same service furnished by a hospital outpatient department, thus establishing site-neutral payment for hospital outpatient departments, FQHCs, and RHCs. We explained that the CAA, 2023 is silent with respect to the payment methodology for IOP services provided by CMHCs. Based on our analysis of CMHC costs, we stated that we continue to observe that CMHCs incur significantly different costs than hospitals in the provision of PHP services, and stated that we anticipate in the future there will be significant differences between CMHCs' and hospitals' costs of furnishing IOP services as well. We explained that we believe it is appropriate to continue to recognize the differences in cost structures for different providers of PHP. We further explained that this is of particular importance not only to the Medicare program, but also for the Medicare beneficiaries that CMHCs serve, who incur a 20 percent copay on all PHP services under Part B. Therefore, we proposed to continue calculating CMHC payment rates based solely on CMHC claims. However, we stated that we were also considering whether establishing a site-neutral payment for all providers of IOP using data from all providers of IOP would be more appropriate in an effort to increase access to mental health services. In order to inform public awareness, we calculated combined payment rates for the proposed rule by using the broader OPPS data from both hospitals and CMHCs to estimate the costs associated

with providing days with three and four services from the proposed list of services, which is reproduced in Table 96 of this final rule with comment period. We provided these alternative cost calculations in Table 46 in section VIII.D.3.b of the CY 2024 OPPS/ASC proposed rule. We solicited comments on whether this approach would be more appropriate to consider for establishing payment beginning in CY 2024. Specifically, we stated that we were interested in any information from commenters on how IOPs may structure their service days, and how the differences in cost structures of CMHCs might affect a site-neutral payment for IOP services. We also solicited comments on any ways IOP days could differ from PHP days, and considerations that could affect payment.

We received a number of public comments on these proposals. Our summaries and responses to the comments we received are included in the following paragraphs.

Comment: Overall, commenters expressed support for the proposed methodology of calculating PHP and IOP rates using a broader set of OPPS data. Several commenters expressed support for the proposed payment for intensive outpatient services and the proposed increases to payment rates for partial hospitalization services for CY 2024. One commenter raised concerns that using a broader set of OPPS data may result in inadequate reimbursement for hospital-based PHPs that furnish IOPs, given the additional resource costs associated with these sites of care.

Response: We appreciate the support from commenters. As noted earlier, we proposed to use a broader set of OPPS data in order to capture data from claims that are not identified as PHP, but that include the service codes and intensity required for a PHP day. In general, our analysis finds that non-PHP days furnished in the hospital outpatient setting that include 3 services and 4 or more services generally have comparable costs to PHP days furnished in the hospital setting with a comparable number of services provided. As we have discussed in prior rulemaking (85 FR 86075; 84 FR 61343), data from a small number of providers with low service costs per day have driven fluctuations in PHP payment rates, which has necessitated certain policies to stabilize payment in the past. We believe that using a broader set of OPPS data for days with a similar type and number of services appropriately provides stability for the calculation of PHP and IOP payment rates for CY 2024.

Comment: Commenters strongly supported the proposal to stratify payment for PHP and IOP days into 3-service and 4-service days. Several commenters stated that bifurcating each service into two tiers takes into account the varying levels of need among individuals receiving services. Commenters also strongly supported our proposal to make payment at the applicable 3-service rate for PHP and IOP days with fewer than 3 services. Commenters expressed that this flexibility is particularly important for ensuring that the new IOP benefit is made available to patients.

Response: We appreciate the support for the proposal to stratify payment and to make payment for days with fewer than 3 services. We share the commenters' view that these proposed policies are important for supporting access to the new IOP benefit and appropriately matching payment to daily service intensity for patients participating in both PHPs and IOPs. We are reiterating our expectation that days with fewer than three services should be very infrequent, and we are reminding readers that we intend to monitor the provision of these days among providers and individual patients.

Comment: Commenters generally supported the proposal to calculate the per diem payment rates for IOP based on the proposed per diem payment rates for PHP. As noted earlier in this final rule, several commenters raised concerns that the proposal to pay the same rates for PHP and IOP may be driving the proposed requirement that a service from the ''primary list'' be provided for each day that received payment. These commenters encouraged CMS to revisit this question in future rulemaking as cost and claims data are available, to analyze the key differences between IOP and PHP, including the prevalence of certain services within the bundle.

Response: We appreciate the support from commenters regarding the proposal. As we stated in the proposed rule, we proposed to use the PHP rates, calculated using the broader OPPS data set, as the basis for the proposed CY 2024 IOP rates, because IOP is a newly established benefit for which we do not have definitive data on utilization.

Regarding the statement that the proposed payment policy is the reason for the proposal to require a primary service for each day that receives payment, we are clarifying that this is not the case. As we noted earlier in this CY 2024 OPPS/ASC final rule, the purpose of the primary list is to ensure that IOPs and PHPs are being provided with an appropriate level of intensity to ensure program integrity. Although we expect IOPs to be less intensive than PHPs and to involve fewer weekly hours, we nevertheless expect the services provided to be of an intensity that is commensurate with treating the patient's condition. Because we have proposed to pay IOP on a per diem basis, we believe it is important to ensure a minimum standard of program intensity for each date of service.

Comment: A few commenters expressed support for establishing separate payment rates that recognize the cost differences between hospital outpatient departments and CMHCs. These commenters agreed with CMS that hospitals and CMHCs have different cost structures, and encouraged CMS to finalize payment rates that reflect these differences.

In contrast, several commenters opposed the proposal to establish separate payment rates for hospital outpatient departments and CMHCs, advocating for the alternative combined site-neutral payment rates presented in the proposed rule. These commenters stated that the stark discrepancy in rates between HOPDs and CMHCs for partial hospitalization services may not be representative of these entities' true cost structures. These commenters further noted that the addition of IOP to the Medicare service array may encourage additional facilities around the country to elect to enroll in Medicare as CMHCs. Commenters advocating for site-neutral payment responded to CMS' concerns regarding coinsurance burdens for CMHC patients by stating a large percentage of the low-income patients served by community-based behavioral health providers are dual eligible beneficiaries, for whom Medicaid typically covers Medicare coinsurance costs.

Response: We appreciate the comments we received on this topic. As we noted in the proposed rule, the best available data that we have at this time for assessing the cost of IOP services comes from PHP and OPPS days with similar services provided at the expected intensity level. Current data for partial hospitalization do reflect significant cost structure differences between hospitals and CMHCs, and our longstanding payment policies reflect those differences. We have no factual basis at this time on which to assume, as many commenters suggest, that the stark difference between hospital and CMHC payment rates for PHP services indicate that such services do not reflect the actual cost structure differences between facility types.

We recognize that there is uncertainty about the cost structures of CMHCs that

may in the future enroll in Medicare to provide IOP services. As we noted in the proposed rule, we intend to analyze actual IOP utilization data beginning in CY 2024 to understand the actual structure and costs associated with these programs. We are not adopting the commenter's recommendation to finalize the alternative site neutral payment rates for this CY 2024 OPPS/ASC final rule, but we will take these comments into consideration to potentially inform future rulemaking.

Comment: Interested parties overwhelming advocated for establishing the OPPS daily mental health cap based on proposed APC 5864, rather than APC 5863 as proposed. Commenters stated that this would be consistent with CMS's historical use of the highest PHP per diem payment amount as the basis for the OPPS daily mental health cap.

Response: We appreciate the comments' feedback regarding the proposal. We agree with commenters that the proposed APC 5864 would be the most resource intensive mental health service and would be appropriate to finalize as the basis for the OPPS daily mental health cap in CY 2024. As discussed in section II.A.2.c.(1) of this CY 2024 OPPS/ASC final rule, we are finalizing the use of APC 5864 to establish the payment rate for APC 8010 in CY 2024, rather than using APC 5863 as proposed.

Final Decision: After consideration of the public comments we received, we are finalizing our proposal to establish separate APC per diem payment rates for PHP days with 3 services and 4 or more services and to establish separate APC per diem payment rates for CMHCs and hospital-based PHPs. We are also finalizing our proposal to set APC per diem payment rates for IOP days based on the APC per diem payment rates for PHP in CY 2024. Lastly, we are finalizing our proposal to make payment at the 3-service rate for PHP or IOP days that have fewer than 3 services.

a. PHP APC Changes and Effects on Geometric Mean Per Diem Costs

For CY 2024 and subsequent years, we are finalizing a revision to our existing methodology to calculate the CMHC and hospital-based PHP geometric mean per diem costs to incorporate the larger data set under the OPPS, including PHP and non-PHP hospital claims for mental health services. We are finalizing our proposal to use the latest available CY 2022 claims data, and CY 2021 cost data. This is consistent with the overall use of cost data for the OPPS, which is discussed in section II.A.1.a. of this final rule with comment period. In addition, we are establishing four separate PHP APC per diem payment rates: two for CMHCs (APC 5853 and APC 5854) and two for hospital-based PHPs (APC 5863 and APC 5864). Following this methodology, we will use the geometric mean per diem cost of $90.02 for CMHCs providing 3-service days (APC 5853), and the geometric mean per diem cost of $161.80 for CMHCs providing 4-service days (APC 5854), as the basis for developing the CY 2024 CMHC PHP APC per diem rates. Additionally, we will use the geometric mean per diem cost of $266.35 for hospital-based providers providing 3-service days (APC 5863), and the geometric mean per diem cost of $367.79 for hospital-based providers providing 4-service days (APC 5864) as the basis for developing the CY 2024 hospital-based PHP APC per diem rates. Lastly, we are establishing four separate IOP APC per diem payment rates: two for CMHCs (APC 5851 and APC 5852 for 3-service days and 4-service days, respectively) and two for hospital-based IOPs (APC 5861 and APC 5862 for 3-service days and 4-service days, respectively) using the same above 3-service day and 4-service day geometric mean per diem costs finalized for the PHP APC per diem rates.

b. Development of the PHP and IOP APC Geometric Mean Per Diem Costs

The types of items and services paid as PHP (and that will be paid as IOP) can also be provided outside of those benefits by hospitals; therefore, we sought to understand the costs of those services in our preliminary analysis to consider options for the proposed payment rates for IOP services. In preparation for this CY 2024 final rule, in collaboration with physicians, we developed a consolidated list of all HCPCS codes that would be appropriate for identifying IOP and PHP services for analytic purposes. We refer readers to section VIII.C of this final rule with comment period for more detailed information on the consolidated list of HCPCS codes applicable for IOP and PHP services.

We calculated the final payment rates for hospital-based providers based on costs for days with three services and days with four services using the data from all OPPS claims for hospitals and calculated the final payment rates for CMHCs based on costs for days with three services and days with four services using only the data from CMHC claims. As discussed in section VIII.B.1.a of the CY 2022 OPPS/ASC final rule with comment period (86 FR 63666 through 63668), the costs for CMHC service days are calculated using cost report information from HCRIS. Although we anticipate that IOP weeks would generally include 9–19 hours of services and PHP weeks would generally include 20 or more hours of services, we did not restrict the data for this analysis by weekly hours. Because IOP is a new benefit, we do not have definitive data on utilization. However, if IOP utilization is similar to the data we analyzed for beneficiary weeks with 9 to 19 hours of mental health services, then we expect that IOP days will mostly include three services or fewer but may sometimes include four or more. Given the uncertainty about how IOPs will structure their service days in the future, we proposed and believe it is appropriate to finalize 3-service day and 4-service day APCs for IOP with payment rates that are the same as the rates for the 3-service day and 4-service day APCs for PHP.

We analyzed all CMHC and hospital claims data under the OPPS used to set final rates for this CY 2024 final rule. We identified all patient days that included three or more services from the list in Table 98. As discussed in section VIII.D.3 of this final rule with comment period, we calculated PHP payment rates for days with three services and days with four or more services, and we utilized these PHP payment rates for the IOP APCs as well. We are finalizing our proposal to calculate separate rates for hospitals and CMHCs.

c. CY 2024 PHP and IOP APC Geometric Mean Per Diem Costs

Following this structure, the final calculated CY 2024 PHP geometric mean per diem cost for all CMHCs for providing 3 services per day is $90.02, which we will use for calculating the payment rate for the 3-service day APC, CMHC APC 5853. The final calculated CY 2024 geometric mean per diem cost for all CMHCs for providing four or more services per day is $161.80, which we will use for calculating the payment rate for the 4-service day APC, CMHC APC 5854. As noted, the calculated CY 2024 hospital-based PHP APC geometric mean per diem cost for hospital-based PHP providers that provide 3 services per service day is $266.35, which we will use for calculating the payment rate for the 3-service day hospital-based PHP APC 5863. The calculated CY 2024 hospital-based PHP APC geometric mean per diem cost for hospital-based PHP providers that provide 4 or more services per day is $367.79, which we will use for calculating the payment rate for the 4-service day hospital-based PHP APC 5864.

Similarly, the calculated CY 2024 IOP geometric mean per diem cost for all

CMHCs for providing 3 services per day is $90.02, which we will use for calculating the payment rate for the 3-service day APC, CMHC APC 5851. The calculated CY 2024 geometric mean per diem cost for all CMHCs for providing 4 or more services per day is $161.80, which we will use for calculating the payment rate for the 4-service day APC, CMHC APC 5852. The calculated CY 2024 hospital-based IOP APC geometric mean per diem cost for hospital-based IOP providers that provide 3 services per service day is $266.35, which we will use for calculating the payment rate for the 3-service day hospital-based IOP APC 5861. The calculated CY 2024 hospital-based IOP APC geometric mean per diem cost for hospital-based IOP providers that provide 4 services per day is $367.79, which we proposed to use for calculating the payment rate for the 4-service day hospital-based IOP APC 5862.

We intend to monitor the provision of services in both PHP and IOP programs to better understand utilization patterns, and we are finalizing our proposal to set equal payment rates for PHP and IOP services until actual IOP utilization data becomes available for CY 2026 ratesetting, at which point we anticipate reevaluating our payment rate methodology if necessary. In addition, we solicited comments on the service mix used to develop the per diem amounts for both PHP and IOP. We stated that we are interested in whether the proposed approach is appropriate, and any feedback commenters have on the service mix provided within each program.

The final CY 2024 PHP geometric mean per diem costs are shown in Table 101 and are used to derive the final CY 2024 PHP APC per diem rates for CMHCs and hospital-based PHPs-. As stated in section VIII.D.3 of this final rule with comment period, we are finalizing our proposal to use the same 3—service day and 4-service day geometric mean per diem PHP costs for the CY 2024 CMHC and hospital-based IOP APCs. The final CY 2024 PHP and IOP APC per diem rates are included in Addendum A to this final rule with comment period (which is available on our website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Hospital-Outpatient-Regulations-and-Notices.html*) and in Table 101.

TABLE 101: CY 2024 PHP AND IOP APC GEOMETRIC MEAN PER DIEM COSTS

CY 2024 APC	Group Title	Final PHP and IOP APC Geometric Mean Per Diem Costs
5851	Intensive Outpatient (3 services per day) for CMHCs	$90.02
5852	Intensive Outpatient (4 or more services per day) for CMHCs	$161.80
5853	Partial Hospitalization (3 services per day) for CMHCs	$90.02
5854	Partial Hospitalization (4 or more services per day) for CMHCs	$161.80
5861	Intensive Outpatient (3 services per day) for hospital-based IOPs	$266.35
5862	Intensive Outpatient (4 or more services per day) for hospital-based IOPs	$367.79
5863	Partial Hospitalization (3 services per day) for hospital-based PHPs	$266.35
5864	Partial Hospitalization (4 or more services per day) for hospital-based PHPs	$367.79

E. Outlier Policy for CMHCs

For CY 2024, we proposed to update the calculations of the CMHC outlier percentage, cutoff point and percentage payment amount, outlier reconciliation, outlier payment cap, and fixed dollar threshold according to previously established policies to include intensive outpatient services. These topics are discussed in more detail. We refer readers to section II.G.1 of this final rule with comment period 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 and 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), the CY 2020 OPPS/ASC final rule with comment period (84 FR 61350), and the CY 2021 OPPS/ASC final rule with comment period (85 FR 86082).

We estimated CMHC per diem payments and outlier payments for this rule by using the most recent available utilization and charges from CMHC claims, updated CCRs, and the proposed payment rates for PHP APCs 5853 and 5854. We recognize that CMHCs would be permitted to provide and bill for IOP beginning in CY 2024 and would be paid under IOP APCs 5851 and 5852. However, we have not included estimates of utilization for these APCs, because the latest available claims from CY 2022 do not reflect the provision of IOP services. For increased transparency, we are providing a more detailed explanation of the existing

calculation process for determining the CMHC outlier percentages. To calculate the CMHC outlier percentage, we follow three steps:

- Step 1: We multiply 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 estimate 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 the CY 2022 OPPS/ASC proposed rule). That threshold is determined by multiplying the provider's estimated paid days by 3.4 times the total of CMHC PHP APC and CMHC IOP payment rates. If the provider's costs exceed the threshold, we multiply that excess by 50 percent, as described in section VIII.E.3 of this final rule with comment period, 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.E.5 of this final rule with comment period, 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 sum 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 determine 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).

We proposed to continue to calculate the CMHC outlier percentage according to previously established policies. However, beginning in CY 2024, CMHCs will be permitted to provide and bill for intensive outpatient services for Medicare patients. Therefore, we proposed to expand the calculation of the CMHC outlier percentage to include PHP and IOP, because we anticipate that total payments will increase for CMHCs in CY 2024. We proposed to maintain our current methodology for calculating the CMHC outlier percentage, but to apply it to payments for IOP services as well as PHP services beginning in CY 2024. Therefore, based on our CY 2024 payment estimates, including our estimates of both PHP and IOP services, CMHCs are projected to receive 0.01 percent of total hospital outpatient payments in CY 2024, excluding outlier payments. We proposed 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.

We did not receive any public comments on our proposal and are finalizing our proposal as proposed.

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 was 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 exceeded 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), CY 2020 OPPS/ASC final rule with comment period (84 FR 61351), the CY 2021 OPPS/ASC final rule with comment period (85 FR 86082 through 86083), the CY 2022 OPPS/ASC final rule with comment period (86 FR 63670), and the CY 2023 OPPS/ASC final rule with comment period (87 FR 72004). For CY 2024, we proposed 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. In addition, we proposed to extend this policy to intensive outpatient services. That is, for CY 2024, if a CMHC's cost for partial hospitalization services paid under CMHC PHP APCs 5853 or 5854 exceeds 3.4 times the payment rate for the APC (either CMHC APC 5853 or 5854), the outlier payment would be calculated as: [0.50 × (CMHC cost − (3.4 × (PHP APC payment)))].

Similarly, if a CMHC's cost for intensive outpatient services paid under CMHC IOP APCs 5851 or 5852 exceeds 3.4 times the payment rate for the APC (either CMHC APCs 5851 or 5852), the outlier payment would be calculated as: [0.50 × (CMHC cost − (3.4 × (IOP APC payment)))].

We did not receive any public comments on our proposal and are finalizing our proposed policy as proposed.

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 led 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 2023 OPPS/ASC and CY 2019 OPPS/ASC final rules with comment period (83 FR 58874 and 58875 and 81 FR 79678 through 79680).

We proposed to continue these policies for partial hospitalization services provided through PHPs for CY 2024. In addition, since CMHCs will be permitted to provide and bill for

intensive outpatient services for Medicare patients we proposed to extend these policies to include intensive outpatient services in order to encompass the full scope of services that CMHCs will be permitted to furnish. The current outlier reconciliation policy requires that providers whose outlier payments meet a specified threshold 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 (as established in the CY 2009 OPPS/ASC final rule with comment period (73 FR 68596 through 68599)). We note that the current threshold for outlier reconciliation for hospitals is $500,000, and there is no threshold for CMHCs (that is, all outlier payments are subject to reconciliation for CMHCs whose overall ancillary CCRs change by plus or minus 10 percentage points or more). 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 at: *https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c04.pdf*).

We did not receive any public comments on our proposal and are finalizing our proposed policy as proposed.

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). Our analysis of CY 2014 claims data found that CMHC outlier payments began to increase similarly to the way they had prior to CY 2004. This was due to inflated cost from three CMHCs that accounted for 98 percent of all CMHC outlier payments that year and received outlier payments that ranged from 104 percent to 713 percent of their total per diem payments. To balance our concern about disadvantaging CMHCs with our interest in protecting the benefit from excessive outlier payments and to mitigate potential inappropriate outlier billing vulnerabilities, we finalized the CMHC outlier payment cap at 8 percent of the CMHC's total per diem payments (81 FR 79694 and 79695) to limit the impact of inflated CMHC charges on outlier payments. 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. We proposed to maintain the 8 percent outlier payment cap for CY 2024 and apply it to both PHP and IOP payments. We note that the 8 percent would be calculated as 8 percent of total per diem PHP and IOP payments for CY 2024. As discussed earlier in this rule, beginning in CY 2024, CMHCs will be permitted to provide and bill for intensive outpatient services for Medicare patients. Therefore, we proposed to expand the calculation of the CMHC outlier cap to include both PHP and IOP, because we anticipate that total payments will increase for CMHCs in CY 2024. Therefore, we proposed to calculate the 8 percent outlier payment cap for each CMHC in a way that would encompass the full scope of services that CMHCs will be permitted to furnish in CY 2024.

We did not receive any public comments on our proposal and therefore, we are finalizing as proposed.

6. Fixed-Dollar Threshold

In the CY 2018 OPPS/ASC final rule with comment period (82 FR 59267 and 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. Currently, for CY 2023, 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), the CY 2021 OPPS/ASC final rule with comment period (85 FR 86083), the CY 2022 OPPS/ASC final rule with comment period (86 FR 63508), and the CY 2023 OPPS/ASC final rule with comment period (87 FR 72004). We proposed to continue this policy for CY 2024 and not set a fixed-dollar threshold for the CMHC PHP APCs (5853 or 5854) or IOP APCs (5851 or 5852).

Comment: Several commenters urged CMS to implement a site-neutral payment for CMHCs and hospital-based providers for PHP and IOP services. Commenters stated that a site-neutral payment would eliminate the need for a separate outlier policy for CMHCs.

Response: We disagree with commenters who believe that a site-neutral payment would eliminate the need for a separate outlier policy for CMHCs. As discussed in the CY 2004 OPPS final rule with comment period (68 FR 63469 and 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. Furthermore, to balance our concern about disadvantaging CMHCs with our interest in protecting the benefit from excessive outlier payments and to mitigate potential inappropriate outlier billing vulnerabilities, we finalized the CMHC outlier payment cap at 8 percent of the CMHC's total per diem payments (81 FR 79694 and 79695) to limit the impact of inflated CMHC charges on outlier payments. In conclusion, CMS does not believe payment methodology has any effect on outlier policy.

Final Decision: After consideration of the public comments we received, we are finalizing our proposed policy as proposed.

F. Rural Health Clinics (RHCs) and Federally Qualified Health Centers (FQHCs)

1. Background

a. Statutory Background

The Rural Health Clinic Services Act of 1977 (Pub. L. 95–210, December 13, 1977), amended the Act by enacting section 1861(aa) of the Act to extend Medicare and Medicaid entitlement and payment for rural health clinics (RHCs), which are defined as being primarily engaged in furnishing outpatient services by physicians and certain nonphysician practitioners, and for services and supplies incidental to their services. ''Nonphysician practitioners'' included nurse practitioners and physician assistants. (Subsequent legislation extended the definition of covered RHC services to include the services of clinical psychologists, clinical social workers, certified nurse midwives, marriage and family therapist, and mental health counselors). The statutory payment requirements for RHC services are set forth at section 1833(a)(3) of the Act, which states that RHCs are paid reasonable costs, less the amount a provider may charge as described in clause of section 1866(a)(2)(A) of the Act, but in no case may the payment exceed 80 percent of such costs.

Section 1861(aa)(2) of the Social Security Act (42 U.S.C. 1395x(aa)(2)) defines the term ''rural health clinic'', in relevant part, as a facility that is located in an area that is not an urbanized area and in which there are insufficient numbers of needed health care practitioners and is not a rehabilitation agency or a facility primarily for the care and treatment of mental diseases. Additionally, the law includes a basic requirement that the facility is primarily engaged in providing health care services furnished by physicians, physician assistants, nurse practitioners, clinical psychologists, and clinical social workers to outpatients.

Section 4161 of the Omnibus Budget Reconciliation Act of 1990 (Pub. L. 101–508, November 5, 1990) (OBRA 90) established Federally Qualified Health Centers (FQHCs) in 1990 to be effective beginning on October 1, 1991. The law mandated that FQHCs furnish services that are typically furnished in an outpatient setting.

Section 1861(aa)(3) of the Act extends Medicare and Medicaid entitlement and payment for those services defined as RHC services under section 1861(aa)(1) of the Act, preventive services defined under section 1861(ddd)(3) of the Act, and preventive primary health services that a center is required to provide under section 330 of the Public Health Service Act furnished at a FQHC. Section 1861(aa)(4) of the Act describes the statutory requirements that FQHCs must meet to qualify for Medicare payment. Section 10501(i)(3)(A) of the Affordable Care Act (Pub. L. 111–148) added section 1834(o) of the Act to establish a new system of payment for the costs of FQHC services under Medicare Part B (Supplemental Medical Insurance) based on prospectively set rates. Section 1834(o)(2)(A) of the Act, the FQHC prospective payment system (PPS) was effective beginning on October 1, 2014. In addition, section 10501(i)(3)(B) of the Affordable Care Act added section 1833(a)(1)(Z) to the Act to specify that Medicare payment for FQHC services under section 1834(o) of the Act shall be 80 percent of the lesser of the actual charge or the amount determined under section 1834(o) of the Act.

Regulations pertaining to RHC and FQHC benefits are codified at 42 CFR part 405, subpart X.

b. Medicare Part B Payment of RHC and FQHC Services

As provided in 42 CFR part 405, subpart X, of our regulations, RHC and FQHC visits generally are face-to-face encounters between a patient and one or more RHC or FQHC practitioners during which one or more RHC or FQHC qualifying services are furnished. RHC and FQHC practitioners are physicians, NPs, PAs, certified nurse-midwife (CNMs), clinical psychologists (CPs), and clinical social workers, and under certain conditions, a registered nurse or licensed practical nurse furnishing care to a homebound RHC or FQHC patient in an area with a shortage of home health agencies. We note, effective January 1, 2024, marriage and family therapist and mental health counselor services are considered RHC services in accordance with section 1861(aa)(1)(B) of the Act as amended by section 4121(b) of CAA, 2023, which is incorporated into FQHC services through section 1861(aa)(3)(A) of the Act. In the CY 2024 PFS proposed rule, we propose to codify payment for MFTs and MHCs at § 405.2411 (88 FR 52398). Only medically necessary medical, mental health, or qualified preventive health services that require the skill level of an RHC or FQHC practitioner are RHC or FQHC billable visits. Services furnished by auxiliary personnel (for example, nurses, medical assistants, or other clinical personnel acting under the supervision of the RHC or FQHC practitioner) are considered incident to the visit and are included in the per-visit payment.

Section 130 of the Consolidated Appropriations Act, 2021 (CAA, 2021) (Pub. L. 116–260, December 27, 2020), updated section 1833(f) of the Act by restructuring the payment limits for RHCs beginning April 1, 2021. As of April 1, 2021, all RHCs are subject to payment limits on the all-inclusive rate (AIR), and this limit will be determined for each RHC in accordance with section 1833(f) of the Act. RHCs generally are paid an AIR for all medically necessary medical and mental health services and qualified preventive health services furnished on the same day (with some exceptions). The AIR is subject to a payment limit, meaning that an RHC will not receive any payment beyond the specified limit amount.

FQHCs were paid under the same AIR methodology until October 1, 2014. Subsequently, FQHCs began to transition to the FQHC PPS system, in which they are paid based on the lesser of the FQHC PPS rate or their actual charges. The FQHC PPS rate is adjusted for geographic differences in the cost of services by the FQHC PPS geographic adjustment factor (GAF). The rate is increased by 34 percent when an FQHC furnishes care to a patient that is new to the FQHC, or to a beneficiary receiving an initial preventive physical examination (IPPE) or has an annual wellness visit (AWV).

Both the RHC AIR and FQHC PPS payment rates were designed to reflect the cost of all services and supplies that an RHC or FQHC furnishes to a patient in a single day. The rates are not adjusted for the complexity of the patient health care needs, the length of the visit, or the number or type of practitioners involved in the patient's care. RHCs and FQHCs are required to file a cost report annually to determine their payment rate, which reflects adjustments for GME payments, bad debt, and influenza, pneumococcal and COVID–19 vaccines and covered monoclonal antibody products used as pre-exposure prophylaxis prevention of COVID–19 and their administration.

There are additional payments for non-face-to-face services for care management services including chronic care management (CCM), principal care management (PCM), chronic pain management (CPM), general behavior health integration (GBHI), psychiatric collaborative care model (CoCM), and virtual communications (§ 405.2464(c)).

Additionally, for FQHCs, § 405.2462(d) describes a ''grandfathered tribal FQHC'' as a FQHC that is operated by a tribe or tribal organization under the Indian Self-

Determination and Education Assistance Act (ISDEAA); was billing as if it were a provider-based to an Indian Health Service (IHS) hospital on or before April 7, 2000, and is not currently operating as a provider-based department of an IHS hospital. We refer to these tribal FQHCs as ''grandfathered tribal FQHCs'' to distinguish them from freestanding tribal FQHCs that are currently being paid the lesser of their charges or the adjusted national FQHC PPS rate, and from provider-based tribal clinics that may have begun operations subsequent to April 7, 2000.

Under the authority in section 1834(o) of the Act to include adjustments determined appropriate by the Secretary, we revised §§ 405.2462 and 405.2464 to pay these grandfathered tribal FQHCs on the Medicare outpatient per visit rate as set annually by the IHS, and not the FQHC PPS payment rates (80 FR 71089). Such payment rates for outpatient medical care (also referred to as outpatient hospital services) furnished by the IHS and tribal facilities is set annually by the IHS under the authority of sections 321(a) and 322(b) of the Public Health Service Act (the PHS Act) (42 U.S.C. 248 and 249(b)) (Pub. L. 83–568 (42 U.S.C. 2001(a)), and the IHCIA, based on the previous year cost reports from Federal and tribal hospitals. The outpatient per visit rate is only applicable for those IHS or tribal facilities that meet the definition of a provider-based department as described at § 413.65(m), or a ''grandfathered'' tribal FQHC as described at § 405.2462(d)(1). There is a higher outpatient per visit rate for IHS and tribal Medicare visits in Alaska and a lower general outpatient per visit rate for IHS/tribal Medicare visits in the lower 48 States (IHS does not operate any hospitals or facilities in Hawaii or the territories, and thus, no rates are set in those localities). For CY 2023, the outpatient per visit rate for Medicare visits in Alaska is $801 and $620 in the lower 48 States.

2. Establishment of Intensive Outpatient Services Benefit by Section 4124 of the CAA, 2023

a. Section 4124 of the Consolidated Appropriations Act of 2023

As we discuss in the CY 2024 OPPS proposed rule (88 FR 49714 and 49715) section 4124 of Division FF of the CAA, 2023 established Medicare coverage for intensive outpatient program (IOP) services furnished by a hospital to its outpatients, or by a community mental health center (CMHC)), a FQHC or a RHC, 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, effective January 1, 2024.

We explained that an IOP is a distinct and organized outpatient program of psychiatric services provided for individuals who have an acute mental illness, which includes, but is not limited to conditions such as depression, schizophrenia, and substance use disorders. We noted an IOP is thought to be less intensive than a partial hospitalization program (PHP).

This new provision mandated several changes to the RHC and FQHC policies, including scope of benefits and services, certification and plan of care requirements, and special payment rules for IOP services in RHCs and FQHCs, all of which are discussed in the paragraphs below.

3. IOP Scope of Benefits and Scope of Services in RHC and FQHC Settings

a. Background

As described in section 1861(aa) of the Act and codified under §§ 405.2411 and 405.2446, the current scope of benefits for RHC and FQHC services are those services covered in a RHC, FQHC, or other outpatient setting, including a patient's place of residence, or a Medicare-covered Part A skilled nursing facility (SNF) when provided by a physician, nurse practitioner, physician assistant, certified nurse midwife, clinical psychologist, or a clinical social worker. RHC/FQHC services may also be covered for individuals who have elected hospice when provided by an RHC/FQHC physician, nurse practitioner, or physician assistant employed or under contract with the RHC or FQHC at the time the services are furnished, who has been designated by the patient as his or her attending physician. Starting January 1, 2024, services of a marriage and family therapist (MFT) or mental health counselor (MHC) are covered under RHC/FQHC services if such MFT or MHC is employed or under contract with the RHC or FQHC at the time the services are furnished.

As defined in § 405.2415, RHCs and FQHCs furnish physicians' services; services and supplies ''incident to'' the services of physicians: Nurse practitioner (NP), physician assistant (PA), certified nurse-midwife (CNM), clinical psychologist (CP), and clinical social worker (CSW) services; and services and supplies incident to the services of NPs, PAs, CNMs, CPs, and CSWs. They may also furnish diabetes self-management training and medical nutrition therapy (DSMT/MNT), transitional care management (TCM) services, and in some cases, visiting nurse services furnished by a registered professional nurse or a licensed practical nurse.

Only medically necessary medical, mental health, or qualified preventive health services that require the skill level of an RHC or FQHC practitioner are RHC or FQHC billable visits. Services furnished by auxiliary personnel (for example, nurses, medical assistants, or other clinical personnel acting under the supervision of the RHC or FQHC practitioner) are considered incident to the visit and are included in the per-visit payment.

RHC and FQHC services also include certain preventive services when specified in statute or when established through the National Coverage Determination (NCD) process. RHCs and FQHCs are paid for the professional component of allowable preventive services when all of the program requirements are met and frequency limits (where applicable) have not been exceeded.

As discussed in the CY 2024 OPPS proposed rule (88 FR 49715), section 4124(b)(4) of the CAA, 2023, amended section 1861(aa)(1) of the Act by adding subparagraph (D) to establish Medicare Part B coverage for IOP services as defined in section 1861(ff)(4) of the Act when these services are furnished by RHCs, which is incorporated for FQHCs by reference in section 1861(aa)(3)(A) of the Act, effective January 1, 2024. We explained that, section 1861(ff)(2) of the Act describes the items and services available under the PHP and IOP benefits. These items and services include: individual and group therapy with physicians or psychologists (or other mental health professionals to the extent authorized under State law); occupational therapy requiring the skills of a qualified occupational therapist; services of social workers, trained psychiatric nurses, and other staff trained to work with psychiatric patients; drugs and biologicals furnished for therapeutic purposes (which cannot, as determined in accordance with regulations, be self-administered); individualized activity therapies that are not primarily recreational or diversionary; family counseling (the primary purpose of which is treatment of the individual's condition); patient training and education (to the extent that training and educational activities are closely and clearly related to individual's care and treatment); diagnostic services; and such other items and services as the Secretary may provide (excluding meals and transportation) that are reasonable

and necessary for the diagnosis or active treatment of the individual's condition, reasonably expected to improve or maintain the individual's condition and functional level and to prevent relapse or hospitalization, and furnished pursuant to such guidelines relating to frequency and duration of services as the Secretary shall by regulation establish, taking into account accepted norms of medical practice and the reasonable expectation of patient improvement.

In the CY 2024 OPPS proposed rule (88 FR 49715), we stated that, in order to be consistent with the scope of benefits required for IOP services under section 1861(ff)(2) of the Act, we proposed to adopt the same standards for IOP services furnished in RHCs and FQHCs as they were proposed for the outpatient hospital setting. For the outpatient hospital setting, we proposed to add regulations at § 410.44 to set forth the conditions and exclusions that would apply for intensive outpatient services (88 FR 49700). Therefore, to be consistent with the statute, we proposed revisions to the RHC and FQHC regulations at 42 CFR part 405, subpart X, that would crosswalk to § 410.44. Specifically, we proposed the following conforming regulatory changes:

- At § 405.2401, Scope and definitions, we proposed to amend the section to add IOP services.
- At § 405.2411, Scope of benefits, we proposed to amend the section to include IOP services.
- At § 405.2446, Scope of services, we proposed to amend this section to include IOP services.

We noted that these proposals would expand access to behavioral health treatment for Medicare beneficiaries and to ensure continuity of care for IOP services to best meet patient needs.

The following is a summary of the public comments received on the scope of benefits for IOP services furnished in RHCs/FQHCs and our responses:

Comment: Many commenters supported our proposal to use the same standards for IOP services furnished in RHCs/FQHCs as in other settings. Commenters stated that these services would expand access to affordable and culturally competent services for the most vulnerable Medicare beneficiaries and hopefully increase rural uptake of this program. One commenter urged CMS to implement these proposals permanently as they will reduce barriers for patients, increase access to crucial services, and improve equity. One commenter encouraged CMS to continue to seek ways to clarify and enhance occupational therapy's role within FQHCs and RHCs. Other commenters urged CMS to provide additional guidance to health centers on classifying professional services furnished by physicians, NPs, PAs, and psychologists during an IOP service.

Response: We appreciate the commenters support. As we noted in the CY 2024 OPPS proposed rule (88 FR 49714) and as discussed in section VIII.B.2 of this final rule with comment period, section 4124 of the CAA, 2023 established Medicare coverage for IOP services to be furnished by FQHCs and RHCs, effective January 1, 2024. Therefore, beginning January 1, 2024, IOP is a permanent benefit that RHCs and FQHCs will be able to furnish in their respective settings.

Regarding occupational therapy's role within RHCs and FQHCs, we note the IOP benefit includes occupational therapy as part of its list of items and services. To reiterate, the types of services covered as intensive outpatient services and the classifications of the types of professional that can provide some of the services include: individual and group therapy with physicians or psychologists or other mental health professionals to the extent authorized under State law; occupational therapy requiring the skills of a qualified occupational therapist, provided by an occupational therapist, or under appropriate supervision of a qualified occupational therapist by an occupational therapy assistant; services of social workers, trained psychiatric nurses, and other staff trained to work with psychiatric patients; drugs and biologicals furnished for therapeutic purposes; individualized activity therapies that are not primarily recreational or diversionary; family counseling, the primary purpose of which is treatment of the individual's condition; patient training and education, to the extent the training and educational activities are closely and clearly related to the individual's care and treatment; and diagnostic services. CMS is unclear about what the commenter meant by ''classifying professional services,'' but we note that physicians, NPs, PAs, and psychologists are practitioners in FQHCs and as such can furnish IOP services. As with any new benefit under Medicare for RHCs and FQHCs, we will be updating our sub-regulatory guidance and providing outreach and education.

After consideration of the public comments we received, we are finalizing our proposal to adopt the same standards for IOP services furnished in RHCs and FQHCs as in the outpatient hospital and CMHC settings, as proposed. That is, IOP services are services that: (1) are reasonable and necessary for the diagnosis or active treatment of the individual's condition; (2) are reasonably expected to improve or maintain the individual's condition and functional level and to prevent relapse or hospitalization; (3) are furnished in accordance with a physician certification and plan of care as specified under new regulations at § 424.24(d); and can be individual and group therapy, occupational therapy, drugs and biologicals furnished for therapeutic purposes, which cannot be self-administered, family counseling, beneficiary education, and diagnostic services. Accordingly, we are finalizing our proposal to make conforming regulatory changes to §§ 405.2401, 405.2411, and 405.2446. We note a detailed discussion regarding the final policies under § 410.44 are available in section VIII.B.2 of this final rule with comment period.

b. Certification and Plan of Care Requirements for IOPs in RHC and FQHC Settings

Section 4124(b)(2)(B) of the CAA, 2023 amended section 1861(ff) of the Act to add paragraph (4) to define intensive outpatient services as the items and services prescribed by a physician for an individual determined (not less frequently than once every other month) by a physician to have a need for such services for a minimum of 9 hours per week and provided under a program described in paragraph (3) (that is, an outpatient program of mostly mental health related services and therapies provided by a hospital or CMHC on an outpatient basis) under the supervision of a physician. The services must be provided 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.

In the CY 2024 OPPS proposed rule (88 FR 49716), we stated to be consistent with physician certification and plan of care requirements required for IOP under section 1861(ff)(4) of the Act, we proposed to adopt the same standards for RHCs and FQHCs as they were proposed for the outpatient hospital setting. For the outpatient hospital setting, we proposed to codify the content of the certification and plan of treatment requirements for intensive outpatient services at § 424.24(d) (88 FR 49702). We explained that physicians would be required to certify that an

individual needs IOP services for a minimum of 9 hours per week and no more than 19 hours per week, as set out in section 4124 of CAA, 2023. This certification would require documentation to include that the individual requires such services for a minimum of 9 hours per week; require the first certification as of the 30th day of IOP services; and require that the certification of IOP services occur no less frequently than every other month. Therefore, to be consistent with the statute, we proposed to revise our regulations at 42 CFR part 405, subpart X, to specify that for the purpose of furnishing IOP services RHCs and FQHCs must similarly meet the certification and plan of care requirements at proposed § 424.24(d).

As discussed in the CY 2024 OPPS proposed rule (88 FR 49716), we also proposed to establish the same patient eligibility criteria for intensive outpatient services as described in proposed § 410.44(c). Specifically, we proposed that intensive outpatient services are intended for patients who: (1) require a minimum of 9 hours per week of therapeutic services as evidenced in their plan of care; (2) are likely to benefit from a coordinated program of services and require more than isolated sessions of outpatient treatment; (3) do not require 24-hour care; (4) have an adequate support system while not actively engaged in the program; (5) have a mental health diagnosis; (6) are not judged to be dangerous to self or others; and (7) have the cognitive and emotional ability to participate in the active treatment process and can tolerate the intensity of the intensive outpatient program.

The following is a summary of the public comments received on the certification and plan of care requirements for IOP services furnished in RHCs/FQHCs and our responses:

Comment: Commenters were supportive of CMS' proposal to adopt the same standards of physician certification and plan of care requirements for IOP services furnished in RHCs and FQHCs. One commenter recommended that CMS ensure that IOP certification appointments count as FQHC visits by amending the Medicare FQHC-specific payment codes to allow for a physician visit with the purpose of evaluating a patient for IOP (or recertifying the patient) to qualify as a billable mental health ''visit.''

Response: We appreciate the support received from commenters. In response to comments regarding the IOP certification appointments counting as an FQHC visit, we note that medically necessary medical, mental health, or qualified preventive health services that require the skill level of an RHC or FQHC practitioner are RHC or FQHC billable visits. We believe that the physician determination of the need for a patient to receive IOP services, certification for IOP services and recertification would generally be tied to an E/M visit and qualify as an RHC or FQHC billable visit. We believe that the FQHC Specific Payment Code list of qualifying visits under FQHC PPS [166] includes an array of services and appears to capture the type of visit, that is a medical or mental health service that could determine a patient's need for IOP and certification or recertification.

Comment: We received a comment from an RHC association in response to the comment solicitation in the CY 2024 OPPS proposed rule on peer services, and whether these would be appropriate to include for PHPs and IOPs (88 FR 49707). The commenter supports including services that are furnished by a peer support specialist as IOP services. They stated that rural areas are facing a dearth of behavioral health practitioners and oftentimes rely upon professionals with less intensive education and training requirements, like peer support specialists. The commenter further stated that peer support specialists also bring lived experience to their work, which can help them address the unique needs of rural beneficiaries with behavioral health diagnoses and that peer support specialists could be treated similarly to community health workers in CMS' proposed community health integration services.

Response: We thank the commenter for raising this concern. As discussed in section VIII.C of this final rule with comment period, CMS is adopting principal illness navigation (PIN) services as applicable to IOP to be included as IOP services after consideration of the comments received in support of the inclusion of peer support specialist services. Specifically, we discuss the appropriateness of the PIN services described by codes G0023, G0024, G0140, and G0146. Consequently, to the extent that such services are permissible under § 410.44, RHCs and FQHCs could provide them as part of the IOP benefit.

We believe peer support workers are people who have been successful in the recovery process who help others experiencing similar situations. Through shared understanding, respect, and mutual empowerment, peer support workers help people become and stay engaged in the recovery process and reduce the likelihood of relapse. Peer support services can effectively extend the reach of treatment beyond the clinical setting into the everyday environment of those seeking a successful, sustained recovery process. Peer support workers typically engage in a wide range of activities, including: advocating for people in recovery; sharing resources and building skills; building community and relationships; leading recovery groups; and mentoring and setting goals.

With regard to RHCs and FQHCs, we believe that peer support specialists are considered auxiliary personnel, and as such can provide RHC/FQHC services under the direct supervision of the RHC or FQHC practitioner, as long as the peer support specialists are certified or trained to provide all elements in the corresponding service and be authorized to perform them under applicable State law and regulations. A detailed discussion regarding PIN services is available in section II.E of the CY 2024 PFS final rule.

After consideration of the public comments we received, we are finalizing our proposal to adopt the same standards for physician certification and plan of care requirements for RHCs and FQHCs providing IOP services as in the outpatient hospital and CMHC settings. In summary, certification requirements include the physician certifying and documenting that the patient has a need for a minimum of 9 hours of IOP services and must occur at least once every other month.[167] The patient's individualized plan of treatment should address all of the conditions that are being treated by the IOP. Recertification of IOP should occur at least every 60 days.

Accordingly, we are finalizing that for the purpose of furnishing IOP services, RHCs and FQHCs must similarly meet the certification and plan of care requirements at § 424.24(d). This provision is codified in the RHC/FQHC regulations in the final revisions to §§ 405.2401, 405.2411, and 405.2446 by way of the crosswalk to § 410.44 as finalized above in section VIII.B.3. of this final rule with comment period. That is, in § 410.44(a)(3) we have finalized requirements that intensive outpatient services are furnished in

[166] *https://www.cms.gov/medicare/medicare-fee-for-service-payment/fqhcpps/downloads/fqhc-pps-specific-payment-codes.pdf.*

[167] We note in the CY 2024 OPPS proposed rule (88 FR 49716), we incorrectly summarized the proposed language for § 424.24(d), that is, (1) that the physician must also certify that an individual needs IOP services for no more than 19 hours per week and (2) that it is a requirement for the first certification take place as of the 30th day of IOP services.

accordance with a physician certification and plan of care as specified under § 424.24(d). We note a detailed discussion regarding the final policies under § 424.24(d) are available in section VIII.B.3 of this final rule with comment period.

In addition, we are finalizing the same patient eligibility criteria for intensive outpatient services as described § 410.44(c), as proposed. Specifically, we are finalizing requirements that intensive outpatient services are available for patients who meet the following criteria: (1) require a minimum of 9 hours per week of therapeutic services as evidenced in their plan of care; (2) are likely to benefit from a coordinated program of services and require more than isolated sessions of outpatient treatment; (3) do not require 24-hour care; (4) have an adequate support system while not actively engaged in the program; (5) have a mental health diagnosis; (6) are not judged to be dangerous to self or others; and (7) have the cognitive and emotional ability to participate in the active treatment process and can tolerate the intensity of the intensive outpatient program. We note a detailed discussion regarding the final policies under § 410.44(c) are available in section VIII.B.2.a. of this final rule with comment period.

4. Special Payment Rules for Intensive Outpatient Services

Under Medicare Part B, payment to RHCs for services (defined in § 405.2411) furnished to beneficiaries is made on the basis of an all-inclusive payment methodology subject to a maximum payment per-visit and annual reconciliation. Our regulations at § 405.2470 provide that RHCs are required to submit cost reports to allow the Medicare Administrative Contractor (MAC) to determine payment in accordance with 42 CFR part 405, subpart X, and instructions issued by CMS. The beneficiary is responsible for the Medicare Part B deductible and coinsurance amounts. Section 1866(a)(2)(A)(ii) of the Act and implementing regulations at § 405.2410(b) establish beneficiary coinsurance at an amount not to exceed 20 percent of the clinic's reasonable charges for covered services.

Under Medicare Part B, FQHCs are paid under the FQHC PPS for services (defined in § 405.2446) furnished to beneficiaries. The statutory payment requirements for FQHC services are set forth at section 1834(o) of the Act. In addition, section 1833(a)(1)(Z) of the Act requires Medicare payment for FQHC services, determined under section 1834(o) of the Act, to be 80 percent of the lesser of the actual charge or the amount determined under section 1834(o) of the Act. Under the FQHC PPS, FQHCs are paid based on the lesser of the FQHC's actual charge for the service or the PPS rate (§ 405.2462(g)(1)). The FQHC PPS rate is subsequently adjusted for certain circumstances as described under § 405.2464(b)(2). The Medicare Part B deductible does not apply to FQHC services. The beneficiary is responsible for a coinsurance amount of 20 percent of the lesser of the FQHC's actual charge for the service or the adjusted PPS rate.

As we discuss in the CY 2021 PFS final rule (85 FR 84699 through 84710), the FQHC PPS base payment is annually increased by the percentage increase in the FQHC market basket, which reflects the operating and capital cost structures for freestanding FQHC facilities. Beginning with CY 2017, FQHC PPS payments were updated using a 2013-based FQHC market basket. A complete discussion of the 2013-based FQHC market basket can be found in the CY 2017 PFS final rule (81 FR 80393 through 80403). In the CY 2021 PFS final rule, we finalized the rebasing and revising of the FQHC market basket to reflect a 2017 base year. The 2017-based FQHC market basket is primarily based on Medicare cost report data for freestanding FQHCs for 2017, which are for cost reporting periods beginning on and after October 1, 2016, and prior to September 31, 2017. We explained that we used data from cost reports beginning in FY 2017 because these data were the latest available, complete data for calculating the major cost weights for the market basket at the time of rulemaking. We also explained that CMS updates the market basket periodically so that the cost weights reflect a current mix of goods and services purchased in providing FQHC services.

Seven FQHCs that have been determined to be grandfathered tribal FQHCs and due to this designation are paid based on the lesser of the outpatient per visit rate or their actual charges, as set out at § 405.2462(f). These grandfathered tribal FQHCs are paid the outpatient per visit rate for furnishing FQHC services.

In addition to the normal package of services, RHCs and FQHCs receive payment for certain additional services. In the CY 2022 PFS final rule (86 FR 65205 and 65206), we implemented section 132 of CAA, 2021, which amended section 1834(o) of the Act and added a new section 1834(y) to the Act, to provide statutory authority for FQHCs and RHCs, respectively, to receive payment for hospice attending physician services. In the CY 2023 PFS final rule (87 FR 69463, 69737 through 69739) we implemented sections 304(b) and (c) of division P of the CAA, 2022 (Pub. L. 117–103, March 15, 2022). Those subsections modified sections 1834(y) and 1834(o)(4) of the Act, respectively, to delay in-person visit requirements in order to for RHCs and FQHCs to receive payment for mental health visits furnished via telecommunications technology.

As we discuss in the CY 2024 OPPS proposed rule (88 FR 49716 and 49717), section 4124(c) of the CAA, 2023 further amended section 1834(o) of the Act and section 1834(y) of the Act, to provide special payment rules for both FQHCs and RHCs, respectively, for furnishing intensive outpatient services. Section 4124(c)(1) of the CAA, 2023 amended section 1834(o) of the Act to add a new paragraph (5)(A) to require that payment for IOP services furnished by FQHCs be equal to the amount that would have been paid under Medicare for IOP services had they been covered outpatient department services furnished by a hospital. In addition, section 4124(c)(2) of the CAA, 2023 amended section 1834(y) of the Act to add a new paragraph (3)(A) to require that payment for IOP services furnished by RHCs be equal to the amount that would have been paid under Medicare for IOP services had they been covered outpatient department services furnished by a hospital.

In the CY 2024 OPPS proposed rule (88 FR 49707 through 49711), we provide a detailed discussion of the proposed CY 2024 payment rate methodology for IOP. We proposed to establish two IOP APC per diem payment rates for hospital-based IOPs (APC 5861 and APC 5862 for 3-service days and 4-service days, respectively).

Consequently, in the CY 2024 OPPS proposed rule (88 FR 49716 and 49717), we addressed our proposed payment policy for RHCs and FQHCs that furnish IOP services. We stated that we believe that it is appropriate to provide a payment structure that supports beneficiaries in an IOP where the utilization is typically structured to be days with three or fewer services. Therefore, we proposed that the rate determined for APC 5861 (Intensive Outpatient (3 services per day) for hospital-based IOPs) would be the payment rate for IOP services furnished in an RHC. For IOP services furnished in FQHCs, we proposed that payment be based on the lesser of a FQHC's actual charges or the rate determined for APC 5861. Additionally, we proposed that grandfathered tribal FQHCs will

continue to have their payment based on the outpatient per visit rate when furnishing IOP services. That is, payment is based on the lesser of a grandfathered tribal FQHC's actual charges or the outpatient per visit rate. We proposed to revise §§ 405.2410, 405.2462, and 405.2464 in the regulations to reflect the payment amount for IOP services and how the Medicare Part B deductible and coinsurance are applied.

In addition, we solicited comment on whether the payment rate for IOP services furnished in RHCs and FQHCs should be adjusted to reflect the variations in costs of furnishing services in different geographic areas and what approaches would be appropriate for determining the value of the adjustment. We also solicited comment on whether the hospital-based IOP APC 5862 for 4-service days would be appropriate for RHCs and FQHCs.

In the CY 2024 OPPS proposed rule (88 FR 49716 and 49717), we discussed the proposals for coding and billing for IOP services under the OPPS. We explained that beginning January 1, 2024, the hospital outpatient department and CMHCs would be able to furnish items and services of both PHPs and IOPs. We stated that we believed it was appropriate to align these programs by using a consolidated list of HCPCS codes would identify the full range of services that both IOPs and PHPs provide to Medicare beneficiaries for billing purposes. We explained that those settings are paid under the OPPS and since they can furnish either PHP or IOP, when submitting a claim to CMS for payment they would be required to report a new condition code 92 to differentiate between PHP and IOP.

We explained that, while RHCs and FQHCs are not authorized to furnish PHP services, we proposed to also require RHCs and FQHCs to report condition code 92 to identify intensive outpatient claims. Since RHCs and FQHCs are paid for IOP services outside of the RHC AIR methodology and FQHC PPS, we believe the condition code reporting approach would allow us to operationalize a 3 service per day payment amount using the final list of HCPCS codes used to identify the full range of services for IOP. In addition, we proposed to align with the requirement under the OPPS, which is in order to qualify for IOP payment, at least one service must be from the Intensive Outpatient Primary list.

We stated, section 4124(c)(1) of the CAA, 2023 amended section 1834(o) of the Act to add a new paragraph (5)(B) to require that costs associated with intensive outpatient services not be used to determine the amount of payment for FQHC services under the FQHC PPS. Likewise, section 4124(c)(2) of the CAA, 2023 amended section 1834(y) of the Act to add a new paragraph (3)(B) to require that costs associated with intensive outpatient services not be used to determine the amount of payment for RHC services under the methodology for all-inclusive rates (established by the Secretary) under section 1833(a)(3) of the Act. Therefore, we proposed conforming revisions under § 405.2468. In addition, we stated conforming revisions would be made to the cost reporting instructions to account for these changes.

We received many comments on our proposals to implement the special payment rule provisions required by section 4124(c)(1) and (2) of the CAA, 2023. The following is a summary of the public comments received on the special payment rules for IOP services furnished in RHCs/FQHCs and our responses:

Comment: Commenters were generally supportive of payment for IOP services furnished by RHCs/FQHCs to be paid outside of the RHC AIR and the FQHC PPS and be paid at the hospital outpatient department (HOPD) rate. Commenters were supportive of CMS' proposal for establishing an IOP APC per diem payment rates for hospital-based IOP for a 3-service day and the use of the condition code for IOP services and agreed with the applicability for RHCs and FQHCs. Commenters also supported CMS' calculation of the IOP payment methodology. Commenters stated that they understood that the statutory language is clear on RHC payment being ''equal to the amount that would have been paid under this title for such services had such services been covered HOPD services furnished by a hospital.''

Response: We appreciate the commenters support on the special payment rules as it relates to payment for IOP services at the HOPD rate.

Comment: One commenter stated that flexibilities granted within this new benefit for other providers should be extended to RHCs as well and asked CMS to allow RHCs to bill for the 3-service day, in the occasional instance when a patient completes three or fewer services in a day, as well.

Response: As we discuss above, in the CY 2024 OPPS proposed rule (88 FR 49717) we proposed to align with the requirement under the OPPS, that in order to qualify for IOP payment, at least one service must be from the Intensive Outpatient Primary list. We note Table 99 of this final rule with comment period identifies the list of intensive outpatient primary services. We believe that this policy is consistent with the commenter's request. In addition, since we otherwise did not receive comment on the proposal, we are finalizing it as proposed. We continue to believe that it is appropriate to provide a payment structure that supports beneficiaries in an IOP where the utilization is typically structured to be days with three or fewer services.

Comment: We received a few comments with respect to CMS' solicitation of comments on whether the hospital-based IOP APC 5862 for 4-service days would be appropriate for RHCs and FQHCs. Several commenters requested that CMS apply the hospital-based IOP rate for 4-service days to RHCs/FQHCs to account for any variations in the cost of furnishing these services in RHCs compared to other settings and geographic areas. One commenter stated that to help address disparities that hinders access to diagnosis and treatment for severe mental illness (SMI), major depressive disorder (MDD), and postpartum depression (PPD) due to severe mental health provider shortages, CMS should finalize an upward variation in the payment rate. The commenter stated that this issue disproportionately impacts rural communities and minorities. Another commenter stated that given IOP is an entirely new benefit and that there is no data on its utilization or cost, CMS should grant broad flexibilities to all providers eligible for the benefit so it can be used as necessary for patients whether three or four separate qualifying IOP services are reported on the claim with condition code 92, the RHC should be eligible to receive the associated payment, $284.00 or $368.18, respectively, similar to how the program will be structured for hospital-based IOPs.

Response: We appreciate feedback in response to our comment solicitation on whether the hospital-based IOP APC 5862 for 4-service days would be appropriate for RHCs and FQHCs. We did not propose the stratified payment rate structure in the initial year of this new benefit for a couple reasons. Section 1861(aa)(2)(K)(iv) of the Act describes an RHC and states that an RHC is not a rehabilitation agency or a facility which is primarily for the care and treatment of mental diseases. Given this statutory provision, we believe uptake will be slow since these settings currently focus on primary care service. We believe providing a single payment rate valued at 3 services is adequate in these settings since the expected acuity of the patients are such that they

typically do not need more than 3 services per day.

We do not believe that access would be hindered in these early stages of a new benefit. Considering a week's worth of care which is how the physician certifies the individual, RHCs and FQHCs will be paid each day an IOP service is furnished whether it is 1 or more so in the rare occasion someone is in the clinic and receives 4 services (but is paid for 3), there could be days that week where someone is in the clinic and receives 1 service (but is paid for 3).

Since this is a new program for these settings, we encourage RHCs and FQHCs to report all of the IOP services they furnish on the claim so that we can gather data. We are excited for RHCs and FQHCs to have the opportunity to furnish IOP services and we are interested to see these programs grow. We plan to monitor utilization of IOP services in these and other settings to inform refinements in the future.

Comment: A few commenters requested that CMS clarify that an FQHC's payment amount for IOP services would be the lesser of the FQHC's actual charges for IOP services or the payment amount for a hospital outpatient department providing IOP services.

Response: In response to commenters request that CMS clarify FQHC payment, we refer the commenter to the discussion in the proposed rule (88 FR 49716 and 49717), that the statutory payment requirements for FQHC services are set forth in section 1834(o) of the Act. In addition, section 1833(a)(1)(Z) of the Act requires Medicare payment for FQHC services, determined under section 1834(o) of the Act, to be 80 percent of the lesser of the actual charge or the amount determined under section 1834(o) of the Act.

When we apply this framework, section 1834(o)(5)(A) of the Act as amended by CAA, 2023 requires payment for IOP services furnished by FQHCs be equal to the amount that would have been paid under Medicare for IOP services had they been covered outpatient department services furnished by a hospital. Therefore, this payment amount determined under section 1834(o) of the Act, is subject to the lesser of provisions required under section 1833(a)(1)(Z) of the Act. To clarify, as we finalize above, an FQHC's payment amount for IOP services would be the lesser of the FQHC's actual charges for IOP services or the rate determined for APC 5861.

Comment: With respect to CMS' solicitation of comments on whether the payment rate for IOP services furnished in RHCs/FQHCs should be adjusted to reflect the variations in cost of furnishing services in different geographic areas, one commenter stated that to offer these services, RHCs may need to recruit and retain additional providers and staff or make additional investments in their clinics with associated expenses that may be higher due to their rural locations. The commenter further stated that many RHCs face challenges with reliable broadband connection, limited professional staff, etc. Therefore, they would support a payment adjustment of 5% for rural providers (practicing in areas of 50,000 or less) offering IOP services.

A few commenters did not support a geographic adjustment for reimbursement of IOP services furnished in RHCs because RHC reimbursement methodology for the Original Medicare program does not have a mechanism for applying a geographic adjustment, and adding the geographic adjustment as an additional factor will result in inconsistency and unnecessary complexity. Other commenters stated that they did not believe the application of a geographical adjuster is statutorily required or required by regulation since payment for IOP is not under the FQHC PPS and did not believe a geographical adjuster is necessary for the purposes of payment for IOP services. These commenters urged CMS adopt policies that ensure payments for IOP services are equal, no matter the location of the health center.

Response: We appreciate feedback in response to our comment solicitation on whether the payment rate for IOP services furnished in RHCs and FQHCs should be adjusted to reflect the variations in costs of furnishing services in different geographic areas and what approaches would be appropriate for determining the value of the adjustment and may take this information into consideration for future rulemaking.

Comment: There were a few comments related to billing for IOP services. Some commenters stated that the proposal did not mention whether RHCs/FQHCs will be required to use specific coding (*i.e.,* list each HCPCS code for each discreet service provided in an IOP service day) on IOP claims and think that doing so would be beneficial in that it would improve CMS' access to complete information on the provision of IOP across various settings. Other commenters stated that CMS should clarify if FQHCs should bill for professionals' services (*i.e.,* MD, NPs, PA, and psychologists) via the FQHC PPS or use their Part B enrollment. These commenters believe that health centers should be permitted to allocate the allowable costs like salary, contracting and/or benefits costs associated with these professionals' time under the ''FQHC services'' cost report, if it cannot be included under their IOP cost report. Some commenters requested that CMS provide operational clarifications on how it plans to require FQHCs to bill for IOP services.

Response: We thank the commenters for their questions on billing for IOP services. We agree that specific coding for IOP services will improve CMS access to complete information and provide us with more data with which to monitor IOP services. In response to comments on the use of specific coding on IOP claims, we stated in CY 2024 OPPS proposed rule (88 FR 49717), we proposed to also require RHCs and FQHCs to report condition code 92 to identify intensive outpatient claims. Since RHCs and FQHCs are paid outside of the RHC AIR methodology and FQHC PPS, respectively, for IOP services we believe the condition code reporting approach will allow us to operationalize a 3 service per day payment amount using the final list of HCPCS codes used to identify the full range of services for IOP and therefore we proposed to adopt the same list of services. The list of proposed HCPCS codes is included in Table 96 of this final rule with comment period for reference. In addition, we proposed to align with the requirement under the OPPS, which is in order to qualify for IOP payment, at least one service must be from the Intensive Outpatient Primary list. Table 97 of this final rule with comment period identifies the proposed list of intensive outpatient primary services. Regarding commenters' request for CMS to clarify if FQHCs should bill for professionals' services (*i.e.,* MD, NPs, PA, and psychologists) via the FQHC PPS or use their Part B enrollment, as IOP services are a new benefit for RHCs and FQHCs, the service is billed on the FQHC claim and not on a professional claim using the practitioners Part B enrollment. Therefore, we would like to reiterate that although RHCs and FQHCs are paid outside of the RHC AIR methodology and FQHC PPS, respectively, for IOP services, FQHCs should bill the same way that they currently bill today, that is, on the FQHC claim. We will be issuing sub regulatory guidance and billing instructions related to the RHC and FQHC IOP policies finalized in this final rule as is typically done with any new service.

Comment: One commenter agrees and supports the proposal to pay Grandfathered Tribal FQHCs that furnish IOP services based on the outpatient per visit rate via the IHS AIR.

Response: We appreciate the support received from the commenter.

After consideration of the public comments we received, we are finalizing our proposal to implement the special payment rules for IOP services as proposed. We are finalizing that the rate determined for APC 5861 (Intensive Outpatient (3 services per day) for hospital-based IOPs) is the payment rate for IOP services furnished in an RHC. For IOP services furnished in FQHCs, the payment is based on the lesser of a FQHC's actual charges or the rate determined for APC 5861. Additionally, grandfathered tribal FQHCs will continue to have their payment based on the outpatient per visit rate when furnishing IOP services. That is, payment is based on the lesser of a grandfathered tribal FQHC's actual charges or the outpatient per visit rate. Accordingly, we are finalizing revisions to §§ 405.2410, 405.2462, and 405.2464 in the regulations to reflect the payment amount for IOP services and how the Medicare Part B deductible and coinsurance are applied. Finally, we are finalizing to require RHCs and FQHCs to report condition code 92 to identify intensive outpatient claims. Tables 98 and 99 of this final rule with comment period display the final HCPCS applicable for IOP and the final IOP primary services, respectively.

c. FQHC Supplemental Payments

As discussed in the May 2, 2014 final rule with comment period (79 FR 25461), section 1833(a)(3)(B)(i)(II) of the Act requires that FQHCs that contract with MA organizations be paid at least the same amount they would have received for the same service under the FQHC PPS. This provision ensures FQHCs are paid at least the Medicare amount for FQHC services. Therefore, if the MA organization contract rate is lower than the amount Medicare would otherwise pay for FQHC services, FQHCs that contract with MA organizations would receive a wrap-around payment from Medicare to cover the difference (see § 422.316). If the MA organization contract rate is higher than the amount Medicare would otherwise pay for FQHC services, there is no additional payment from Medicare.

In the CY 2024 OPPS proposed rule (88 FR 49717), we stated that we believe the special payment rule, is also included in the FQHC PPS rate as described in section 1834(o) of the Act and therefore, IOP services are included in the wrap-around payment. We proposed to make revisions under § 405.2469 to reflect these changes.

The following is a summary of the public comments received on the FQHC supplemental payment for IOP services furnished in FQHCs and our responses:

Comment: Commenters were generally supportive of CMS' proposal on the FQHC supplemental payments. Some commenters stated that the proposed rule failed to acknowledge that health centers are reimbursed outside of the FQHC PPS rate for IOP, which requires a different supplemental payment rate methodology and strongly urged CMS to adopt a broader interpretation of the special payment rule to ensure health centers are paid up to the original Medicare amount that would be paid for IOP services, which is not FQHC PPS. Commenters requested that CMS clarify in the final rule that supplemental payments for Medicare Advantage (MA) beneficiaries cover the difference between the contract rate and the IOP service rate.

Response: We would like to reiterate that we stated in the CY 2024 OPPS proposed rule (88 FR 49717), that IOP services provided in an FQHC are also subject to the wrap-around payment. We stated that this provision ensures FQHCs are paid at least the Medicare amount for FQHC services, which includes FQHC PPS and now IOP services. Therefore, if the MA organization contract rate is lower than the amount Medicare would otherwise pay for FQHC IOP services, FQHCs that contract with MA organizations would receive a wraparound payment from Medicare to cover the difference (see § 422.316). We further stated that if the MA organization contract rate is higher than the amount Medicare would otherwise pay for FQHC IOP services, there is no additional payment from Medicare for IOP services.

After consideration of the public comments, we are finalizing our proposal as proposed, that is revising § 405.2469 to reflect that payment for IOP services are subject to the wrap-around payments.

5. Multiple Visits

a. Background

Currently, RHC and FQHC encounters with more than one health professional and multiple encounters with the same health professional that take place on the same day and a single location constitute a single visit, with the following exceptions:

- A patient has a medical visit and a mental health visit on the same day; or
- A patient has an initial preventive physical exam visit and a separate medical or mental health visit on the same day.

In the CY 2024 OPPS proposed rule (88 FR 49717), we explained that since IOP services are behavioral health services, we did not believe it would be appropriate to pay for a mental health visit and IOP services on the same day. In the case of a medical visit, an encounter can include a medical visit and a mental health visit or a medical visit and IOP services. An encounter cannot include two mental health visits on the same day. As such, we proposed to make amend § 405.2463(c) in the regulations to clarify that we will permit a mental health visit or IOP services on the same day as a medical visit.

The following is a summary of the public comments received on multiple visits for IOP services furnished in FQHCs and our responses:

Comment: We received a few comments on multiple visits. Commenters were generally supportive of CMS' proposal. Some commenters suggested that CMS allow, at a minimum, for an exception so that under emergency circumstances, an FQHC/RHC mental health visit could be furnished (and billable) on the same day that IOP services are provided. The commenters understood that that payment for IOP in FQHCs/RHCs, like IOP in other settings, will be subject to the clinician exclusions described in proposed 42 CFR 410.44(b) and that under this provision, the clinical services of various professionals, when delivered as part of an IOP care plan, are nonetheless unbundled and not paid for as IOP services under the OPPS, but instead, under the relevant Part B methodology. However, given that this provision will also apply to IOP furnished in FQHCs/RHCs, commenters stated that a prohibition on same-day payment for mental health visits in RHC/FQHC settings may be inappropriate. Other commenters strongly urged CMS to allow for a FQHC ''mental health visit'' to occur on the same day as IOP services. These commenters expressed concern that under the proposed rule, health centers risk providing a range of services to a patient without adequate reimbursement due to same-day billing restrictions and believe there could be instances where same-day IOP and mental health visits could occur. They stated as an example that when an IOP patient receives individual therapy sessions with physicians or psychologists as part of an IOP day, it appears that such a service would be billed separately under the relevant methodology (FQHC PPS). They further state that as patient centered medical homes, health centers should not be precluded from providing two different services to a patient on a single day and should be able to bill an FQHC PPS

mental health service and IOP service if delivered on the same day. Another commenter recommended CMS clarify that the IOP benefit does not preclude beneficiaries from receiving other services, including remote mental health services.

Response: We thank the commenters for raising these concerns. As we stated in the proposed rule (88 FR 49717), IOP services are behavioral health services, and we did not believe it would be appropriate to pay for a mental health visit and IOP services on the same day. We understand that in the HOPD setting, additional mental health services may be provided, but are capped at a payment amount not to exceed the IOP or PHP payment amounts. We did not intend to imply that additional services would not be reportable. Under the RHC AIR and FQHC PPS, when there are multiple visits on the same day, we permit those services to be reported, however, we only pay for one visit. We believe the same situation applies here, that is, if additional mental health visits are needed in addition of the 3–IOP services per day, we would expect an RHC or FQHC to report those services on the claim. Payment for the service would be included in the IOP rate similar to how the additional mental health services would be paid for under the OPPS.

After consideration of the public comments, we are finalizing our proposal with a clarification. We are amending § 405.2463(c) in the regulations to state that we will pay a mental health visit or IOP services on the same day as a medical visit. We are clarifying that if a mental health visit is furnished the same day as IOP services, all services are covered under Medicare Part B, however, we will only pay the IOP rate and the mental health visit will be considered packaged. While there could be emergency circumstances for which a mental health visit and IOP services are furnished, at this time we believe that it is unlikely that an FQHC or RHC would simultaneously have a specific patient enrolled in the IOP and need a separate and distinct mental health service delivered at the same FQHC or RHC, in a given day of service. In addition, we believe that the payment amount is adequate if these situations occur, since the rate is based on the costs associated with administering an IOP in the hospital setting which represent a resource intensive program and, therefore, we should not pay more for a day with individual services. As we mentioned above, we recognize that this is a new program for these settings, we encourage RHCs and FQHCs to report all of the services they furnish on the claim so that we can gather data. We plan to monitor utilization of IOP services in these and other settings to inform refinements in the future.

6. Other Regulatory Updates

In addition to the regulatory changes described in this section of the rule, we proposed a revision to § 405.2400 to reflect that 42 CFR part 405, subpart X, is based not only on the provisions of sections 1833, 1861(aa), 1834(o) of the Act, but also the provisions under section 1834(y) of the Act. We believed we inadvertently did not revise the regulations when the CAA, 2021 amended section 1834 of the Act to add new paragraph (y), as we discuss in the CY 2022 PFS final rule (86 FR 65205 through 65206).

We did not receive any comments on the proposal. Therefore, we are finalizing our proposal as proposed to revise § 405.2400 to reflect that 42 CFR part 405, subpart X, is not based only on the provisions of sections 1833, 1861(aa), 1834(o) of the Act, but also the provisions under section 1834(y) of the Act.

G. Modifications Related to Medicare Coverage for Opioid Use Disorder (OUD) Treatment Services Furnished by Opioid Treatment Programs (OTPs)

1. Background

Section 2005 of the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act (SUPPORT Act) (Pub. L. 115–271, October 24, 2018) established a new Medicare Part B benefit category for OUD treatment services furnished by OTPs during an episode of care beginning on or after January 1, 2020. In the CY 2020 Physician Fee Schedule (PFS) final rule (84 FR 62630 through 62677 and 84 FR 62919 through 62926), we implemented Medicare coverage and provider enrollment requirements and established a methodology for determining the bundled payments for episodes of care for the treatment of OUD furnished by OTPs. We established new codes and bundled payments for weekly episodes of care that include methadone, oral buprenorphine, implantable buprenorphine, injectable buprenorphine or naltrexone, and non-drug episodes of care, as well as add-on codes for intake and periodic assessments, take-home dosages for methadone and oral buprenorphine, and additional counseling. For CY 2024, we proposed modifications to the regulations and policies governing Medicare coverage and payment for OUD treatment services furnished by OTPs in both the CY 2024 OPPS proposed rule (88 FR 49717 through 49723) as well as the CY 2024 PFS proposed rule (88 FR 52413 through 52416).

2. Statutory Authority for Coverage of Opioid Use Disorder Treatment Service Provided by OTPs

Intensive outpatient programs (IOPs) [American Society of Addiction Medicine (ASAM) Level 2.1 of Care] are diverse and flexible programs that can provide both a step-up and step-down level of care for the treatment of substance use disorders (SUDs). IOPs may offer a step-down level of care in cases where a patient has been stabilized in a hospital facility or residential treatment program but continues to need services to maintain or achieve further treatment progress. IOPs also offer a step-up level of care in cases where a patient may need a higher level of care that is more structured or intensive than what can be provided in a typical outpatient treatment setting that offers care on a less frequent basis.[168] IOPs can be housed in an OTP, specialty addiction treatment facility, community mental health center (CHMC), or another setting.[169] According to the National Substance Use and Mental Health Services Survey, as of 2021, approximately 557 OTPs offer IOP services nationwide (30.1 percent of SUD treatment facilities offering OTPs).[170] Section 4124 of the Consolidated Appropriations Act (CAA), 2023, which was enacted on December 29, 2022, provides for Medicare coverage and payment for IOP services in hospital outpatient department (HOPDs), CMHCs, rural health clinics (RHCs), and federally qualified health centers (FQHCs). However, section 4124 of the CAA, 2023 did not address coverage for IOP services furnished in OTP settings.

Section 1861(jjj)(1) of the Act defines ''opioid use disorder (OUD) treatment services'' as items and services that are furnished by an OTP for the treatment of OUD, including FDA-approved opioid agonist and antagonist

[168] *https://www.ncbi.nlm.nih.gov/books/NBK64088/.*

[169] The ASAM National Guideline for the Treatment of Opioid Use Disorder (2020): *https://sitefinitystorage.blob.core.windows.net/sitefinity-production-blobs/docs/default-source/guidelines/npg-jam-supplement.pdf?sfvrsn=a00a52c2_2.*

[170] Substance Abuse and Mental Health Services Administration, National Substance Use and Mental Health Services Survey (N–SUMHSS), 2021: Annual Detailed Tables. Rockville, MD: Substance Abuse and Mental Health Services Administration, 2023. Weblink: *https://www.samhsa.gov/data/sites/default/files/reports/rpt39450/2021%20N-SUMHSS%20Annual%20Detailed%20Tables_508_Compliant_2_8_2023.pdf.*

medications, dispensing and administration of such medications, substance use counseling, individual and group therapy, toxicology testing, and other items and services that the Secretary determines are appropriate (not including meals or transportation). For matters related to payment for OUD treatment services, section 1834(w) of the Act establishes that the Secretary shall pay bundled payments to OTPs when they furnish OUD treatment services to an individual during an episode of care. Section 1834(w)(2) of the Act states that for purposes of making payments to OTPs, the Secretary may establish one or more bundles based on the type of medication provided (such as buprenorphine, methadone, naltrexone, or a new innovative drug), the frequency of services, the scope of services furnished, characteristics of the individuals furnished such services, or other factors as the Secretary determine[s] appropriate. We interpret the statutory language at sections 1861(jjj) and 1834(w) of the Act to grant the Secretary authority to establish more than one bundled payment to OTPs for OUD treatment services furnished during an episode of care provided that the scope of services is medically reasonable and necessary for the treatment of OUD. In the CY 2020 PFS final rule (84 FR 62644), we finalized a definition of OUD treatment services as those items and services that are specifically enumerated in section 1861(jjj)(1) of the Act and finalized the weekly bundled payment for an episode of care. After considering public comments, under the discretion granted to the Secretary under section 1861(jjj)(1)(F) of the Act, we also included additional items and services, including intake activities and periodic assessments within the definition of OUD treatment services specified in 42 CFR 410.67(b) (84 FR 62634). In addition, under our authority under section 1834(w)(2) to create one or more bundled payments, we finalized that we would utilize add-on codes as a way to operationalize the creation of more than one bundled payment by making payment adjustments to the weekly bundled payment for the additional items and services.

Furthermore, CMS aims to ensure that Medicare beneficiaries have appropriate access to high quality care for the treatment of OUD, and that services provided to treat SUD under the Medicare OTP benefit are consistent with the services that are available in other settings covered under Medicare Part B. For example, when CMS first established payment policy for OTPs under Medicare Part B in the CY 2020 PFS final rule (84 FR 62630 through 62677 and 84 FR 62919 through 62926), we considered the available benefits payable under Medicare at that time in determining what items to propose to include in the bundled payment for OUD treatment services furnished by OTPs. In light of new legislation (CAA, 2023) granting authority for Medicare payment of IOP services provided by other types of health care providers, we believe it is appropriate to revisit the range of services covered under the current benefit for OUD treatment services furnished by OTPs.

In the CY 2023 PFS proposed rule, we solicited comments on whether there is a gap in coding under the PFS or other Medicare payment systems that may be limiting access to needed levels of care for treatment of mental health or SUD treatment for Medicare beneficiaries (87 FR 45943 and 45944). Specifically, we sought information on multiple issues, including: whether there is a gap in coding under Medicare payment systems that may be limiting access to needed levels of care for treatment of SUD; the extent to which potential gaps would best be addressed by the creation of new codes or billing rules; additional information related to IOP services, including their settings, scope and types of offered services, and practitioners involved; and, other relevant information to the extent it would inform our ability to ensure Medicare beneficiaries have access to this care. In response, many commenters noted that IOPs serve as a ''step-up'' level of care for individuals in need of more services/supports, close monitoring, and structured therapy, but who cannot stabilize at a lower level of care provided in an office setting. Commenters also noted that IOPs simultaneously serve as a ''step-down'' level of care for individuals who have more stabilized biomedical conditions and may no longer need to be hospitalized but cannot be discharged safely. Commenters mentioned that IOPs are tailorable to patient characteristics and are often flexible in the length, frequency, and days of treatment, but that typically patients receive at least 9 hours a week of care. Moreover, commenters stated that IOPs may be provided at stand-alone IOP facilities, OTPs, partial hospitalization programs, residential treatment centers, detoxification centers, or within a private outpatient office setting. Commenters further encouraged CMS to allow coverage for IOP services across the full continuum of care settings so that patients can receive the care they need in the setting that is most clinically appropriate. Furthermore, several commenters emphasized the importance of ensuring access to care for IOP services provided in OTP settings. For example, one commenter recommended ''that CMS also consider whether the agency has regulatory authority to extend coverage of any new IOP billing codes to OTPs.'' Other commenters also preferred the IOP payment methodology to be amenable and complementary to the weekly bundled payment of OTPs, including a building block methodology with drug and non-drug components, and add-on codes for greater clinical complexity. As a whole, commenters were very receptive to expanding access to IOP services in multiple settings of care, including within OTPs.

Addressing the opioid crisis by expanding coverage for quality treatment options and reducing barriers to care continues to remain a high priority for CMS. Across the U.S., the rates of OUD have increased more than threefold and opioid-related mortality has increased by almost 18 percent amongst older adults in the past decade.[171] From 2015–2019, nearly 1.7 million (3 percent of all) Medicare beneficiaries had a SUD, though only 11 percent of those beneficiaries received treatment for their condition in a given year.[172] Among Medicare beneficiaries with a SUD, one-third reported that financial barriers were a reason for not receiving treatment. Research from the Office of the Assistant Secretary for Planning and Evaluation (ASPE) indicates that health plans that offer coverage for a greater number of IOP services per enrollee experience higher rates of SUD treatment initiation and continued engagement within their enrollee populations.[173] This suggests that IOP services could result in an increased rate of SUD treatment initiation and continued engagement. Therefore, expanding access to IOP services in other settings and reducing financial barriers to access to IOP services through coverage could potentially increase the number of Medicare beneficiaries seeking and completing treatment for a SUD, including among Medicare beneficiaries who are members of populations that have historically been less likely to receive such treatment. Studies have shown that among individuals in need of SUD treatment, Hispanic, Black, and

[171] *https://www.sciencedirect.com/science/article/pii/S0749379721000921?via%3Dihub.*

[172] *https://doi.org/10.15585/mmwr.mm675152e1.*

[173] *https://aspe.hhs.gov/sites/default/files/private/pdf/260791/BestSUD.pdf.*

Asian populations are less likely to receive outpatient SUD treatment for their condition than their White counterparts, suggesting greater barriers to treatment access for these populations.[174] Other evidence indicates that Black Americans significantly underutilize specialty SUD treatment and are also less likely to complete their SUD treatment programs compared to White Americans, but these disparities are reduced when Black Americans have access to health insurance.[175] This evidence suggests that financial barriers impede initiation and completion of SUD treatment; in turn, providing health insurance coverage for SUD treatment services (such as IOP services) may lessen the impact of these financial barriers for all Medicare beneficiaries, including those who are more likely to experience these barriers. Some evidence also shows that zip codes in the U.S. within which there is at least one OTP tend to have a higher proportion of residents who are minorities (Black and Hispanic) and a lower proportion of White residents, compared to zip codes in the U.S. without any OTPs,[176] and surveys of services provided by OTPs demonstrate that the majority of OTPs (82.6 percent) conduct community outreach services to those in need of treatment for OUD.[177] This suggests that OTPs may be uniquely positioned to reach minority populations in need of IOP services, which would improve their access to SUD treatment services. In addition, from 2015 to 2019 and prior to implementation of the OTP benefit, Medicare beneficiaries younger than 65 years old were more likely to receive SUD treatment than those aged 65 years old or greater, due to more beneficiaries over age 65 reporting they could not afford treatment or that the treatment was not covered by Medicare or other insurance.[178] Even after implementation of the OTP benefit, eliminating health disparities in access to SUD treatment for this older age bracket remains a priority. Therefore, we believe that expanding access to coverage and payment under Medicare for IOP services provided by OTPs may have a meaningful and positive impact on health equity, including for Medicare beneficiaries that may face barriers in accessing treatment, such as racial/ethnic minorities and/or beneficiaries aged 65 or older. Lastly, CMS' Behavioral Health Strategy includes multiple stated goals and objectives to promote person-centered behavioral health care.[179] Expanding access to coverage and payment under Medicare for IOP services provided by OTPs may help strengthen access to SUD prevention, evidence-based treatment, and recovery services, as well as advance the equity and quality of behavioral health services, which are consistent with the goals of CMS' Behavioral Health Strategy.

3. Coverage of IOP Services Furnished by OTPs

a. Inclusion of IOP Services Furnished by OTPs in the Definition of Opioid Use Disorder Treatment Service

In recognition of the evidence provided in the discussion above, we understand that some Medicare beneficiaries may continue to face barriers in accessing treatment for their OUD. Additionally, we note that many OTPs nationwide already provide IOP services and that IOP services can be effective in promoting greater treatment initiation and engagement, which may improve health outcomes. For these reasons, and in order to expand access to behavioral health treatment for Medicare beneficiaries with OUD and ensure continuity of care between different treatment settings and levels of care, in the CY 2024 OPPS/ASC proposed rule CMS proposed to establish payment under Part B for IOP services furnished by OTPs for the treatment of OUD for CY 2024 and subsequent years.

As explained previously, section 1861(jjj)(1) of the Act defines ''opioid use disorder treatment service'' as items and services that are furnished by an OTP for the treatment of OUD, including FDA-approved opioid agonist and antagonist medications, dispensing and administration of such medications, substance use counseling, individual and group therapy, toxicology testing, and other items and services that the Secretary determines are appropriate (not including meals or transportation). IOP services are intended to treat individuals with an acute mental illness and/or substance use disorder, including those with an OUD. We believe that IOP services are similar to the specific services enumerated in section 1861(jjj)(1) of the Act, and the services and intensity of care required to provide intensive outpatient services under Level 2.1 of the ASAM continuum of care are a step-up from the services within the existing OTP benefit. The ASAM criteria's strength-based multidimensional assessment takes into account a patient's needs, obstacles and liabilities, as well as their strengths, assets, resources, and support structure; this information is used to determine the appropriate level of care across a continuum.[180] OTP services that are currently covered under the OTP benefit are at the Outpatient (Level 1) level of care, whereas IOP services are classified as Level 2.1 on ASAM's continuum of care. Individuals who meet the criteria for IOP services generally require more frequent and intensive services.

Because the Secretary has discretion under section 1861(jjj)(1)(F) of the Act to add other items and services furnished by an OTP for the treatment of OUD, as appropriate, we proposed to add a new paragraph (ix) to the definition of ''opioid use disorder treatment service'' in § 410.67(b) defining a new category of services called ''OTP intensive outpatient services'' and incorporate OTP intensive outpatient services in the definition that are covered under the Part B OTP benefit. Specifically, we proposed to define OTP intensive outpatient services as those services specified in proposed 42 CFR 410.44(a)(4) when furnished by an OTP as part of a distinct and organized intensive ambulatory treatment program for the treatment of Opioid Use Disorder and that offers less than 24-hour daily care other than in an individual's home or in an inpatient or residential setting. OTP intensive outpatient services are services that are reasonable and necessary for the diagnosis or active treatment of the individual's condition; are reasonably expected to improve or maintain the individual's condition and functional level and to prevent relapse or hospitalization; and are furnished in accordance with a physician certification and plan of care. We proposed that in order to qualify as ''OTP intensive outpatient services,'' a physician must certify that the individual has a need for such services for a minimum of 9 hours per week and requires a higher level of care intensity compared to existing OTP services. The specific services that we proposed to be considered OTP intensive outpatient services would include any of the following:

[174] *https://www.samhsa.gov/data/sites/default/files/reports/rpt35326/2021NSDUHSUChartbook102221B.pdf.*

[175] *https://www.sciencedirect.com/science/article/pii/S0376871619302443.*

[176] *https://pubmed.ncbi.nlm.nih.gov/36645315/.*

[177] *https://www.samhsa.gov/data/sites/default/files/reports/rpt39450/2021%20N-SUMHSS%20Annual%20Detailed%20Tables_508_Compliant_2_8_2023.pdf.*

[178] *https://www.sciencedirect.com/science/article/pii/S0749379722001040.*

[179] *https://www.cms.gov/cms-behavioral-health-strategy.*

[180] *https://www.asam.org/asam-criteria/about-the-asam-criteria.*

- Individual and group therapy with physicians or psychologists or other mental health professionals to the extent authorized under State law.
- Occupational therapy requiring the skills of a qualified occupational therapist, provided by an occupational therapist, or under appropriate supervision of a qualified occupational therapist by an occupational therapy assistant as specified in part 484.
- Services of social workers, trained psychiatric nurses, and other staff trained to work with psychiatric patients.
- Drugs and biologicals furnished for therapeutic purposes, subject to the limitations specified in § 410.29, excluding opioid agonist and antagonist medications that are FDA-approved for use in treatment of OUD or opioid antagonist medications for the emergency treatment of known or suspected opioid overdose.
- Individualized activity therapies that are not primarily recreational or diversionary.
- Family counseling, the primary purpose of which is treatment of the individual's condition.
- Patient training and education, to the extent the training and educational activities are closely and clearly related to the individual's care and treatment.
- Diagnostic services that are reasonable and necessary for the diagnosis or active treatment of the individual's condition, with the exception of toxicology testing.

We proposed to exclude FDA-approved opioid agonist or antagonist medications for the treatment of OUD or opioid antagonist medications for the emergency treatment of known or suspected opioid overdose, specifically, methadone, buprenorphine, naltrexone and naloxone, from the definition of OTP intensive outpatient services because these medications are already included as part of the weekly bundled payment for an episode of care or as an adjustment to the bundled payment. However, we solicited comment on the types of drugs and biologicals that are furnished as part of an IOP program (for example, whether IOPs furnish drugs used for emergent interventions), and the extent to which these drugs overlap with medications included in the existing weekly bundles described by HCPCS codes G2067 through G2073 and/or add-on codes described by G2078 (take-home supply of methadone), G2079 (take-home supply of oral buprenorphine), G2215 (take-home supply of nasal naloxone), G2216 (take-home supply of injectable naloxone), and G1028 (take-home supply of nasal naloxone; 2-pack of 8mg per 0.1 mL nasal spray). We explained that this information would help to inform our consideration of the extent to which the drugs and biologicals furnished as part of an IOP program would already be covered under the drug component of the weekly bundled payment and the existing add-on payments or would need to be reflected in the proposed IOP add-on payment adjustment discussed in the next section. Similarly, we proposed to exclude toxicology testing from the types of diagnostic services that would be included in the definition of OTP intensive outpatient services because toxicology testing is already included within the definition of ''opioid use disorder treatment service'' and paid for as part of the weekly bundled payment for an episode of care.

We received many public comments from a variety of commenters on our proposal to establish coverage for IOP services provided by OTPs and to include IOP services furnished by OTPs in the definition of opioid use disorder treatment service. The comments and our responses to these comments are included below.

Comment: We received many comments in strong support of our proposal to establish coverage for IOP services provided by OTPs, with some commenters expressing appreciation specifically for the proposed inclusion of ''OTP intensive outpatient services'' under ''OUD treatment services'' at § 410.67(b). Commenters agreed with CMS exercising its authority under sections 1861(jjj)(1)(F) and 1834(w) of the Act to establish coverage and payment for IOP services furnished at OTPs for beneficiaries who have an OUD. Commenters expressed that the proposal would improve access to OUD treatment, enhance continuity of care for patients with an OUD who need more intensive support and services, ensure that OTPs are reimbursed by Medicare for the full range of services they provide to beneficiaries, and promote efforts to improve health equity for racial/ethnic populations and older beneficiaries. Commenters expressed that establishing coverage for IOP services at additional sites of care, like OTPs, would further drive value for patients and provide another tool for providers to fight the ongoing opioid epidemic. Another commenter expressed support for our proposal and stated that our proposal goes beyond what was required of CMS in the original provisions specified in the CAA, 2023, which first authorized coverage and payment for IOP services under Medicare in only hospital outpatient departments, CMHCs, RHCs, and FQHCs.

Response: We appreciate the support from commenters for our proposal to extend coverage for IOP services to OTPs for the treatment of OUD among Medicare beneficiaries and for recognition that our proposal would extend coverage for IOP services beyond the care settings addressed in the CAA, 2023 by allowing IOP services to be furnished in OTP settings. We agree that establishing coverage for IOP services at OTPs and including OTP intensive outpatient services under the definition of OUD treatment services could improve continuity of care between different treatment settings and levels of care, expand access to treatment for Medicare beneficiaries with an OUD, and further promote health equity among Medicare beneficiaries.

Comment: Several commenters agreed with the proposal to exclude FDA-approved opioid agonist or antagonist medications for the treatment of OUD or opioid antagonist medications for the emergency treatment of known or suspected opioid overdose (e.g, methadone, buprenorphine, naltrexone, and naloxone) from the definition of OTP intensive outpatient services since these medications are already included as part of the weekly bundled payment for an episode of care or as an adjustment to the bundled payment and since all necessary and appropriate Medications for Opioid Use Disorder (MOUD) should already be included in the bundle. Additionally, one commenter responded to our comment solicitation requesting additional details on the types of drugs or biologicals that can be provided within an IOP program, and if these drugs or biologicals overlap with existing medications included in the OTP weekly bundles or add-on codes for take-home medications. They stated that often medications administered as part of an IOP include drugs that cannot be self-administered such as extended-release formulations of buprenorphine and naltrexone used to treat OUD. The same commenter further requested that CMS provide clarification on whether the service associated with the administration of extended-release formulations of buprenorphine and naltrexone would be billed outside the add-on code for IOP services.

Response: We thank commenters for agreeing with our proposal to exclude FDA-approved opioid agonist or antagonist medications for the emergency treatment of known or suspected opioid overdose from the definition of OTP intensive outpatient services. We also thank the commenter

who submitted additional information on the types of medications that are typically administered under an IOP. We note that extended-release formulations of buprenorphine and naltrexone, which the commenter stated are common medications used in IOP settings, and their administration by a healthcare professional are already covered under the existing weekly bundles described by HCPCS codes G2069 (medication-assisted treatment, buprenorphine (injectable)) and G2073 (medication-assisted treatment, naltrexone). Therefore, these services should continue to be billed using the existing codes describing weekly bundled payments to OTPs and not by billing the add-on payment for IOP services furnished by OTPs.

Comment: One commenter stated that they supported CMS' proposal that would permit IOP and partial hospitalization program (PHP) services to be offered in OTPs.

Response: We would like to clarify that the CY 2024 OPPS/ASC proposed rule included a proposal to provide coverage for IOP services furnished at OTPs, but not a proposal to provide coverage for PHP services furnished at OTPs. PHPs provide services to patients needing higher levels of care, requiring 20 or more hours of services per week (ASAM Level of Care 2.5), compared to IOPs which consists of at least 9 hours and no more than 20 hours per week of treatment services (ASAM Level of Care 2.1).[181]

Comment: One commenter requested that the requirement for an ''adequate support system while not engaged in the program'' be removed, since this requirement is not reflected in the eligibility criteria for many other Medicare services and since individuals who need IOP services often do not have an adequate support system.

Response: We clarify here that the requirement for an ''adequate support system while not engaged in the program'' was not proposed as a requirement for beneficiaries in need of IOP services in OTP settings. Rather, we proposed requirements under paragraph (ix) of the definition of ''opioid use disorder treatment service'' in 42 CFR 410.67(b) that ''OTP intensive outpatient services'' must be ''reasonable and necessary for the diagnosis or active treatment of the individual's condition; are reasonably expected to improve or maintain the individual's condition and functional level and to prevent relapse or hospitalization; and are furnished in accordance with a physician certification and plan of care, in which a physician must certify that the individual has a need for at least a minimum of nine hours of services per week and requires a higher level of care intensity compared to other non-intensive outpatient OTP services.'' We note that this requirement for an ''adequate support system while not engaged in the program'' applies to PHP programs and for IOP services in other settings but not OTPs. For a discussion of this requirement and other conditions and exclusions pertaining to IOP services furnished in other settings, please reference section VIII.B.2.a of this final rule with comment period.

Comment: We received multiple comments encouraging CMS to allow IOP services furnished by OTPs under Medicare to be extended to individuals with mental health conditions and SUDs other than OUD. Another commenter recommended that CMS articulate these broader diagnostic eligibilities for OTP intensive outpatient services in regulation.

Response: We thank commenters for this feedback and acknowledge that OTPs may be treating individuals with a variety of mental health and SUD-related conditions, as well as co-occurring conditions in addition to OUD. However, section 1861(jjj)(1) of the Act, as added by section 2005 of the SUPPORT Act, established Medicare coverage for OUD treatment services furnished by OTPs and defined ''opioid use disorder treatment services'' as ''items and services that are furnished by an opioid treatment program for the treatment of opioid use disorder.'' Therefore, Medicare payment to OTPs must be for the purposes of treating OUD. When OTPs provide mental health and/or SUD services to individuals for primary conditions other than OUD, they would not be payable under Medicare. However, IOP services for the treatment of mental health and/or SUD services are payable under Medicare at hospital outpatient departments, CMHCs, FQHCs, and RHCs.

Comment: One commenter requested that CMS remove the requirement for a minimum of 9 hours per week to receive coverage for IOP services, since they believed that some patients may face challenges meeting these standards if they do not have adequate means or resources. In contrast, several other commenters stated that CMS' proposal to require nine hours of services per week is appropriate.

Response: We did not propose to require a minimum of 9 hours of services per week for IOP services furnished by an OTP, as the commenter suggests. Rather, we proposed, at paragraph (ix) of the definition of ''opioid use disorder treatment service'' in § 410.67(b) that ''a physician must certify that the individual has a need for a minimum of nine hours of services per week and requires a higher level of care intensity compared to other non-intensive outpatient OTP services.'' Requiring a physician to certify this level of need, that is, a minimum of 9 hours of IOP services per week, is consistent with existing clinical standards that describe the intensity of these services as specified under the Substance Abuse and Mental Health Services Administration's (SAMHSA) treatment guidance. Additionally, we proposed that by billing for IOP services, OTPs would be attesting to the fact that they have furnished at least nine services for that week that would otherwise qualify as OTP intensive outpatient services as discussed in section VIII.G.3.a of the CY 2024 OPPS proposed rule (88 FR 49720). We acknowledge that not all services will necessarily be 60 minutes in duration, therefore, if an OTP furnishes a minimum of nine services, regardless of the length of each service, these would meet the threshold to bill for IOP services for the treatment of OUD. We understand that there may be weeks where beneficiaries do not necessarily meet the minimum of 9 services per week for IOP services, and we note that if a beneficiary does not meet the minimum of 9 services per week of IOP services, an OTP can still continue to bill the weekly bundles and add-on codes described by G2067 through G2080, and G2115, G2216, and G1028, as long as all applicable requirements are met.

Comment: Several commenters requested additional services be considered for the purposes of payment for IOP services, including FDA-approved medical devices that aid in the reduction of withdrawal symptoms associated with SUDs, community health integration (CHI), social determinants of health, principal illness navigation services, and case management and care coordination services.

Response: We appreciate commenters raising awareness of other types of services that could be considered as potential IOP services furnished by an OTP. In the proposed rule, we proposed to include coverage for IOP services furnished by OTPs for the treatment of OUD in a manner that would be consistent with the scope of services proposed in other settings as specified in the proposed 42 CFR 410.44(a)(4). We

[181] *https://www.asam.org/asam-criteria/about-the-asam-criteria.*

believed this would help ensure Medicare beneficiaries have access to the same types of services across benefit categories and settings of care for IOP services. For a more in-depth discussion regarding the list of potential services for IOP payment, please see the discussion in section VIII.B.2.a of this final rule with comment period. We may consider future updates to this list of services for Medicare payment purposes, including to OTPs through future rulemaking.

Comment: Multiple commenters recommended that CMS specify the practitioners who would be permitted to deliver OTP IOP services. Other commenters requested that CMS ensure flexibility in the types of professionals that are able to provide counseling to patients as it does with the existing OTP benefit.

Response: We thank the commenters for this comment. In the proposed rule, we did not propose to limit the types of professionals that can provide IOP services. Instead, in section VIII.G.3.a of the CY 2024 OPPS proposed rule (88 FR 49720), as reflected in proposed paragraph (ix) of the definition of ''opioid use disorder treatment service'' in § 410.67(b) in the cross reference to § 410.44(a)(4), we listed examples of the types of professionals who could potentially provide OTP IOP services, such as physicians, psychologists, occupational therapists, social workers, trained psychiatrist nurses, or other mental health professionals to the extent authorized under State law and scope of practice requirements. However, this was not a comprehensive list. We additionally note that if any professionals are not authorized under state law or scope of practice requirements to furnish therapy and counseling services, the therapy or counseling services provided by these professionals would not be covered as OTP intensive outpatient services. This would also be consistent with existing guidance for counseling and therapy services under the non-drug component of the existing OTP weekly bundles.[182]

Comment: One commenter said they would appreciate if CMS could clarify any distinction between the existing scope of services included in the OTP benefit and the scope of services described under the proposed add-on payment adjustment for IOP services. They also stated they would appreciate learning how billing and coding requirements may differ under the proposed IOP add-on payment adjustment versus the existing OTP bundles and/or add-on codes.

Response: We appreciate this request for clarification. The existing OTP weekly bundled payment includes both non-drug and drug components for an episode of care, as well as add-on codes for additional services furnished and take-home medications, as specified in 42 CFR 410.67(d)(2) and (4). Specifically, these are described by HCPCS codes G2067 through G2080, and G2115, G2216, and G1028. OTP services that are currently covered under the OTP benefit are at the Outpatient (Level 1) level of care and typically require less than 9 hours of care per week, according to ASAM's criteria for the continuum of care.[183] The services included as part of the OTP bundles and/or add-on codes, which are specified at 42 CFR 410.67(b) in the definition of ''opioid use disorder treatment service,'' include FDA-approved opioid agonist and antagonist medications (buprenorphine, methadone, and naltrexone) or opioid antagonist medications for the emergency treatment of known or suspected opioid overdose; overdose education; dispensing and administering of MOUD, if applicable; substance use counseling; individual and group therapy; toxicology testing; intake activities; and periodic assessments. For these services, at least one OUD treatment service must be furnished (from either the drug or non-drug component) to the patient in order to meet the threshold to bill for an episode of care.

Some of the services included in the non-drug component of the OTP bundled payments may be furnished via telecommunications technology. Individual and group therapy and substance use counseling may be furnished using audio-video technology, as clinically appropriate, and via audio-only technology if two-way audio/video communications technology is not available to the beneficiary, provided all other applicable requirements are met, as specified in paragraphs (iii) and (iv) of the definition of ''opioid use disorder treatment service'' in 42 CFR 410.67(b). Initiation of treatment with buprenorphine (but not methadone) via the OTP intake add-on code may be furnished via two-way audio-video communications technology, and via audio-only communication technology when audio-video technology is not available to the beneficiary, to the extent that the use of audio-video telecommunications technology to initiate treatment with buprenorphine is authorized by the Drug Enforcement Administration (DEA) and SAMHSA at the time the service is furnished, as specified in paragraph (vi) of the definition of ''opioid use disorder treatment service'' in 42 CFR 410.67(b). Additionally, as of CY 2023, these services furnished via OTP mobile units are considered for the purposes of determining Medicare payments to OTPs under the bundled payment codes and/or add-on codes to the extent that the services are medically reasonable and necessary and are furnished in accordance with SAMHSA and DEA guidance. Currently, periodic assessments are allowed to be furnished via audio-only telecommunication through CY 2023, and finalized in the CY 2024 PFS final rule (87 FR 69404; November 18, 2023) so that these services may be furnished audio-only through the end of CY 2024, to the extent that use of audio-only communications technology is permitted under the applicable SAMHSA and DEA requirements at the time the service is furnished, and all other applicable requirements are met. For additional details regarding existing flexibilities regarding use of telecommunications under the OTP benefit, commenters can also reference Chapter 17 of the Medicare Benefit Policy Manual for Opioid Treatment Programs.[184]

In contrast, IOP services correspond to Level 2.1 of ASAM's continuum of care and range between 9 hours or more per week and no more than 20 hours per week for adults requiring a higher acuity of care compared to those at the outpatient level of care (Level 1), which reflects the intensity of services currently described by the existing OTP benefit. The proposed adjustment for IOP services furnished at OTPs for the treatment of OUD would serve as an add-on code that can be billed in conjunction with the existing weekly bundles for medication assisted treatment, such as HCPCS codes G2067 through G2075, and would reflect additional services required for patients with an OUD who need more intensive and more frequent care than is typical at the outpatient level. The proposed list of services for IOP services furnished at OTPs, which is reflected in proposed paragraph (ix) of the definition of ''opioid use disorder treatment service'' in § 410.67(b) by the inclusion of the language, ''one or more services specified in § 410.44(a)(4),'' includes

[182] Page 5, 40.1.1 Aspects of the Bundle, Non-drug component: *https://www.cms.gov/files/document/chapter-17-opioid-treatment-programs-otps.pdf.*

[183] *https://www.asam.org/asam-criteria/about-the-asam-criteria.*

[184] *https://www.cms.gov/files/document/chapter-17-opioid-treatment-programs-otps.pdf.*

individual and group therapy with physicians or psychologists or other mental health professionals to the extent authorized under State law, which may be more intensive in nature than other therapy services delivered to patients at Level 1 of the ASAM continuum of care as in the existing OTP benefit; occupational therapy requiring the skills of a qualified occupational therapist, provided by an occupational therapist, or under appropriate supervision of a qualified occupational therapist by an occupational therapy assistant; services of social workers, trained psychiatric nurses, and other staff trained to work with psychiatric patients; drugs and biologicals furnished for therapeutic purposes, subject to the limitations specified in § 410.29, excluding opioid agonist and antagonist medications that are FDA-approved for use in treatment of OUD or opioid antagonist medications for the emergency treatment of known or suspected opioid overdose; individualized activity therapies that are not primarily recreational or diversionary; family counseling, the primary purpose of which is treatment of the individual's condition; patient training and education, to the extent the training and educational activities are closely and clearly related to the individual's care and treatment; and, diagnostic services that are reasonable and necessary for the diagnosis or active treatment of the individual's condition, with the exception of toxicology testing. We proposed, at § 410.67(d)(4)(i)(F), that at least nine IOP services per week would need to be furnished by an OTP in order to reach the threshold to bill for IOP services.

Lastly, we note that while certain services under the existing OTP benefit have additional flexibilities for being furnished via audio-only/audio-video technologies, we did not propose similar telecommunications technology flexibilities for OTP intensive outpatient services and are not finalizing these type of flexibilities for intensive outpatient services at this time. Not extending telecommunications technology flexibilities to OTP intensive outpatient services is consistent with policies being finalized in HOPDs, CMHCs, RHCs, and FQHCs that are also not permitting these types of flexibilities for IOP services. This will also allow CMS additional time to examine the clinical evidence and guidance to ensure that any IOP services furnished to beneficiaries with an OUD can be conducted in a manner that maintains safety and a high quality of care for Medicare beneficiaries.

After consideration of the public comments we received, we are finalizing our proposal to add a new paragraph (ix) to the definition of ''opioid use disorder treatment service'' in § 410.67(b) defining a new category of services called ''OTP intensive outpatient services'' and incorporating ''OTP intensive outpatient services'' in the definition of OUD treatment services that are covered under the Part B OTP benefit. We are excluding FDA-approved opioid agonist or antagonist medications for the treatment of OUD or opioid antagonist medications for the emergency treatment of known or suspected opioid overdose, from the definition of ''OTP intensive outpatient services'' because these medications are already included as part of the weekly bundled payment for an episode of care or as an adjustment to the bundled payment. Additionally, we are finalizing our proposal to exclude toxicology testing from the types of diagnostic services that would be included in the definition of ''OTP intensive outpatient services'' because, similarly, toxicology testing is already included as part of the bundled payment for an episode of care.

b. Establishment of a Weekly Payment Adjustment for IOP Services Furnished by OTPs

Section 1834(w)(2) of the Act provides the Secretary discretion to implement one or more payment bundles based on the type of medication provided, frequency of services, scope of services furnished, characteristics of the individuals furnished such services, and other factors as the Secretary determines appropriate. Currently, ASAM classifies OTP services as outpatient treatment services (under Level 1 of the continuum of care), which are typically provided for less than 9 hours a week, or as a step-down from intensive outpatient services, whereas intensive outpatient services (under Level 2.1 of the continuum of care) are typically provided for more than 9 hours a week and no more than 20 hours a week for adults with more severe needs than those for whom treatment provided according to Level 1 of the continuum of care is clinically appropriate.[185] In order to appropriately reflect the more intensive treatment profile for those individuals receiving IOP services versus OTP services, we proposed to establish a weekly payment adjustment via an add-on code for OTP intensive outpatient services, which is consistent with the weekly bundled payment structure under the existing Medicare OTP benefit. We stated in the CY 2024 OPPS proposed rule that we believe that a code billed on a weekly basis would allow greater flexibility with respect to how IOP services are rendered and how service hours may be distributed over a given week to best meet patient needs. Under the proposal, we proposed that an OTP could bill for the weekly add-on code for OTP intensive services in the same week for the same beneficiary as the existing coding describing a weekly OTP bundle, so long as all applicable billing requirements for each code are met (88 FR 49720). However, we noted that under the proposal, each OTP intensive outpatient service must be medically reasonable and necessary and not duplicative of any service(s) for which OTPs received bundled payments for an episode of care in a given week.

For OTP intensive outpatient services, we proposed to permit OTPs to bill new HCPCS code GOTP1 (Intensive outpatient services; minimum of nine services over a 7-contiguous day period, which can include: individual and group therapy with physicians or psychologists (or other mental health professionals to the extent authorized under State law); occupational therapy requiring the skills of a qualified occupational therapist; services of social workers, trained psychiatric nurses, and other staff trained to work with psychiatric patients; individualized activity therapies that are not primarily recreational or diversionary; family counseling (the primary purpose of which is treatment of the individual's condition); patient training and education (to the extent that training and educational activities are closely and clearly related to individual's care and treatment); diagnostic services; List separately in addition to code for primary procedure. (88 FR 49721)

We proposed to value HCPCS code GOTP1 based on an assumption of a typical case of three IOP services furnished per day for approximately 3 days per week. In response to the comment solicitation on IOP services in the CY 2023 PFS proposed rule, many commenters stated that a typical IOP treatment plan consists of at least 9 hours of skilled treatment services per week, which would follow both the treatment protocol advised by SAMHSA and ASAM level placement criteria.[186] Moreover, the definition of intensive outpatient services in section 4124(b)(2)(B) of the CAA, 2023 specifies

[185] *https://americanaddictioncenters.org/rehab-guide/asam-criteria-levels-of-care.*

[186] *https://www.ncbi.nlm.nih.gov/books/NBK64088/; https://store.samhsa.gov/product/TIP-47-Substance-Abuse-Clinical-Issues-in-Intensive-Outpatient-Treatment/SMA13-4182.*

that in community mental health centers, hospital-based IOPs, RHCs, and FQHCs, an individual in need of IOP services must be certified by a physician to have a need for such services for a minimum of 9 hours per week compared to a minimum of 20 hours per week in a partial hospitalization service treatment program. Therefore, we proposed to calculate the payment rate for add-on code GOTP1 based on 9 services per week. We welcomed comments on whether 9 services per week is representative of the typical number of services furnished to patients with an OUD who receive IOP services at OTPs. (88 FR 49721)

We proposed that by billing HCPCS code GOTP1, the OTP would be attesting to the fact that it has furnished at least nine services for that week that would otherwise qualify as OTP intensive outpatient services as discussed in section VIII.G.3.a of the CY 2024 OPPS proposed rule. We acknowledged that not all OTP intensive outpatient services will necessarily be 60 minutes in duration, or be a time-based service, therefore, we proposed that furnishing nine OTP intensive outpatient services, regardless of the length of each service, would meet the threshold to bill for HCPCS code GOTP1. We noted that this aspect of our proposal differs from the proposed requirement for physician certification, discussed in section VIII.G.3.c. of the CY 2024 OPPS proposed rule, pursuant to which a physician must certify that the individual requires nine hours of OTP intensive outpatient services, and not simply nine OTP intensive outpatient services.

Under the proposal to establish a weekly add-on payment for OTP intensive outpatient services, we stated that no single service could be counted more than once for the purpose of meeting the criteria for billing for any given code. In other words, the same service could not be used to qualify to bill both the weekly bundle and the add-on payment adjustment for OTP intensive outpatient services. Additionally, we recognized that some services furnished as part of OTP intensive outpatient services may be required multiple times a week (for example, occupational therapy, patient education, family counseling, activity therapies) to meet individual patient needs and varying clinical complexity. Such services of the same type would be allowable to meet the minimum of 9 services per week, provided that all services are medically reasonable and necessary.

We noted that the proposal for the calculation of the payment rate for HCPCS code GOTP1 is similar to the payment methodology proposed for IOP services furnished in other settings. We stated that we believed that calculating the payment rate for the proposed add-on payment adjustment for OTP intensive outpatient services based on the rate provided in a hospital setting would promote greater consistency, site neutrality, and parity with payment rates proposed for IOPs in a majority of other settings, including hospital-based IOPs, FQHCs, and RHCs. Please see a more detailed discussion regarding this payment methodology in section VIII.D of this final rule.

We acknowledged that, since IOP services have not been covered or paid under Medicare to date, CMS did not have direct data to estimate utilization and costs of IOP services. However, many of the items and services included in IOP services have been and are currently paid for by Medicare as part of the PHP benefit or under the OPPS more generally. Therefore, in our preliminary ratesetting exercise, we identified, in consultation with clinicians, a list of HCPCS codes for services that would be reasonably included as part of IOP services. Please see a more comprehensive list of these HCPCS codes used to inform the payment methodology during our preliminary ratesetting exercise in Table 43 within section VIII.C of the CY 2024 OPPS proposed rule (88 FR 49704 and 49705). The inclusion of many of these services was informed by comments we received in response to comment solicitations in the CY 2023 OPPS/ASC and PFS proposed rules. For example, some of these codes correspond to services for individual and group therapy, occupational therapy, individualized activity therapies, family counseling, and patient training and education.

For the majority of these identified HCPCS codes, the most recent utilization data available was for OPPS claims paid for dates of service in CY 2022, and the most recent cost data available was from the cost reports in CY 2021. Based on this cost and utilization data from CY 2021 and CY 2022, respectively, the estimated payment rate for 3 services per day based on APC 5861 (Intensive Outpatient (1–3 services) for Hospital-based IOPs) was $280.80, at the time of drafting the proposed rule; 3 services per day for 3 days a week would therefore be equal to $842.40. Because we proposed that OTP intensive outpatient services include individual and group therapy, which are also already included in the non-drug component of the OTP bundled payments for an episode of care, we proposed to subtract the amount that corresponds to the individual and group therapy rate in the non-drug component of the OTP bundled payment from our estimate of $842.40 in order to establish the amount of the OTP intensive outpatient services add-on payment. Specifically, in the CY 2020 PFS final rule (84 FR 62658), we finalized a building block methodology to calculate the rate for the non-drug component based on established non-facility rates for similar services under the Medicare PFS, the Medicare Clinical Laboratory Fee Schedule (CLFS), and state Medicaid programs. For group therapy, we used CPT code 90853 (Group psychotherapy (other than of a multiple-family group)) as a reference code, which at the time of drafting the CY 2020 PFS final rule, in CY 2019, was assigned a non-facility rate of $27.39. In order to account for the application of the annual update to the non-drug component, the adjusted amount for group psychotherapy was $28.36. For individual therapy, in the CY 2023 PFS final rule (87 FR 69773), we finalized an update to the reference code used in the non-drug component to be based on the CY 2019 non-facility rate for CPT code 90834 (Psychotherapy, 45 minutes with patient), which was $91.18, and which we adjusted to account for the application of the annual update in the intervening years, resulting in $94.37. Therefore, we proposed an add-on payment adjustment of approximately $719.67 for HCPCS code GOTP1 ($842.40 − ($28.36 + $94.37)). We sought comment on whether the proposed add-on payment adjustment accurately reflects the typical resource costs involved in furnishing IOP services at OTPs. We also sought comment on our proposal to adjust the proposed add-on payment adjustment to account for individual and group therapy included in the non-drug component of OTP bundled payments for an episode of care.

In accordance with the methodology used to update the payment rate for other services payable under the OTP benefit, we proposed to apply an annual update based on the percentage increase in the Medicare Economic Index (MEI) to the payment rate HCPCS code GOTP1, as described in § 414.30. Additionally, consistent with the methodology used to determine payment for non-drug services furnished under the OTP benefit, we proposed to apply a geographic adjustment to the payment for HCPCS

code GOTP1 based on the Geographic Adjustment Factor (GAF), as described in § 414.26. Furthermore, consistent with the policy that applies for other OUD treatment services furnished by OTPs, a beneficiary copayment amount of zero would apply for OTP intensive outpatient services. Lastly, we also sought comment on the impact the proposal may have on dually eligible individuals, specifically, the extent to which this expanded coverage and payment may supplant Medicaid coverage for dually eligible individuals, versus the extent to which it would supplement Medicaid if it were fundamentally different from what Medicaid covers in a given state.

We recognized in the CY 2024 OPPS proposed rule (88 FR 49722) that we proposed to adopt per diem rates for IOP services furnished in other settings, including CMHCs, hospital-based settings, FQHCs, and RHCs, and that per diem rates are used in the payment methodology for IOP services in some state Medicaid programs. Therefore, we also sought comment on whether a daily per diem rate based on 3 service hours per day would be more appropriate for OTP settings, especially if one payment methodology over the other would be less disruptive to OTPs as it relates to coordination of benefits. Lastly, we sought feedback about the experiences of furnishing IOP services within OTP settings, including the extent to which it is similar to or different than furnishing IOP services in other settings. We stated that we believed this additional information may be helpful to understand the clinical complexity of patients enrolled in OTPs who are in need of IOP services for OUD and to compare the level of care and type of services that may supplement and/or exceed those ordinarily provided under the existing OTP benefit, in order to help inform potential future rulemaking on this topic.

We proposed to add a new paragraph (d)(4)(i)(F) to § 410.67 in order to describe the new adjustment to the bundled payment for OTP intensive outpatient services. Additionally, we proposed to amend § 410.67(d)(4)(ii) to add that the payment amounts for OTP intensive outpatient services will be geographically adjusted using the Geographic Adjustment Factor described in § 414.26. Lastly, we proposed to amend § 410.67(d)(4)(iii) to add that payment for OTP intensive outpatient services will be updated annually using the Medicare Economic Index described in § 405.504(d).

We received many public comments on our proposal to establish a weekly payment adjustment for IOP services furnished by OTPs. These public comments and our responses to these comments are addressed in the section below.

Comment: We received a few comments regarding our proposal to apply a beneficiary copayment amount of zero for OTP intensive outpatient services, which is consistent with the policy for other OUD treatment services furnished by OTPs. Commenters were very supportive of this, since they stated patient out of pocket costs, even if they are small, are one of the largest deterrents for patients being able to access care.

Response: We thank commenters for expressing their support for this policy regarding beneficiary copayment amounts.

Comment: Many commenters submitted comments regarding the frequency of payment (per-diem or weekly) for the proposed payment rate methodology. The comments were mixed regarding whether a per-diem versus a weekly payment rate would be more appropriate in an OTP setting. Commenters in support of a per-diem approach raised that a beneficiary may need nine or more hours of IOP services per week but may not be able to always attend all the scheduled services each week due to extenuating circumstances. Commenters also noted that in these cases especially, a per diem rate may better approximate the actual number of services delivered in a given week. One commenter recommended a mixed approach, requesting that CMS make a per diem rate available for providers to bill in cases where patients are unable to receive all the scheduled services in a given week, but that CMS should also allow providers to bill the weekly rate when the minimum nine services requirement is met. This commenter also stated that providers should not be penalized if patients cannot attend the minimum number of nine services per week. Many other commenters supported the weekly billing approach. A few commenters stated that a weekly structure would be the easiest to implement, given that Medicare already pays OTPs on a weekly basis, as well as TRICARE, and many State Medicaid programs. One commenter encouraged CMS to allow some level of flexibility if a weekly payment is finalized, such as partial payment or allowing OTPs to average the number of service hours over multiple weeks, so that an OTP is not expected to go without payment for the week when less than nine services are furnished.

Response: We appreciate the comments related to the proposed frequency of payment for OTP intensive outpatient services. We understand that a beneficiary may have one or a number of extenuating circumstances, which may make it difficult in a given week to meet the weekly minimum nine services requirement for the weekly payment approach. However, in the CY 2024 OPPS/ASC proposed rule, we stated that a code billed on a weekly basis may allow greater flexibility than a per diem approach with respect to how IOP services are rendered. We believe that a weekly payment approach would allow more flexibility for how service hours could be distributed over a given week to best meet patient needs, including in a manner to balance frequent IOP treatment with other obligations such as work, childcare, school, household activities, etc., compared to a per-diem approach that would require a specific number of service hours per day. Furthermore, we believe that a weekly billing structure may allow OTPs to more easily verify that the required number of IOP services have been furnished. Statutory requirements, SAMHSA treatment guidance, and clinical standards from ASAM indicate that a minimum of nine skilled treatment services is standard for IOPs. The proposed payment amount for GOTP1 is based on nine services per week, which is consistent with these existing standards. Additionally, less than nine IOP services rendered per week would be consistent with the intensity of care at the outpatient level, which is already reflected in the existing OTP benefit. In response to commenters' who stated that OTPs should not be penalized if patients cannot attend the minimum number of nine services per week, we affirm that OTPs can continue to bill the weekly bundles and add-on codes described by G2067 through G2080, and G2115, G2216, and G1028, to receive payment for treating Medicare beneficiaries with an OUD, as long as all applicable requirements are met.

Finally, most comments in response to the CY 2023 PFS comment solicitation on IOPs and in response to the proposed rule indicated a preference for a weekly billing structure in OTP settings. We continue to believe that a weekly billing structure is appropriate at this time. However, we will continue to monitor the billing structure to ensure that Medicare beneficiaries with an OUD do not face barriers to accessing OTP intensive outpatient services and may consider adjustments as needed through future rulemaking.

Comment: Multiple commenters expressed concern regarding our proposal to subtract the payment rate for individual and group therapy when

calculating the weekly payment adjustment for IOP services furnished by OTPs. Commenters stated that OTPs who offer individual and group therapy services as part of an IOP conduct these services in a way that is separate and distinct from the therapy services they are already providing to Medicare beneficiaries under the existing OTP benefit. Commenters further explained that these individual and group therapy services are more intensive and would be additional, not duplicative services, compared to the existing covered therapy services built into the weekly bundled payment. Commenters also stated that an IOP is a critically important level of care for individuals who need more intensive and structured treatment than outpatient services, but who can live safely in their homes and communities without needing 24-hour treatment in residential or inpatient settings. Therefore, commenters requested that CMS not exclude the payment amount for individual and group counseling services from the payment methodology for the IOP payment adjustment.

Response: We appreciate commenters raising these concerns. We proposed to deduct the payment rates for individual and group therapy services from the payment rate for IOP services because we believed that these therapy services may be duplicative of services included in the non-drug component of the OTP bundled payment. However, we are persuaded by the public comments received that requested that we do not deduct the payment rate for individual and group therapy services from the payment methodology for the IOP payment adjustment. Commenters explained that the individual and group therapy services furnished as part of an IOP are more intensive in nature and may be furnished on a more frequent basis than those therapy services in the non-drug component of the OTP bundled payment, thus they would not be duplicative in nature. Additionally, we were persuaded by the rationale that IOP services are often more intense than at an outpatient level since they are often provided as a step-down from residential or inpatient settings, whereby patients may still need intensive therapy services at a higher acuity of care but may not necessarily require 24-hour treatment. Furthermore, in response to the comment solicitation for IOP services in the CY 2023 PFS proposed rule, commenters raised that therapy services furnished in IOP services are structured, goal-oriented, and often focus on social skill rehabilitation and ongoing engagement. We also note that IOP services are usually provided at Level 2.1 of the ASAM continuum of care, which is likely to reflect therapy services that are more intensive, compared to services provided at the outpatient level within the existing OTP benefit and that are described by Level 1 of the ASAM continuum of care. We understand that individual and group therapy services are fundamental to many IOPs. We do not want to disincentivize OTPs furnishing necessary care for Medicare beneficiaries with an OUD who need more intensive therapy, by establishing a payment rate that does not reflect the resources involved in furnishing these services. Therefore, in consideration of these comments, we are finalizing a payment methodology for the IOP payment adjustment that does not deduct the amount for individual therapy (based on the CY 2019 non-facility rate for CPT code 90834, which was $91.18) and for group therapy (based on the CY 2019 non-facility rate for CPT code 90853, which was $27.39) and their annual update adjustments. The finalized payment amount for GOTP1 for CY 2024 is $*778.20.* We are reflecting this policy change in new § 410.67(d)(4)(i)(F) by removing the proposed language, ''excluding an amount equivalent to the amount included in the OTP weekly bundled payment for individual and group therapy.''

Comment: We received a few comments regarding payment neutrality among multiple care settings. Specifically, commenters advocated that a site-neutral set of payment rates should be applied to all providers of IOP services, including hospital outpatient departments, CMHCs, FQHCs, RHCs, and OTPs. One commenter further noted that as additional claims and cost data become available in the years after the IOP benefit is implemented, CMS can then evaluate whether adjustments and different payment rates are appropriate for different settings.

Response: We thank the commenters for their feedback. As we stated in the proposed rule, we did not have direct data to estimate utilization and cost of IOP services at the time of setting proposed payment rates since IOP services have not been covered or paid under Medicare to date. We agree with the commenter that it would be appropriate to continue to monitor cost and utilization data over time, and if future adjustments are needed, we may consider these refinements to the payment rate for future rulemaking. Additionally, we note that by finalizing a policy to not deduct an amount for individual and group therapy from the adjustment for IOP services furnished by OTPs, as detailed in the discussion above, the payment rate for OTPs would be consistent with the payment rate for most other settings under Medicare. We would continue to base our payment rate for OTPs on APC 5861 (Intensive Outpatient (1–3 services) for Hospital-based IOPs), which is reflected in the payment methodologies for the other settings and would help promote site neutrality.

Comment: One commenter expressed appreciation that CMS clarified that OTP intensive outpatient services do not necessarily need to be one hour in duration and that the same IOP service can be performed more than once per week to meet the nine-services threshold per week. The commenter requested that CMS finalize these flexibilities.

Response: We thank the commenter for their support of these proposed flexibilities for OTPs furnishing intensive outpatient services.

Comment: One commenter expressed concern regarding the proposal to update the payment for OTP intensive outpatient services annually using the Medicare Economic Index (MEI). The commenter stated that the MEI reflects the cost of physician practices but does not adequately capture the cost and care delivery structures in the OTP setting. The commenter raised that OTPs are more similar to hospital outpatient departments because they include interdisciplinary teams, case management services, Clinical Laboratory Improvement Amendments (CLIA)-waived services, medication management and diversion control systems, and other services. The commenter further added that OTPs are subject to rigorous oversight, accreditation, and certification standards. For these reasons, and because the MEI mirrors general inflation more than medical inflation, the commenter contended that the MEI is not an appropriate update factor and suggested that instead the Inpatient Prospective Payment System (IPPS) market basket update would be a better indicator for annual price growth.

Response: We appreciate hearing from the commenter on this issue. However, we note that the payment amounts for other services under the existing OTP benefit are annually updated by the MEI, as described in 42 CFR 410.67(d)(4)(iii). We did not propose to modify the update factor for the non-drug component of the bundled payment for an episode of care, and we do not believe it would be appropriate to apply a different update factor for IOP

services furnished by OTPs without also adjusting the update factor for the non-drug component in the existing weekly bundle. However, we may consider this issue for future rulemaking.

Comment: One commenter did not object to the payment methodology for setting the weekly payment rate for IOP services furnished in OTPs or the actual payment amount, but pointed out that OTPs may be benefitting from a higher payment rate for IOP services than CMHCs. The same commenter believed it would be inequitable for CMS to provide the higher IOP rate to new entity types furnishing IOP services compared to CMHCs.

Response: We thank the commenter for their feedback. While we are uncertain how long OTPs have historically furnished IOP services, we do note that SAMHSA data suggests that approximately 557 OTPs offer IOP services nationwide as of 2021, thus we do not necessarily believe OTPs would be new entities furnishing intensive outpatient services.[187] In establishing payment to OTPs for these services, we are seeking to finalize a payment rate that would be consistent with the payment rate for IOP services in most other settings under Medicare, which would promote site neutrality. For additional information on the payment methodology for IOP services delivered in CMHCs, please reference section VIII.D.3. of this final rule with comment period.

Comment: In response to our request for comment regarding the experiences of furnishing IOP services within OTP settings, including to the extent to which it is similar to or different than furnishing IOP services in other settings, several commenters expressed that Medicare beneficiaries who need IOP services in addition to other traditional OTP services often have complex and co-occurring SUDs and/or mental health conditions. One commenter described that often patients in an OTP will have OUD in addition to co-occurring SUDs and or mental health conditions, where patients in other settings may not. Another commenter mentioned that some OTPs may be treating other individuals who only have a mental health condition and are receiving IOP treatment, but who do not receive other treatment at the OTP. Finally, one commenter urged CMS to develop payment policies or crosswalk codes that enable OTPs to deliver IOP services to patients who have mental health conditions or SUDs that are not just OUD.

Response: We appreciate commenters sharing this valuable information regarding various experiences of furnishing IOP services in an OTP setting. As previously stated, we note that section 1861 of the Act requires Medicare coverage for services furnished by OTPs to be for the treatment of OUD. However, we may consider these issues, including ways to further improve access to care for Medicare beneficiaries with an OUD who experience other co-occurring conditions, for future rulemaking.

After considering public comments, we are modifying our proposed payment methodology for calculating the payment adjustment for IOP services furnished by OTPs in one respect. We are finalizing our proposal to add a new paragraph (d)(4)(i)(F) to § 410.67 to describe the new adjustment to the bundled payment for OTP intensive outpatient services. However, we are not finalizing our proposal to deduct the amount for individual and group therapy that is included in the non-drug component of the OTP bundled rates. Accordingly, we are revising the proposed new § 410.67(d)(4)(i)(F) to strike ‘‘, excluding an amount equivalent to the amount included in the OTP weekly bundled payment for individual and group therapy,’’ in response to the public comments. We are finalizing that the adjustment will be made when at least nine services of OTP intensive outpatient services are furnished in a week. We are also finalizing a payment methodology to price HCPCS code GOTP1 based on the estimated payment rate of 3 services per day based on APC 5861 (Intensive Outpatient (1–3 services) for Hospital-based IOPs), which is $259.40, multiplied by 3 to reflect 3 days a week (for a weekly payment methodology), which results in a final payment rate of $778.20.[188] Additionally, we note that GOTP1 was a placeholder code for OTPs to bill for providing IOP services and that the final code is HCPCS code G0137 *(Intensive outpatient services; minimum of nine services over a 7-contiguous day period, which can include individual and group therapy with physicians or psychologists (or other mental health professionals to the extent authorized under State law); occupational therapy requiring the skills of a qualified occupational therapist; services of social workers, trained psychiatric nurses, and other staff trained to work with psychiatric patients; drugs and biologicals furnished for therapeutic purposes, excluding opioid agonist and antagonist medications that are FDA-approved for use in treatment of OUD or opioid antagonist medications for the emergency treatment of known or suspected opioid overdose; individualized activity therapies that are not primarily recreational or diversionary; family counseling (the primary purpose of which is treatment of the individual's condition); patient training and education (to the extent that training and educational activities are closely and clearly related to individual's care and treatment); diagnostic services (not including toxicology testing); (provision of the services by a Medicare-enrolled Opioid Treatment Program); List separately in addition to code for primary procedure, if applicable).*

We are also finalizing our proposal to amend § 410.67(d)(4)(ii) to add that the payment amount for OTP intensive outpatient services will be geographically adjusted using the Geographic Adjustment Factor (GAF) described in § 414.26. Lastly, we are finalizing our proposal to amend § 410.67(d)(4)(iii) to add that payment for OTP intensive outpatient services will be updated annually using the Medicare Economic Index described in § 405.504(d).

c. Certification and Plan of Care Requirements for IOPs in OTP Settings

In order to be consistent with physician certification and plan of care requirements for IOP services furnished in other settings of care and to ensure, to the extent possible, that IOP services are only provided and paid for when medically necessary and appropriate for the beneficiary, we proposed to adopt the same standards set forth in § 424.24(d)(1) through (3) for OTPs providing OTP intensive outpatient services (for more detailed discussions of these proposed standards, please see section VIII.B.3 of the CY 2024 OPPS proposed rule). Specifically, under the proposal, a physician would be required to certify that an individual needs OTP intensive outpatient services for a minimum of 9 hours per week, which is consistent with treatment standards specified by SAMHSA and minimum hour standards described by ASAM's

[187] Substance Abuse and Mental Health Services Administration, National Substance Use and Mental Health Services Survey (N–SUMHSS), 2021: Annual Detailed Tables. Rockville, MD: Substance Abuse and Mental Health Services Administration, 2023. Weblink: *https://www.samhsa.gov/data/sites/default/files/reports/rpt39450/2021%20N-SUMHSS%20Annual%20Detailed%20Tables_508_Compliant_2_8_2023.pdf.*

[188] We note that in the CY 2024 OPPS/ASC proposed rule, the payment rate of 3 services per day for APC 5861 (Intensive Outpatient (1–3 services) for Hospital-based IOPs) was $280.80. However, this payment rate has been updated to $259.40 following the publication of the proposed rule based on more recent cost data and is used as the base rate for IOP services furnished by OTPs.

Level 2.1 of care for IOP services.[189] This certification would require: documentation in the patient's medical record to include that the individual requires such services for a minimum of 9 hours of services per week; the first recertification as of the 30th day of IOP services; and that the certification of IOP services occur no less frequently than every other month. Accordingly, we proposed to revise § 410.67 of our regulations to add a paragraph (c)(5) to specify that OTPs must furnish OTP intensive outpatient services consistent with the requirements regarding content of certification, plan of care requirements, and recertification requirements as set forth under proposed § 424.24(d)(1) through (3).

Regarding the recertification requirements, given that OTP services are billed on a weekly basis, we proposed that the required recertification could occur any time during an episode of care in which the 30th day from the start of IOP services (and every other month thereafter) falls. We noted that in the CY 2020 PFS final rule (84 FR 62641), we defined an episode of care as a 1-week (contiguous 7-day) period at § 410.67(b). In the CY 2021 PFS final rule (85 FR 84691), we clarified that OTPs may choose to apply a standard billing cycle by setting a particular day of the week to begin all episodes of care, or they may choose to adopt weekly billing cycles that vary across patients, and we proposed to adopt the same approach here. We welcomed comments on these proposals.

We noted that the proposal requires that the physician certify a need for at least 9 hours of services per week, which differs from our proposal that in order to bill for the add-on payment adjustment for OTP intensive outpatient services, the OTP must attest that it provided 9 such services to the beneficiary in a week. Given that services can vary in duration and that some services are not time-based, we stated that we believed it would be administratively simpler for OTPs to count the number of services furnished rather than to count the number of hours for purposes of billing the add-on payment adjustment for OTP intensive outpatient services. Additionally, as described in section VIII.G.3.b. of this final rule with comment period, our proposed payment rate was based on the number of services furnished per day, rather than the number of hours, consistent with the proposals for IOP payment in other settings. In contrast, for the purposes of certification and plan of care requirements for IOPs in OTP settings, we stated that we believed that requiring a physician to certify that a beneficiary requires a minimum of 9 hours of services per week is consistent with existing clinical guidance describing the intensity of care for IOP services.[190] Additionally, a minimum of 9 hours of services per week is consistent with proposals for the certification and plan of care requirements for IOPs in other care settings. We welcomed comments on both of these proposals, including whether this distinction accurately reflects the practice patterns of OTPs furnishing IOP services.

We received multiple comments on our proposal for certification and plan of care requirements for IOPs in OTP settings. The comments and our responses to these commenters are included below.

Comment: A few commenters requested that CMS not finalize the proposed requirement for recertification for OTP intensive outpatient services ''as of the 30th day'' of IOP services as written in proposed paragraph (c)(5) to § 410.67. Commenters raised that they did not believe it is appropriate to consider finalizing a shorter interval for the first recertification or for the subsequent recertification. Instead, they suggested that the first recertification should be modified for OTPs to be consistent with the proposal for recertification in other settings at § 424.24(d)(3)(ii), which states, ''no less frequently than every 60 days.'' Commenters believed this may reduce burden and unnecessary documentation requirements on providers. Another commenter did not believe that recertification should be required every other month and instead recommended that a redetermination occur when it is clinically necessary according to the treatment plan, such as when a new episode of care begins. A different commenter urged CMS to consider extending recertification to every 90 days instead.

Response: We appreciate commenters raising these issues regarding the shorter interval for the first recertification in OTP settings. In the CY 2024 OPPS proposed rule (88 FR 49722), we stated that ''this certification would require documentation in the patient's medical record to include that the individual requires such services for a minimum of 9 hours per week; require the first recertification as of the 30th day of IOP services; and require that the certification of IOP services occur no less frequently than every other month.'' In the proposed regulatory text, we stated ''OTPs that provide OTP intensive outpatient services must meet the requirements set forth in § 424.24(d)(1) through (3) of this chapter related to content of certification, plan of treatment, and recertification for the purposes of furnishing OTP intensive outpatient services, except that the recertification required under § 424.24(d)(3)(ii) may occur any time during an episode of care in which the 30th day from the start of IOP services falls.'' We are persuaded by the majority of commenters who requested that we not require a recertification ''as of the 30th day of services,'' as we agree that the recertification requirements should be consistent with the other settings paying for IOP services under Medicare. Accordingly, we are not finalizing our proposal to require a recertification as of the 30th date of services, and are instead finalizing that recertification must occur no less frequently than every 60 days, which is consistent with the requirement at § 424.24(d)(3)(ii). We believe this change will promote consistency with the requirements for IOP services in other care settings under Medicare, as well as limit potential additional and unnecessary administrative requirements for OTPs. Accordingly, we are deleting the phrase '', except that the recertification required under § 424.24(d)(3)(ii) of this chapter may occur any time during an episode of care in which the 30th day from the start of IOP services falls'' from paragraph (c)(5) of § 410.67.

Comment: Multiple commenters requested that CMS modify the physician certification and plan of care requirements to include other behavioral health professionals. A few commenters recommended that CMS align these requirements for certification and plan of care with existing clinical standards of practice and state requirements to permit other non-physician professionals, including psychologists, clinical social workers, and other behavioral health professionals to perform eligibility assessments, develop treatment plans, and certify the need for services. Multiple commenters noted that requiring only a physician to complete these requirements would be a significant barrier to care and add additional burden on providers. Other commenters noted that ASAM level of

[189] *https://www.ncbi.nlm.nih.gov/books/NBK64088/; https://store.samhsa.gov/product/TIP-47-Substance-Abuse-Clinical-Issues-in-Intensive-Outpatient-Treatment/SMA13-4182.*

[190] *https://www.ncbi.nlm.nih.gov/books/NBK64088/;* https://store.samhsa.gov/product/TIP-47-Substance-Abuse-Clinical-Issues-in-Intensive-Outpatient-Treatment/SMA13-4182.

care determinations do not require a physician to complete the assessment and that anyone trained to do level of care determinations may complete them and that SUD counselors are certified and licensed differently at the state level and this should be explicitly permitted and addressed.

Response: We thank commenters for raising this important issue. After considering the public comments, we understand that requiring a physician to conduct certification and develop a plan of care may create additional issues for practices and regions that face a provider shortage and/or limited capacity to regularly complete these requirements. Evidence indicates that there is less access to OTPs in rural areas,[191] and also that nearly 60 percent of all mental health professional shortage areas are located in rural areas.[192] Additionally, we recognize that evidence has shown physicians spend up to one-fifth of working hours per week on administrative tasks with psychiatrists spending the highest proportion of their time on administration compared to other types of physicians.[193] We also understand that other non-physician practitioners, including but not limited to, clinical social workers, psychologists, nurse practitioners, mental health counselors, and marriage and family therapists, have increasingly played a critical role in interdisciplinary care teams and filling important gaps in care.

We note that section 4124 of the CAA, 2023 includes provisions for physician certification and plan of care requirements that require a physician to certify a need for IOP services. However, while the CAA, 2023 does not address IOP services furnished in OTP settings, our proposals to pay for IOP services in OTP settings were made under the statutory authority of sections 1861(jjj)(1) and 1834(w)(2) of the Act. We are persuaded by the commenters that practitioners other than physicians can appropriately conduct the certification, recertification, and plan of care requirements, and we agree that allowing additional practitioner types to perform the certification, recertification, and plan of care requirements will likely help to expand access to care. We believe we have statutory flexibility to finalize that the certification, recertification, and plan of care requirements may be performed by non-physician practitioners, as permitted by state law and consistent with scope of practice requirements. Additionally, we note that certain non-physician practitioners are authorized under Medicare to perform certification activities.[194] Therefore, we are finalizing that in addition to physicians, the following non-physician practitioners may perform the required certification and plan of care requirements for IOP services furnished in the OTP setting: nurse practitioners, physician assistants, clinical psychologists, clinical social workers, mental health counselors, marriage and family therapists, and any other non-physician practitioners as defined in section 1842(b)(18)(C) of the Act, as permitted by state law and consistent with scope of practice requirements. These flexibilities would also be extended to any physician requirements, pertaining to the individual being under the care of a physician and to a physician's diagnosis, as described in § 424.24(d)(1)(ii) and (d)(2)(A), so that they could also be performed by non-physician practitioners.

Comment: We received comments on several topics that were outside the scope of the proposed rule. Those topics included the following: a recommendation that CMS develop crosswalk codes that enable IOP to be delivered in freestanding community-based SUD treatment facilities; a request that CMS allow structured outpatient addiction programs to bill the add-on payment adjustment for OTP intensive outpatient services; and a request that CMS develop an add-on code for contingency management services in OTPs for individuals with a stimulant use disorder.

Response: While some of these comments are either outside of our statutory authority and/or out of scope for this final rule because they do not relate to the specific proposals included in the proposed rule, we appreciate the feedback and may consider these recommendations for future rulemaking.

After consideration of the public comments received, we are finalizing our proposed definition of OTP intensive outpatient services in paragraph (ix) of definition of ''opioid use disorder treatment service'' at 42 CFR 410.67(b), with modifications to specify that non-physician practitioners, in addition to physicians, may perform the required certification that the individual has a need for such services, plan of treatment requirements, and recertification requirements, as permitted by state law and consistent with scope of practice requirements. These non-physician practitioners may include, but are not limited to, nurse practitioners, physician assistants, clinical psychologists, clinical social workers, mental health counselors, licensed marriage and family therapists, and other non-physician practitioners, as defined in section 1842(b)(18)(C) of the Act.

We are finalizing a modification to our proposal for certification and plan of care requirements for OTP intensive outpatient services at proposed new paragraph (c)(5) at § 410.67 by specifying that, for the standards set forth in the proposed § 424.24(d)(1) through (3), a physician and/or non-physician practitioner could perform the requirements for certification, plan of care, and recertification for the purposes of furnishing OTP intensive outpatient services, as permitted by state law and scope of practice requirements. We are also striking language that states ''in which the 30th day from the start of IOP services falls'' for consistency with policies in other care settings under Medicare. We are finalizing that the first recertification and subsequent recertifications for OTP intensive outpatient services must occur no less frequently than every 60 days, consistent with § 424.24(d)(3)(ii). Accordingly, we are finalizing at § 410.67(c)(5) that OTPs that provide OTP intensive outpatient services must meet the requirements set forth in § 424.24(d)(1) through (3) related to content of certification, plan of treatment, and recertification for the purposes of furnishing OTP intensive outpatient services, except that the recertification required under § 424.24(d)(3)(ii) may occur any time during an episode of care.

d. Correction to the OTP Regulation Text

We also proposed to correct a typographical error at § 410.67(d)(3), which currently states ''At least one OUD treatment service described in paragraphs (b)(1) through (5) of this section must be furnished to bill for the bundled payment for an episode of care.'' This provision should refer to paragraphs (i) through (v) of the definition of OUD treatment service in paragraph (b). Accordingly, we propose to correct this sentence to read, ''At least one OUD treatment service described in paragraphs (i) through (v) of the definition of *opioid use disorder treatment service* in paragraph (b) of this section must be furnished to bill for the

[191] *https://pubmed.ncbi.nlm.nih.gov/35512612/.*

[192] Designated Health Professional Shortage Areas Statistics, Third Quarter of Fiscal Year 2023, Designated HPSA Quarterly Summary: *https://data.hrsa.gov/default/generatehpsaquarterlyreport.*

[193] *https://pubmed.ncbi.nlm.nih.gov/25626223/.*

[194] *https://www.cms.gov/medicare/enrollment-renewal/providers-suppliers/chain-ownership-system-pecos/ordering-certifying#eligible-specialty-types.*

bundled payment for an episode of care.''

We did not receive any public comments on our proposal to correct a typographical error at § 410.67(d)(3). We are finalizing our proposal to revise § 410.67(d)(3) to instead state ''At least one OUD treatment service described in paragraphs (i) through (v) of the definition of *opioid use disorder treatment service* in paragraph (b) of this section must be furnished to bill for the bundled payment for an episode of care.''

H. Payment Rates Under the Medicare Physician Fee Schedule for Nonexcepted Items and Services Furnished by Nonexcepted Off-Campus Provider-Based Departments of a Hospital

1. Background

In the CY 2017 OPPS/ASC final rule with comment period (81 FR 79727) in the discussion of the proposed implementation of section 603 of the Bipartisan Budget Act (BBA) of 2015 (Pub. L. 114–74, November 2, 2015), we established the PHP payment rate under the Medicare Physician Fee Schedule (MPFS) for nonexcepted off-campus PBDs as equivalent to the level of payment made to CMHCs for furnishing three or more PHP services per day. We noted that when a beneficiary received outpatient services in an off-campus department of a hospital, the total Medicare payment for those services is generally higher than when those same services are provided in a physician's office. Similarly, when partial hospitalization services are provided in a hospital-based PHP, Medicare pays more than when those same services are provided by a CMHC. Our rationale for adopting the CMHC per diem rate for APC 5853 as the MPFS payment amount for nonexcepted PBDs providing PHP services was because CMHCs are freestanding entities that are not part of a hospital, but they provide the same PHP services as hospital-based PHPs. This is similar to the differences between freestanding entities paid under the MPFS that furnish other services also provided by hospital-based entities. Similar to other entities currently paid for their technical component services under the MPFS, we believe CMHCs would typically have lower cost structures than hospital-based PHPs, largely due to lower overhead costs and other indirect costs such as administration, personnel, and security. We explained that we believe that paying for nonexcepted hospital-based partial hospitalization services at the lower CMHC per diem rate aligns with section 603 of the BBA of 2015, while also preserving access to PHP services.

2. Payment for PHP and IOP Furnished by Nonexcepted Off-Campus Hospital Outpatient Departments

As discussed in section VIII.D of the CY 2024 OPPS/ASC proposed rule, we proposed to change our methodology for calculating PHP payment rates by establishing separate payment rates for 3-service and 4-service days. We also proposed to establish IOP payment rates for 3-service and 4-service days beginning in CY 2024. Because CMHCs have different cost structures than hospitals, we proposed to establish separate CMHC and hospital rates for 3-service and 4-service PHP and IOP days. We proposed to utilize the CMHC rates for PHP and IOP as the payment rates for PHP and IOP services furnished by nonexcepted off-campus hospital outpatient departments. Specifically, we proposed to utilize the separate CMHC rates for 3-service and 4-service PHP days as the MPFS rates, depending upon whether a nonexcepted off-campus hospital outpatient department furnishes 3 or 4 PHP services in a day. Similarly, we also proposed to utilize the CMHC rates for 3-service and 4-service IOP days as the MPFS rates, depending upon whether a nonexcepted hospital outpatient department furnishes 3 or 4 IOP services in a day.

As discussed in section VIII.D of the CY 2024 OPPS/ASC proposed rule, we solicited comment on our proposed payment rates for PHP and IOP services, as well as whether commenters believe it would be appropriate to consider establishing a combined rate for 3-service days in hospitals and CMHCs, and a combined rate for 4-service days in hospitals and CMHCs. We also considered whether it would be appropriate to apply a different methodology for calculating the PHP and IOP rates for nonexcepted off-campus hospital outpatient departments and we solicited comments on alternative methodologies commenters believed would be appropriate. For example, we considered whether it would be appropriate to apply the PFS Relativity Adjuster of 40 percent, which was established in the CY 2018 PFS rule (82 FR 53030) and which applies to most other nonexcepted OPPS services furnished by a nonexcepted off-campus hospital outpatient department.

Comment: Several commenters urged CMS to implement a site-neutral payment for nonexcepted off-campus provider-based hospital departments (PBDs). Commentors argued that Congress' goal for enacting section 603 of the Bipartisan Budget Act (BBA) of 2015 (Pub. L. 114–74, November 2, 2015) and CMS's 2017 transition to PFS payment rates for PBDs was motivated by a desire to move to a site-neutral payment methodology. Furthermore, commenters stated that providing reduced payment for PHP and IOP services furnished by excepted off-campus PBDs could reduce beneficiaries' access to behavioral health services.

Response: We appreciate the concerns that commenters raised about Medicare beneficiaries' access to behavioral and mental health services. We note that our longstanding policy to pay nonexcepted off-campus provider-based departments at the CMHC rate for PHP services aligns with section 603 of the BBA of 2015, while also preserving access to PHP services. We do not believe that this policy reduces access to behavioral health services, because similar to other entities currently paid for their technical component services under the MPFS, we believe CMHCs would typically have lower cost structures than hospital-based PHPs, largely due to lower overhead costs and other indirect costs such as administration, personnel, and security.

After consideration of the public comments we received, we are finalizing our proposal to apply the CMHC PHP and IOP per diem rates as the MPFS rates for PHP and IOP services furnished by nonexcepted off-campus PBDs.

IX. Services That Will Be Paid Only as Inpatient Services

A. Background

Established in rulemaking as part of the initial implementation of the OPPS, the inpatient only (IPO) list identifies services for which Medicare will only make payment when the services are furnished in the inpatient hospital setting because of the invasive nature of the procedure, the underlying physical condition of the patient, or the need for at least 24 hours of postoperative recovery time or monitoring before the patient can be safely discharged (70 FR 68695). The IPO list was created based on the premise (rooted in the practice of medicine at that time), that Medicare should not pay for procedures furnished as outpatient services that are performed on an inpatient basis virtually all of the time for the Medicare population, for the reasons described above, because performing these procedures on an outpatient basis would not be safe or appropriate, and therefore not reasonable and necessary under Medicare rules (63 FR 47571). Services

included on the IPO list were those determined to require inpatient care, such as those that are highly invasive, result in major blood loss or temporary deficits of organ systems (such as neurological impairment or respiratory insufficiency), or otherwise require intensive or extensive postoperative care (65 FR 67826). There are some services designated as inpatient only that, given their clinical intensity, would not be expected to be performed in the hospital outpatient setting. For example, we have traditionally considered certain surgically invasive procedures on the brain, heart, and abdomen, such as craniotomies, coronary-artery bypass grafting, and laparotomies, to require inpatient care (65 FR 18456). Designation of a service as inpatient only does not preclude the service from being furnished in a hospital outpatient setting but rather means that Medicare will not make payment for the service if it is furnished to a Medicare beneficiary in the hospital outpatient setting (65 FR 18443). Conversely, the fact that a procedure is not on the IPO list should not be interpreted to mean the procedure is only appropriately performed in the hospital outpatient setting (70 FR 68696).

As part of the annual update process, we have historically worked with interested parties, including professional societies, hospitals, surgeons, hospital associations, and beneficiary advocacy groups, to evaluate the IPO list and to determine whether services should be added to or removed from the list. Interested parties are encouraged to request reviews for a particular code or group of codes; and we have asked that their requests include evidence that demonstrates that the procedure was performed on an outpatient basis in a safe and appropriate manner in a variety of different types of hospitals—including but not limited to—operative reports of actual cases, peer-reviewed medical literature, community medical standards and practice, physician comments, outcome data, and post-procedure care data (67 FR 66740).

We traditionally have used five longstanding criteria to determine whether a procedure should be removed from the IPO list. As noted in the CY 2012 OPPS/ASC final rule with comment period (76 FR 74353), we assessed whether a procedure or service met these criteria to determine whether it 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 have explained that while we only require a service to meet one criterion to be considered for removal, satisfying only one criterion does not guarantee that the service will be removed; instead, the case for removal is strengthened with the more criteria the service meets. The criteria for assessing procedures for removal from the IPO list are as follows:

1. Most outpatient departments are equipped to provide the services to the Medicare population.

2. The simplest procedure described by the code may be furnished in most outpatient departments.

3. The procedure is related to codes that we have already removed from the IPO list.

4. A determination is made that the procedure is being furnished in numerous hospitals on an outpatient basis.

5. 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 covered procedures list.

In the past, we have requested that interested parties submit corresponding evidence in support of their claims that a code or group of codes met the longstanding criteria for removal from the IPO list and was safe to perform on the Medicare population in the hospital outpatient setting—including, but not limited to case reports, operative reports of actual cases, peer-reviewed medical literature, medical professional analysis, clinical criteria sets, and patient selection protocols. Our clinicians then thoroughly review all information submitted within the context of the established criteria and if, following this review, we determine that there is sufficient evidence to confirm that the code could be safely and appropriately performed on an outpatient basis, we assign the service to an APC and include it as a payable procedure under the OPPS (67 FR 66740). We determine the APC assignment for services removed from the IPO list by evaluating the clinical similarity and resource costs of the service compared to other services paid under the OPPS and by reviewing the Medicare Severity Diagnosis Related Groups (MS–DRG) rate for the service under the IPPS, though we note we would generally expect the cost to provide a service in the outpatient setting to be less than the cost to provide the service in the inpatient setting.

We stated in prior rulemaking that, over time, given advances in technology and surgical technique, we would continue to evaluate services to determine whether they should be removed from the IPO list. Our goal is to ensure that inpatient only designations are consistent with the current standards of practice. We have asserted in prior rulemaking that, insofar as advances in medical practice mitigate concerns about these procedures being performed on an outpatient basis, we would be prepared to remove procedures from the IPO list and provide for payment for them under the OPPS (65 FR 18443). Further, CMS has at times had to reclassify codes as inpatient only services with the emergence of new information.

We refer readers to the CY 2012 OPPS/ASC final rule with comment period (76 FR 74352 and 74353) for a full discussion of our historic policies for identifying services that are typically provided only in an inpatient setting and that, therefore, will not be paid by Medicare under the OPPS, as well as the criteria we have used to review the IPO list to determine whether any services should be removed.

B. Changes to the Inpatient Only (IPO) List

As stated above, we encourage interested parties to request reviews for a particular code or group of codes for removal from the IPO list. For CY 2024, we received several requests from interested parties recommending particular services to be removed from the IPO list. Following our clinical review, we did not find sufficient evidence that, using the five criteria listed above, these services meet the criteria to be removed from the IPO list for CY 2024. Therefore, we did not propose to remove any services from the IPO list for CY 2024.

We proposed to add nine services for which codes were newly created by the AMA CPT Editorial Panel for CY 2024 to the IPO list. These new services are described by the CPT codes 0790T, 22836, 22837, 22838, 61889, 76984, 76987, 76988, and 76989 (described by placeholder codes X114T, 2X002, 2X003, 2X004, 619X1, 7X000, 7X001, 7X002, and 7X003 respectively in the CY 2024 OPPS/ASC proposed rule) which will be effective on January 1, 2024. After clinical review of these services, we found that they require a hospital inpatient admission or stay and thus, we believe they are not appropriate for payment under the OPPS. We proposed to assign these services to status indicator ''C'' (Inpatient Only) for CY 2024. Additionally, we proposed to reassign CPT code 0646T from status indicator ''E1'' (not payable by Medicare) to ''C,'' effective CY 2024. The CPT codes, long descriptors, and the proposed CY 2024

payment indicators are displayed in Table 102.

Table 102 below contains the proposed changes to the IPO list for CY 2024. The complete list of codes describing services that we proposed to designate as inpatient only services beginning in CY 2024 was also included as Addendum E to the CY 2024 OPPS/ASC proposed rule, which is available via the internet on the CMS website.

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TABLE 102: PROPOSED CHANGES TO THE INPATIENT ONLY (IPO) LIST FOR CY 2024

CY 2024 CPT Code	CY 2024 Long Descriptor	Action	CY 2024 Proposed Status Indicator
0790T	Revision (e.g., augmentation, division of tether), replacement, or removal of thoracolumbar or lumbar vertebral body tethering, including thoracoscopy, when performed	Add to the IPO list	C
22836	Anterior thoracic vertebral body tethering, including thoracoscopy, when performed; up to 7 vertebral segments	Add to the IPO list	C
22837	Anterior thoracic vertebral body tethering, including thoracoscopy, when performed; 8 or more vertebral segments	Add to the IPO list	C
22838	Revision (e.g., augmentation, division of tether), replacement, or removal of thoracic vertebral body tethering, including thoracoscopy, when performed	Add to the IPO list	C
61889	Insertion of skull-mounted cranial neurostimulator pulse generator or receiver, including craniectomy or craniotomy, when performed, with direct or inductive coupling, with connection to depth and/or cortical strip electrode array(s)	Add to the IPO list	C
76984	Ultrasound, intraoperative thoracic aorta (e.g., epiaortic), diagnostic	Add to the IPO list	C
76987	Intraoperative epicardial cardiac (e.g., echocardiography) ultrasound for congenital heart disease, diagnostic; including placement and manipulation of transducer, image acquisition, interpretation and report	Add to the IPO list	C
76988	Intraoperative epicardial cardiac ultrasound (ie, echocardiography) for congenital heart disease, diagnostic; placement, manipulation of transducer, and image acquisition only	Add to the IPO list	C
76989	Intraoperative epicardial cardiac ultrasound (ie, echocardiography) for congenital heart disease, diagnostic; interpretation and report only	Add to the IPO list	C
0646T	Transcatheter tricuspid valve implantation (ttvi)/replacement with prosthetic valve, percutaneous approach, including right heart catheterization, temporary pacemaker insertion, and selective right ventricular or right atrial angiography, when performed	Add to the IPO list	C

BILLING CODE 4150–28–C

Comment: We received several comments in support of our proposal to add the ten services listed in Table 102 above to the IPO list for CY 2024.

Response: We thank the commenters for their support.

Comment: We received one comment requesting that we remove CPT codes 49596 (Repair of anterior abdominal hernia(s) (*i.e.,* epigastric, incisional, ventral, umbilical, spigelian), any approach (*i.e.,* open, laparoscopic, robotic), initial, including placement of mesh or other prosthesis when performed, total length of defect(s); greater than 10 cm, incarcerated or strangulated), 49616 (Repair of anterior abdominal hernia(s) (*i.e.,* epigastric, incisional, ventral, umbilical, spigelian), any approach (*i.e.,* open, laparoscopic, robotic), recurrent, including placement of mesh or other prosthesis when performed, total length of defect(s); 3 cm to 10 cm, incarcerated or strangulated), 49617 (Repair of anterior abdominal hernia(s) (*i.e.,* epigastric, incisional, ventral, umbilical, spigelian), any approach (*i.e.,* open, laparoscopic, robotic), recurrent, including placement of mesh or other prosthesis when performed, total length of defect(s); greater than 10 cm, reducible), 49618 (Repair of anterior abdominal hernia(s) (ie, epigastric, incisional, ventral, umbilical, spigelian), any approach (*i.e.,* open, laparoscopic, robotic), recurrent, including placement of mesh or other prosthesis when performed, total length of defect(s); greater than 10 cm, incarcerated or strangulated), 49621 (Repair of parastomal hernia, any approach (*i.e.,* open, laparoscopic, robotic), initial or recurrent, including placement of mesh or other prosthesis, when performed; reducible), and 49622 (Repair of parastomal hernia, any approach (*i.e.,* open, laparoscopic, robotic), initial or recurrent, including placement of mesh or other prosthesis, when performed; incarcerated or strangulated) from the IPO list for CY 2024. The commenter stated that these codes were related to predecessor codes that were not on the IPO list. The commenter also stated that while patients will typically be admitted to the hospital as inpatients for these services, there are instances when it will be appropriate for the patient to undergo these procedures on an outpatient basis.

Response: We thank the commenter for their recommendation. Our clinical analysis of these services indicates that they require a hospital inpatient admission or stay. While these services are associated with predecessor codes that were not on the IPO list, our OPPS claims review found that many of those predecessor codes had lengths of stay greater than 2 days. Without further evidence that these procedures can be safely performed in the outpatient setting on the majority of the Medicare population, we do not believe that these services can be appropriately removed from the IPO list at this time. Additionally, as we stated in the CY 2022 OPPS/ASC final rule with comment period, while we recognize that there are services currently classified as inpatient only that may be appropriate in the hospital outpatient setting for some Medicare beneficiaries, we continue to strive to balance the goals of increasing physician and patient choice of setting of care with consideration for patient safety for all Medicare beneficiaries (86 FR 63673). Therefore, we are finalizing our proposal to continue to assign these services to status indicator ''C'' for CY 2024.

Comment: We received a few comments requesting that CMS consider reinstating the elimination of the IPO list that was halted in the CY 2022 OPPS/ASC final rule with comment period.

Response: We thank the commenters for their feedback. We are not considering eliminating the IPO list at this time. As stated in the CY 2022 OPPS/ASC final rule with comment period, we believe the IPO list is a valuable tool for ensuring that the OPPS only pays for services that can safely be performed in the hospital outpatient setting and remains a necessary safeguard. In that final rule, we explained that we recognized that while physicians are able to make safety determinations for a specific beneficiary, CMS is in the position to make safety determinations for the broader population of Medicare beneficiaries, that is, the typical Medicare beneficiary. Furthermore, we explained that while we want to afford physicians and hospitals the maximum flexibility in choosing the most clinically appropriate site of service for the procedure, as long as the characteristics of the procedure are consistent with the criteria listed above. For further discussion on our decision to halt the elimination of the IPO list, we refer readers to the CY 2022 OPPS/ASC final rule with comment period (86 FR 63671 through 63711).

Comment: We received multiple comments requesting that we assign services newly removed from the IPO list to New Technology APCs until sufficient data is collected to assign these services to clinical APCs.

Response: We thank the commenters for their input. As we previously stated in the CY 2021 OPPS/ASC final rule with comment period (85 FR 86093), consistent with our regulation at 42 CFR 419.31(a)(1), we classify outpatient services and procedures that are comparable clinically and in terms of resource use into APC groups. As we stated in the CY 2012 OPPS/ASC final rule (76 FR 74224), the OPPS is a prospective payment system that provides payment for groups of services that share clinical and resource use characteristics. It should be noted that for all codes newly paid under the OPPS, including codes removed from the IPO list, our policy has been to assign the service or procedure to an APC based on feedback from a variety of sources, including but not limited to, review of the clinical similarity of the service to existing procedures; advice from CMS medical advisors; information from interested specialty societies; and review of all other information available to us, including information provided to us by the public, whether through meetings with stakeholders or additional information that is mailed or otherwise communicated to us (84 FR 61229). Therefore, we believe assigning procedures removed from the IPO list to existing clinical APCs that are similar in clinical characteristics and resource costs is appropriate. We note that procedures assigned to New Technology APCs cannot be placed in clinical APCs due to insufficient clinical and cost data, unlike the procedures transitioning from the IPO list.

Comment: One commenter wrote that the following statement in the CY 2024 OPPS/ASC proposed rule was incorrect: ''Designation of a service as inpatient only does not preclude the service from being furnished in a hospital outpatient setting but rather means that Medicare will not make payment for the service if it is furnished to a Medicare beneficiary in the hospital outpatient setting'' (65 FR 18443). The commenter stated that this was incorrect because in the Change Request 9097 published on March 13, 2015, CMS revised its billing instructions to allow payment for procedures on the IPO list that are provided to a patient in the outpatient setting on the date of the inpatient admission or during the 3-calendar days preceding the date of inpatient admission to be bundled into the billing of the inpatient admission.

Response: The commenter is correct services on the IPO list performed in the outpatient setting can receive IPPS payment if the patient is admitted on the day of the procedure or within the following 3-calendar days. However, services on the IPO list will not receive payment under the OPPS.

In summary, after consideration of the public comments we received, we are finalizing our proposal to assign CPT codes 0790T, 22836, 22837, 22838, 61889, 76984, 76987, 76988, 76989, and

0646T to status indicator ''C'' for CY 2024. Table 103 below contains the changes to the IPO list for CY 2024. The complete list of codes describing services that are designated as inpatient only services beginning in CY 2024 is also included as Addendum E to this final rule with comment period, which is available via the internet on the CMS website.

BILLING CODE 4150–28–P

TABLE 103: CHANGES TO THE INPATIENT ONLY (IPO) LIST FOR CY 2024

CY 2024 CPT Code	CY 2024 Long Descriptor	Action	CY 2024 Final Status Indicator
0790T	Revision (e.g., augmentation, division of tether), replacement, or removal of thoracolumbar or lumbar vertebral body tethering, including thoracoscopy, when performed	Add to the IPO list	C
22836	Anterior thoracic vertebral body tethering, including thoracoscopy, when performed; up to 7 vertebral segments	Add to the IPO list	C
22837	Anterior thoracic vertebral body tethering, including thoracoscopy, when performed; 8 or more vertebral segments	Add to the IPO list	C
22838	Revision (e.g., augmentation, division of tether), replacement, or removal of thoracic vertebral body tethering, including thoracoscopy, when performed	Add to the IPO list	C
61889	Insertion of skull-mounted cranial neurostimulator pulse generator or receiver, including craniectomy or craniotomy, when performed, with direct or inductive coupling, with connection to depth and/or cortical strip electrode array(s)	Add to the IPO list	C
76984	Ultrasound, intraoperative thoracic aorta (e.g., epiaortic), diagnostic	Add to the IPO list	C
76987	Intraoperative epicardial cardiac (e.g., echocardiography) ultrasound for congenital heart disease, diagnostic; including placement and manipulation of transducer, image acquisition, interpretation and report	Add to the IPO list	C
76988	Intraoperative epicardial cardiac ultrasound (ie, echocardiography) for congenital heart disease, diagnostic; placement, manipulation of transducer, and image acquisition only	Add to the IPO list	C
76989	Intraoperative epicardial cardiac ultrasound (ie, echocardiography) for congenital heart disease, diagnostic; interpretation and report only	Add to the IPO list	C
0646T	Transcatheter tricuspid valve implantation (ttvi)/replacement with prosthetic valve, percutaneous approach, including right heart catheterization, temporary pacemaker insertion, and selective right ventricular or right atrial angiography, when performed	Add to the IPO list	C

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C. Solicitation of Public Comments on the Services Described by CPT Codes 43775, 43644, 43645, and 44204

We solicited comments regarding whether the services described by CPT codes 43775 (Laparoscopy, surgical, gastric restrictive procedure; longitudinal gastrectomy (*i.e.,* sleeve gastrectomy)), 43644 (Laparoscopy, surgical, gastric restrictive procedure; with gastric bypass and roux-en-y gastroenterostomy (roux limb 150 cm or less)), 43645 (Laparoscopy, surgical, gastric restrictive procedure; with gastric bypass and small intestine reconstruction to limit absorption), and 44204 (Laparoscopy, surgical; colectomy, partial, with anastomosis) are appropriate to be removed from the IPO list. At this time, we do not believe that we have adequate information to determine whether the services described by CPT codes 43775, 43644, 43645, and 44204 can be safely performed in the hospital outpatient department setting on the Medicare population. Therefore, we specifically requested information or evidence that these services can be performed safely on the Medicare population in the outpatient setting. We also sought public comments on whether the services described by CPT codes 43775, 43644, 43645, and 44204 specifically meet any of the five criteria to be removed from the IPO list mentioned above.

Comment: We received a significant number of comments in support of maintaining CPT codes 43775, 43644, 43645, and 44204 on the IPO list, many of which were from bariatric surgery healthcare providers and societies. Commenters strongly recommended keeping these four services on the IPO list, with safety being the primary concern. Some commenters noted that while these services can be safely performed in the outpatient setting, those patients are carefully selected and tend to be a younger and healthier population. Commenters had great concern about the safety of performing these services on the Medicare population in the outpatient setting, noting that Medicare beneficiaries tend to be an older population with more comorbidities, even among those younger than 65. Commenters noted that performing these procedures in the outpatient setting could lead to greater risks and complications following the procedures. Many commenters also noted logistical concerns. Commenters wrote that receiving these services in the outpatient setting often requires additional follow-up appointments and at-home care, which many Medicare beneficiaries may not have access to. Patients may need to travel extended distances to receive these surgeries and follow-up care, however transportation may be difficult for some beneficiaries, especially in rural areas. Access to these services for Medicare beneficiaries if they are removed from the IPO list was another major concern among commenters, stating that if these services are removed from the IPO list, access to these services at their facilities in the inpatient setting may be limited, affecting those who would require inpatient care. Additionally, several commenters agreed that these services did not meet the criteria to be removed from the IPO list.

Response: We thank the commenters for their feedback.

Comment: We received a few comments in support of removing the four laparoscopic services from the IPO list for CY 2024, with commenters stating that these procedures can be safely performed in the outpatient setting. The commenters noted that advances in medical technology and surgical techniques have increased the safety of these surgeries.

Response: We thank the commenters for their feedback. However, we did not receive additional literature or evidence that these services can be performed safely on the Medicare population in the outpatient setting. We continue to believe that these services do not meet the criteria to be removed from the IPO list. Therefore, after consideration of the public comments we received, we are maintaining CPT codes 43775, 43644, 43645, and 44204 on the IPO list for CY 2024.

X. Nonrecurring Policy Changes

A. Supervision by Nurse Practitioners, Physician Assistants, and Clinical Nurse Specialists of Cardiac Rehabilitation, Intensive Cardiac Rehabilitation, and Pulmonary Rehabilitation Services Furnished to Hospital Outpatients

1. Background

Section 51008(a) of the Bipartisan Budget Act of 2018 (BBA of 2018) (Pub. L. 115–123) amended section 1861(eee)(1) and (2) of the Act to revise the definitions of cardiac rehabilitation (CR) program and intensive cardiac rehabilitation (ICR) program, respectively, to provide that services these programs furnish can be under the supervision of a physician assistant (PA), nurse practitioner (NP), or clinical nurse specialist (CNS). Section 51008(b) of the BBA of 2018 amended section 1861(fff)(1) of the Act similarly to revise the definition of a pulmonary rehabilitation (PR) program to provide that PR services can be furnished under the supervision of these same types of practitioners. Section 51008(c) of the BBA of 2018 provides that these amendments apply to items and services furnished on or after January 1, 2024. Before the effective date of these amendments, only physicians could supervise services furnished as part of CR, ICR, and PR programs.

To implement these amendments, we proposed in the CY 2024 PFS proposed rule to revise the regulations at 42 CFR 410.47 and 410.49, which describe the conditions of coverage for the CR, ICR and PR programs, to provide that physician assistants, nurse practitioners, and clinical nurse specialists can supervise CR, ICR and PR program services. Specifically, the CY 2024 PFS proposed rule proposed to amend §§ 410.47 and 410.49 to provide that supervision of PR, CR, and ICR services can be provided by a physician, PA, NP, or CNS.

2. Conforming Revisions to § 410.27

Correspondingly, to implement the amendments to section 1861(eee)(1) and (2) and (fff) of the Act, and to be consistent with the proposed revisions to §§ 410.47 and 410.49, we proposed to make conforming revisions to § 410.27, which describes the conditions for coverage for therapeutic outpatient hospital or CAH services and supplies provided incident to a physician's or nonphysician practitioner's service.

We explained that currently, § 410.27(a)(1)(iv)(B)(*1*) provides that for PR, CR, and ICR services, direct supervision must be furnished by a doctor of medicine or osteopathy as specified in §§ 410.47 and 410.49. We proposed to delete the reference to a doctor of medicine or osteopathy and retain the cross-reference to §§ 410.47 and 410.49. As the text remaining following this deletion would consist solely of cross-references to the newly revised §§ 410.47 and 410.49, we explained that this would have the effect of expanding who may provide supervision for CR, ICR and PR services under § 410.27 to include PAs, NPs, and CNSs under § 410.27.

In the interim final rule with comment period (IFC) titled ''Policy and Regulatory Provisions in Response to the COVID–19 Public Health Emergency,'' published on April 6, 2020 (the April 6th COVID–19 IFC) (85 FR 19230, 19246, 19286), we changed the regulation at 42 CFR 410.27(a)(1)(iv)(D) to provide that, during a Public Health Emergency as defined in 42 CFR 400.200, the presence of the physician for purposes of the direct supervision

requirement for PR, CR, and ICR services includes virtual presence 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. Specifically, the required direct physician supervision can be provided through virtual presence using audio/video real-time communications technology (excluding audio-only) subject to the clinical judgment of the supervising practitioner. We further amended § 410.27(a)(1)(iv)(D) in the CY 2021 OPPS/ASC final rule with comment period to provide that this flexibility continues until the later of the end of the calendar year in which the PHE as defined in § 400.200 ends or December 31, 2021 (85 FR 86113 and 86299). In the CY 2021 OPPS/ASC final rule with comment period we also clarified that this flexibility excluded the presence of the supervising practitioner via audio-only telecommunications technology (85 FR 86113).

In the CY 2022 PFS final rule, CMS added CPT codes 93797 (Physician or other qualified health care professional services for outpatient cardiac rehabilitation; without continuous ECG monitoring (per session)) and 93798 (Physician or other qualified health care professional services for outpatient cardiac rehabilitation; with continuous ECG monitoring (per session)) and HCPCS codes G0422 (Intensive cardiac rehabilitation; with or without continuous ecg monitoring with exercise, per session) and G0423 (Intensive cardiac rehabilitation; with or without continuous ecg monitoring; without exercise, per session) to the Medicare Telehealth Services List on a Category 3 basis (86 FR 65055).

In order to effectuate a similar policy under the OPPS, where PR, CR, and ICR rehabilitation services could be furnished during the PHE to beneficiaries in hospitals under direct supervision of a physician where the supervising practitioner is immediately available to be present via two-way, audio/video communications technology, in the CY 2023 OPPS/ASC final rule with comment period, we finalized a policy to extend the revised definition of direct supervision to include the presence of the supervising practitioner through two-way, audio/video telecommunications technology until December 31, 2023 (87 FR 72019 and 72020). Under the telehealth flexibilities extended in the CAA, 2023, these services will remain on the Medicare Telehealth Services List through the end of CY 2024. In the interest of maintaining similar policies for direct supervision of PR, CR, and ICR under the OPPS and PFS, we proposed to further revise § 410.27(a)(1)(iv)(B)(*1*) to allow for the direct supervision requirement for CR, ICR, and PR to include virtual presence of the physician through audio-video real-time communications technology (excluding audio-only) through December 31, 2024 and to extend this policy to the nonphysician practitioners, that is NPs, PAs, and CNSs, who are eligible to supervise these services in CY 2024. We solicited comments on whether there are safety and/or quality of care concerns regarding adopting this policy beyond the current or proposed extensions and what policies CMS could adopt to address those concerns if the policy were extended beyond 2023.

For the complete discussion of the final revisions to §§ 410.47 and 410.49, we refer readers to the CY 2024 PFS final rule.

The following is a summary of the comments we received and our responses to those comments.

Comment: All commenters supported our proposal to make conforming revisions to § 410.27 to expand who may provide supervision for CR, ICR, and PR to include Pas, NPs, and CNSs and to allow for the direct supervision requirement for CR, ICR, and PR to include the virtual presence of the physician/nonphysician practitioner through audio-video real-time communications technology (excluding audio-only) through December 31, 2024. These commenters indicated that these changes will improve patient access to historically underutilized services, reduce burden on providers, and be of particular value in rural and other underserved areas where workforce shortages remain acute.

Response: We thank commenters for their support.

Comment: Many of these commenters requested that the availability of virtual direct supervision of these services be made permanent. One of these commenters additionally requested that once the policy is made permanent that CMS retire the requirement for a service-level modifier to identify when direct supervision is provided via appropriate telehealth technology.

Response: We appreciate the commenters' suggestions to make the virtual direct supervision of ICR, CR, and PR permanent. One of our motives for extending the availability of virtual direct supervision of these services until the end of CY 2024 is to allow us to continue to evaluate safety, quality of care, and other considerations related to virtual direct supervision. As such, we will take commenter's suggestions into account in future rulemaking.

Comment: One commenter requested clarity as to how a hospital registered patient could continue to receive CR and PR remotely in their home. The commenter suggested that CMS create a separate HCPCS code for remote cardiac and/or remote pulmonary rehabilitation services, which would temporarily permit hospitals to continue to furnish these services remotely to patients in their homes and receive reimbursement under the OPPS. Another commenter requested that CMS reinstate the PHE flexibilities that allowed a beneficiary's home to serve as a provider-based department of a hospital for cardiac and pulmonary rehabilitation services. Acknowledging that the waiver related to the PHE allowing for this flexibility has ended, this commenter suggested that CMS rely on other waiver authority (such as section 402 demonstration authority) to ensure the continuation of the flexibility.

Response: We appreciate commenters' interest in providing cardiac and pulmonary rehabilitation services remotely to a patient in their home. However, a hospital registered patient cannot currently receive CR or PR remotely in their home. The flexibility to provide CR, PR, and ICR services remotely to a beneficiary in his or her home ended with the expiration of the PHE on May 11, 2023.

Comment: One commenter requested that CMS revise the definition of ''physician prescribed exercise'' under §§ 410.47(a) and 410.49(a) to include Pas. Citing the 2014 final decision memorandum for Cardiac Rehabilitation (CR) Programs—Chronic Heart Failure,[195] this commenter stated that CMS previously declined to modify language in this manner because the Act specifies that the program is under the supervision of a physician. This commenter believed that since this section of the Act has been revised to allow Pas to supervise these programs, CMS should now modify this language accordingly to ''provider prescribed exercise.'' This commenter further requested that if the exact wording cannot be modified due to statutory constraints, CMS should reinterpret the intent of this section to indicate that health professionals authorized to supervise may also prescribe exercise. Additionally, this commenter urged CMS to work with Congress to modify physician-centric language in U.S. Code that prohibits Pas and other health

[195] *https://www.cms.gov/medicare-coverage-database/view/ncacal-decision-memo.aspx?proposed=N&NCAId=270.*

professionals from ordering PR, CR, and ICR. Another commenter noted that under the Accountable Care Organization Realizing Equity, Access, and Community Health (ACO REACH) model, NPs are allowed to establish, review and sign a written care plan for PR and CR and requested that this waiver be standardized across all relevant payment models and that CMS should explore regulatory avenues to remove the barrier for patients to be seen by NPs to increase PR and CR participation.

Response: In the 2014 final decision memorandum for Cardiac Rehabilitation (CR) Programs—Chronic Heart Failure [196] public comment section, CMS responded to a similar request that the language describing CR be changed from ''physician prescribed'' to ''provider prescribed.'' In response to this comment, CMS reiterated that per the Act a CR program (at the time) ''means a physician-supervised program'' at section 1861(eee)(1) of the Act. CMS then further explained that ''physician-prescribed exercise'' is one of the required items listed in section 1861(eee)(3). While the BBA of 2018 expanded the types of practitioners that may supervise PR in section 1861(fff)(1) and CR/ICR in section 1861(eee)(1), it did not amend the items and services that these programs must furnish to also include exercise prescribed by other practitioners in addition to physicians, as section 1861(fff)(2)(A) for PR and section 1861(eee)(3)(A) for CR/ICR were not amended. We understand commenters' requests to expand the role for NPPs in prescribing and ordering these services, and establishing, reviewing, and signing plans of care, however the statutory language does not support the requested changes and CMS does not interpret the statutory changes to allow for such modifications using only a regulatory pathway. We encourage interested parties to work with Congress to explore further statutory changes to support these requests.

Comment: One commenter objected to the term ''nonphysician provider'' and encouraged CMS to fully transition to the use of the practitioner's professional title or to utilize the term ''advanced practice providers'' (APPs) when necessary and to remove all references to ''nonphysician practitioner'' within regulations, guidance, and information collection instruments. The commenter argues that CMS should do so because the term ''nonphysician provider'' fails to recognize the established scope of practice for APPs and their authority to practice to the full extent of their education and clinical preparation.

Response: We appreciate the commenter's concerns and agree with the importance of employing the appropriate designations for practitioners. We note that § 410.27(g) specifically lists the individual practitioners (clinical psychologist, licensed clinical social worker, PA, NP, CNS, or certified nurse-midwife) that are included in the term ''nonphysician practitioner'' for purposes of § 410.27 and §§ 410.47(a) and 410.49(a), which § 410.27, as finalized, now cross-references, specifically lists the individual practitioners (PA, NP, and CNS) that are included in the term ''nonphysician practitioner'' for the purposes of the supervision of ICR, CR and PR. It is therefore unnecessary and would be impractical to replace all instances of ''nonphysician practitioner'' throughout each regulation with a list of each practitioner's professional titles. With respect to replacing ''nonphysician practitioner'' with ''advance practice providers,'' we understand the importance of using the most relevant and up to date terminology to describe these practitioners. However, as acknowledged by the commenter, ''nonphysician practitioner'' is used in multiple regulations, guidance, and other documents and any change in terminology would need to be considered in light of ensuring consistency across these authorities. We will take this suggestion into consideration for future rulemaking.

Comment: One commenter requested clarification as to whether the flexibility for Pas, NPs, and CNSs to directly supervise ICR, CR and PR applies to both PPS hospitals and CAHs.

Response: Yes, the flexibility for Pas, NPs, and CNSs to directly supervise ICR, CR and PR applies to ICR, CR and PR services furnished by CAHs.

Comment: One commenter requested that CMS not restrict direct supervision through virtual presence to a subset of services. In the commenter's view, the decision whether to provide direct supervision through virtual presence via real-time, two-way audio/virtual telecommunications should be left up to the practitioner overseeing the patient's care.

Response: We thank the commenter for their comment and note that for therapeutic services under § 410.27, ICR, CR and PR, are the only services that are subject to direct supervision requirements when furnished to hospital outpatients. For a full discussion of the change in the generally applicable minimum required level of supervision for hospital outpatient therapeutic services from direct supervision to general supervision for services furnished by hospitals and CAHs, we refer readers to the CY 2020 OPPS final rule (84 FR 61359 through 61363) and the CY 2021 OPPS final rule with comment period (85 FR 86110 and 86111).

Comment: Several commenters provided input in response to our comment solicitation as to the existence of safety and/or quality of care concerns regarding the adoption of virtual supervision beyond the current (end of 2023) or proposed (end of 2024) extensions and what policies CMS might adopt to address any such concerns if the policy were extended beyond 2023. One commenter opined that requiring the physician or other supervising professional to be physically present in the same building has negligible patient-safety benefits because a physician's office, clinic, or hospital outpatient department typically has many other practitioners on site who would be available to assist if a physical presence was required. This commenter further contended that a virtually available supervisor might actually enhance patient safety in an emergency because the most appropriate course of action in an emergency is to transfer the patient to an emergency department, not wait for the supervising physician or other practitioner to arrive. The commenter noted that a virtually available supervisor may facilitate a faster transfer of the patient to the emergency department.

Another commenter indicated that they and other interested parties had previously provided CMS with literature on the absence of safety issues when supervision is provided virtually and offered to provide additional information to this effect for CMS's consideration for 2025 rulemaking.

A third commenter stated that because the option to provide direct supervision virtually has only become available recently as a consequence of the PHE, it is unlikely there are any peer-reviewed studies that focus on this aspect of virtual care. However, the commenter indicated that they had included with their comment numerous studies demonstrating the effectiveness and safety of virtual CR and PR services. In the commenter's view, the studies demonstrate that virtual and hybrid delivery of CR and PR services provided by staff are safe, improve health outcomes and adherence, and address barriers to access.

[196] *https://www.cms.gov/medicare-coverage-database/view/ncacal-decision-memo.aspx?proposed=N&NCAId=270.*

Finally, a commenter, prefacing their remarks with a statement that they do not share CMS's concern that virtual supervision inherently gives rise to patient safety issues, indicated that in their experience, numerous clinical staff and auxiliary personnel perform a wide range of tasks easily supervised virtually. The commenter argues that such staff categorically do not perform ''complex, high-risk, surgical, interventional, or endoscopic procedures, or anesthesia procedures'' that CMS has described in the past to explain its concerns with virtual direct supervision and that nonphysician practitioners, to the extent that they assist with such procedures, are subject to higher standards, certifications, and oversight.

Response: We thank commenters for their input regarding safety and/or quality of care concerns related to virtual direct supervision. We will take these comments into consideration for future rulemaking.

Comment: Several commenters appeared to assume that our proposal to extend the availability of virtual direct supervision until the end of 2024 included both outpatient hospital therapeutic services (under § 410.27) and outpatient hospital diagnostic services (under § 410.28), in the same way that the PFS proposed rule proposed to extend the availability of virtual direct supervision to both therapeutic and diagnostic services (under § 410.32) furnished by physicians (88 FR 52302).

One commenter encouraged CMS to extend ''virtual direct supervision'' through the end of 2024, if not beyond, ''and in a manner comparable to the physician fee schedule,'' to ensure that patients continued to have access to robust healthcare choices.

Another commenter submitted complementary comments to both the CY 2024 proposed PFS rule and CY 2024 proposed OPPS rule, referring to the two rules' overlap with respect to certain policies and using nearly identical language to describe its endorsement of both rules' proposals relating to the extension of the availability of virtual direct supervision through 2024. In its comment to the CY 2024 proposed PFS rule, this commenter stated: ''The Agency proposes extending through CY2024 several PHE-era policies not directly addressed by CAA2023, including permitting virtual Direct Supervision of auxiliary personnel by physicians and/or non-physician practitioners. We support the Agency's proposal to extend the present Direct Supervision waiver policies through CY2024.'' In the commenter's corresponding comment to the CY 2024 proposed OPPS rule, they similarly stated: ''The Agency also proposes extending through CY2024 several PHE-era virtual care policies not directly addressed by The Consolidated Appropriations Act of 2023 (''CAA2023''), including permitting virtual Direct Supervision of auxiliary personnel by physicians and/or non-physician practitioners. . . [commenter] strongly supports extending all of those policies in their present state through CY2024. We direct the Agency to our public response to the 2024 MPFS proposed rule for a full discussion.''

Another commenter, in support of their suggestion to make the flexibility to provide direct supervision through real-time audio/video technology permanent, attested to their experience of successfully providing ''clinically appropriate supervision for impacted services such as diagnostic tests and incident-to services through synchronous audio-visual telehealth.''

Response: We appreciate commenters' support and would like to make a clarification with respect to the availability of the virtual direct supervision of hospital and CAH diagnostic services furnished to outpatients in CY 2024. Historically, our policy has been to require that all hospital diagnostic services that are provided directly or under arrangement, whether provided in the main buildings of the hospital, in a PBD of a hospital, or at a nonhospital location, follow the physician supervision requirements adopted in the annual PFS rulemaking (74 FR 60590). Consistent with this policy, until CY 2023 the regulation at 42 CFR 410.28 regarding diagnostic tests furnished to hospital outpatients cross-referenced the definition of supervision levels for diagnostic services in the regulation at 42 CFR 410.32(b)(3), thereby incorporating the definitions of levels of supervision for diagnostic tests for which payment is made under the PFS. This policy—to align the supervision levels for diagnostic services furnished to hospital outpatients with those provided for in the regulation at 42 CFR 410.32(b)(3)—is also reflected in section 20.4.4 of Chapter 6 of the Medicare Benefit Policy Manual,[197] which provides that the supervision levels listed in the quarterly updated Medicare PFS Relative File apply to individual outpatient diagnostic tests.

In the CY 2023 OPPS/ASC final rule with comment period, we revised the regulation at § 410.28 to remove the cross-reference to § 410.32 and include within the regulation text in that provision the definitions of different levels of supervision. Although we removed the cross-reference to section § 410.32, our intent was to continue to align the rules regarding the supervision levels for diagnostic services furnished to hospital outpatients with the rules for supervision levels for diagnostic services described in section § 410.32.

When we removed the cross-references in 42 CFR 410.28 to 42 CFR 410.32, we anticipated continuing to make changes to § 410.28 to ensure that the definitions of the supervision levels remained consistent between the two provisions. Consequently, when the CY 2024 PFS proposed rule proposed to revise § 410.32 to extend the availability of the virtual supervision of direct supervision until the end of 2024, we intended to propose a corresponding revision to § 410.28 in the proposed 2024 OPPS rule to provide for this flexibility for diagnostic services furnished to hospital outpatients. Unfortunately, we inadvertently failed to propose this revision.

Because until CY 2023, an update to the supervision requirements under § 410.32 applied to diagnostic services furnished to hospital outpatients because of the cross-reference to § 410.32 in the regulation at § 410.28, we believe it is possible that the public, long accustomed to section § 410.28 incorporating the definitions in § 410.32 through the cross-reference to that provision, did not realize that an update to § 410.28 had not been proposed and thus did not comment on our unintended failure to update § 410.28. This is supported by comments we received that suggested that commenters were unaware that we had not proposed a revision to the regulation at § 410.28 to extend the virtual supervision of outpatient diagnostic services through the end of 2024. Instead, commenters seemed to assume that our proposal to extend the ability of practitioners to meet the direct supervision requirement through virtual presence included all diagnostic services, whether furnished in a hospital outpatient department or otherwise. Because our intention was to propose a corresponding revision to the regulation text at § 410.28 for consistency with the proposed revision to § 410.27 and commenters supported such a policy, we are812inalizingg a revision to § 410.28(e)(2)(iii) to allow for the direct supervision of diagnostic services to include the virtual presence of the physician or nonphysician practitioner through audio/video real-time communications technology

[197] Available at *https://www.cms.gov/regulations-and-guidance/guidance/manuals/downloads/bp102c06.pdf.*

(excluding audio-only) through December 31, 2024.

After consideration of the public comments we received, we are also finalizing, without modification, our proposal to revise § 410.27(a)(1)(iv)(B)(*1*) to expand the practitioners who may supervise CR, ICR, and PR services to include NPs, Pas, and CNSs and to allow for the direct supervision requirement for CR, ICR, and PR to include the virtual presence of the physician, NP, PA or CNS through audio-video real-time communications technology (excluding audio-only) through December 31, 2024.

B. Payment for Intensive Cardiac Rehabilitation Services (ICR) Provided by an Off-Campus, Non-Excepted Provider Based Department (PBD) of a Hospital

1. Background on Intensive Cardiac Rehabilitation

Section 144(a) of the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) (Pub. L. 110–275) made a number of changes to the Act related to coverage and payment for pulmonary and cardiac rehabilitation services furnished to beneficiaries with chronic obstructive pulmonary disease and certain other conditions, effective January 1, 2010. Specifically, section 144(a)(1)(A) of MIPPA amended section 1861(s)(2) of the Act by adding new subparagraphs (CC) and (DD) to provide for Medicare Part B coverage of items and services furnished under a cardiac rehabilitation (CR) program (as defined in a new section 1861(eee)(1) of the Act); a pulmonary rehabilitation (PR) program (as defined in a new section 1861(fff)(1) of the Act); and an intensive cardiac rehabilitation (ICR) program (as defined in a new section 1861(eee)(4) of the Act). The amendments made by section 144(a) of MIPPA provide for coverage of CR, PR, and ICR program services provided in a physician's office, in a hospital on an outpatient basis, and in other settings determined appropriate by the Secretary.

Section 144(a)(2) of MIPPA amended section 1848(j)(3) of the Act to provide for payment for services furnished in an ICR program under the PFS and also added a new paragraph (5) to section 1848(b) of the Act. Section 1848(b)(5)(A) requires the Secretary for ICR program services to substitute the Medicare OPD fee schedule amount established under the OPPS for cardiac rehabilitation (under HCPCS codes 93797 and 93798 for calendar year 2007, or any succeeding HCPCS codes for cardiac rehabilitation). For a full discussion of implementation of the MIPPA amendments related to coverage and payment for PR, CR, and ICR programs under the OPPS, we refer readers to the CY 2010 OPPS/ASC final rule with comment period (74 FR 60566 through 60574).

2. Background on Section 603 of the Bipartisan Budget Act of 2015 and the PFS Relativity Adjuster

Section 603 of the Bipartisan Budget Act of 2015 (Pub. L. 114–74) (BBA, 2015) (hereinafter referred to as ''section 603'') amended section 1833(t) of the Act by adding a new clause (v) to paragraph (1)(B) and adding a new paragraph (21). As a general matter, under sections 1833(t)(1)(B)(v) and (t)(21) of the Act, applicable items and services furnished by certain off-campus outpatient departments of a provider on or after January 1, 2017, are not considered covered OPD services as defined under section 1833(t)(1)(B) of the Act for purposes of payment under the OPPS and are instead paid ''under the applicable payment system'' under Medicare Part B if the requirements for such payment are otherwise met. Section 603 amended section 1833(t)(1)(B) of the Act by adding a new clause (v), which excludes from the definition of ''covered OPD services'' applicable items and services (defined in paragraph (21)(A) of the section) that are furnished on or after January 1, 2017, by an off-campus PBD, as defined in paragraph (21)(B) of the section.

In the CY 2017 OPPS/ASC final rule with comment period (81 FR 79699 through 79719), we adopted a number of policies to implement section 603. Broadly, we: (1) defined applicable items and services in accordance with section 1833(t)(21)(A) of the Act for purposes of determining whether such items and services are covered OPD services under section 1833(t)(1)(B)(v) of the Act or whether payment for such items and services will instead be made under the applicable payment system designated under section 1833(t)(21)(C) of the Act; (2) defined off-campus PBD for purposes of sections 1833(t)(1)(B)(v) and (t)(21) of the Act; and (3) established policies for payment for applicable items and services furnished by an off-campus PBD (nonexcepted items and services) under section 1833(t)(21)(C) of the Act. To do so, we finalized policies that define whether certain items and services furnished by a given off-campus PBD may be considered excepted and, thus, continue to be paid under the OPPS; established the requirements for the off-campus PBDs to maintain excepted status (both for the excepted off-campus PBDs and for the items and services furnished by such excepted off-campus PBDs); and described the applicable payment system for nonexcepted items and services (generally, the PFS).

To effectuate payment for nonexcepted items and services, in the CY 2017 interim final rule with comment period (81 FR 79720 through 79729), we established a new set of payment rates under the PFS that reflected the relative resource costs of furnishing the technical component of a broad range of services to be paid under the PFS specific to the nonexcepted off-campus PBDs of a hospital. Specifically, we established a PFS Relativity Adjuster that is applied to the OPPS rate for the billed nonexcepted items and services furnished in a nonexcepted off-campus PBD in order to calculate payment rates under the PFS. The PFS Relativity Adjuster reflects the estimated overall difference between the payment that would otherwise be made to a hospital under the OPPS for the nonexcepted items and services furnished in nonexcepted off-campus PBDs and the resource-based payment under the PFS for the technical aspect of those services with reference to the difference between the facility and nonfacility (office) rates and policies under the PFS. Nonexcepted items and services furnished by nonexcepted off-campus PBDs are generally paid under the PFS at the applicable OPPS payment rate adjusted by the PFS Relativity Adjuster of 40 percent (that is, 60 percent less than the OPPS rate) (82 FR 53030).

In the CY 2017 OPPS/ASC final rule with comment period (81 FR 79719 and 79725), we created modifier ''PN'' to collect data for purposes of implementing section 603 but also to trigger payment under the newly adopted PFS-equivalent rates for nonexcepted items and services. Nonexcepted off-campus PBDs bill for nonexcepted items and services on the institutional claim utilizing modifier ''PN'' to indicate that an item or service is a nonexcepted item or service.

For a full discussion of our initial implementation of section 603, we refer readers to the CY 2017 OPPS/ASC final rule with comment period (81 FR 79699 through 79719) and the interim final rule with comment period (79720 through 79729). For a detailed discussion of the current PFS Relativity Adjuster related to payments under section 603, we refer readers to the CY 2018 OPPS/ASC final rule with comment period (82 FR 52356 through 52637) and the CY 2019 PFS final rule with comment period (82 FR 59505 through 59513).

3. Proposal To Modify Claims Processing of HCPCs Codes G0422 and G0423 To Address an Unintended Payment Disparity Caused by Application of the PFS Relativity Adjuster to ICR Services Furnished by Off-Campus Non-Excepted PBDs Hospitals

Since 2010, ICR services provided in the physician's office have been paid at 100 percent of the OPPS rate for CR services as required by 1848(b)(5). Since 2017, ICR services provided by an off-campus, non-excepted PBD of a hospital have been paid at the above-described ''PFS-equivalent'' rate through application of the PFS Relativity Adjuster, which was 50 percent of the OPPS rate in CY 2017 and 40 percent of the OPPS rate in CY 2018 and thereafter, consistent with the above-described implementation of section 603.

This has produced an outcome inconsistent with the text of section 1848(a)(5)(A) and at odds with the intent of section 603, which was to remove the significant disparity in payment rates for the same services depending on whether they were furnished in a physician's office or an off-campus, non-excepted PBD of a hospital. When the PFS Relativity Adjuster was implemented in 2017, payment for the ICR service provided in a physician's office and a PBD of an off-campus, non-excepted hospital was already the same pursuant to section 1848(b)(5)(A), which requires ICR services provided in a physician's office to be paid at the OPPS rate for cardiac rehabilitation. Consequently, application of the 40 percent PFS Relativity Adjuster to payment for ICR provided by an off-campus, non-excepted PBD has resulted in an unintended reimbursement disparity between the two sites of the service, as shown in Table 104.

TABLE 104: 2023 REIMBURSEMENT FOR HCPCS CODES G0422 AND G0423 UNDER THE OPPS ON-CAMPUS RATE, OPPS NON-EXCEPTED RATE AND PFS RATE

HCPCS Code	2023 OPPS On-Campus Rate	2023 OPPS Non-Excepted Rate	2023 Medicare PFS Payment Rate
G0422 (intensive cardiac rehabilitation; with or without continuous ECG monitoring with exercise, per session)	$120.47	$48.03	$120.47
G0423 (intensive cardiac rehabilitation; with or without continuous ECG monitoring without exercise, per session)	$120.47	$48.03	$120.47

This disparity creates a significant barrier to beneficiary access to an already underutilized service. To eliminate this unintended outcome and for consistency with the requirement in section 1848(b)(5)(A) of the Act to substitute the OPPS rate for CR services for the PFS rate for ICR services, we proposed to pay for ICR services provided by an off-campus, non-excepted provider-based department of a hospital at 100 percent of the OPPS rate for CR services (which is also 100 percent of the PFS rate) rather than at 40 percent of the OPPS rate. Effective January 1, 2024, we proposed to exclude ICR from the 40 percent PFS Relativity Adjuster policy at the code level by modifying the claims processing of HCPCS codes G0422 (Intensive cardiac rehabilitation; with or without continuous ECG monitoring with exercise, per session) and G0423 (Intensive cardiac rehabilitation; with or without continuous ECG monitoring without exercise, per session) so that 100 percent of the OPPS rate for CR is paid irrespective of the presence of the ''PN'' modifier (signifying a service provided in a non-excepted off-campus provider-based department of a hospital) on the claim. We solicited comment on whether there are other services for which the OPPS rate is unconditionally used under the PFS, such that these services should be treated similarly for purposes of payment to off-campus, non-excepted provider-based departments of hospitals.

The following is a summary of the comments we received and our responses to those comments.

Comment: All commenters supported our proposal to exclude ICR from the 40 percent PFS Relativity Adjuster at the code level by modifying the claims processing of HCPCS codes G0422 and G0423 so that 100 percent of the OPPS rate for CR is paid irrespective of the presence of the ''PN'' modifier on the claim. These commenters indicated that this change will increase patient access to an underutilized program, particularly in rural and underserved areas.

Response: We thank commenters for their support.

Comment: Many commenters requested that we retroactively review payments made from CY 2017 through CY 2023 for ICR services (HCPCS codes G0422 and G0423) provided by a non-excepted, off-campus PBD and prospectively adjust payment rates to reimburse off-campus PBDs the difference between what was paid what should have been paid.

Response: We appreciate commenters' suggestion and will consider it for future rulemaking.

Comment: Several commenters provided input in response to our request for comment on whether there are other services for which the OPPS rate is unconditionally used under the PFS, such that these services should be treated similarly for purposes of payment to off-campus, non-excepted provider-based departments of hospitals.

One commenter stated that the OPPS rate is unconditionally used under the PFS for the technical component of all diagnostic services subject to the OPPS imaging cap mandated by section 1848(b)(4) of the Act, which limits the

PFS rate to no more than the OPPS rate. The commenter contends that it is illogical to apply a PFS Relative Adjustor to the OPPS rates for these services when doing so results in payment that is lower than what a physician's office would receive, particularly since the OPPS payment rates include packaging of drugs, devices, laboratory, and other ancillary services that are all separately billed by an office. This commenter requested that CMS exempt all imaging tests whereby the OPPS imaging cap is applied and pay these services at 100 percent of the OPPS rate when furnished in a non-excepted, off-campus location.

Response: We do not agree that the OPPS rate is unconditionally used under the PFS for the technical component of all diagnostic services subject to the OPPS imaging cap mandated by section 1848(b)(4), such that these services should be treated similarly for purposes of payment to off-campus, non-excepted provider-based departments of hospitals. There is a fundamental difference between section 1848(j)(3), which is intended to ensure site neutrality between the PFS and the OPPS for payment for ICR rehabilitation services, and section 1848(b)(4), which is intended to impose a limit on the PFS payment for certain imaging services if the payment rate for a particular imaging service exceeds the OPPS payment rate for the same service in a given year.

Comment: The remaining responses to our comment solicitation did not identify any other services for which the OPPS rate is unconditionally used under the PFS but instead suggested services that commenters believed should be excluded from the 40 percent PFS Relativity Adjuster based on payment rate comparisons and other considerations. One commenter, while acknowledging that CR services were not included in the original MIPPA statute that directs coverage and payment of ICR, argued that since CR services are clinically very similar to ICR services and are also underutilized services with a proven record of improving patient quality of life and rehospitalization outcomes, that it would be appropriate for CMS to also exclude CPT codes 93797 (Physician or other qualified health care professional services for outpatient cardiac rehabilitation; without continuous ECG monitoring (per session)) and 93798 (Physician or other qualified health care professional services for outpatient cardiac rehabilitation; with continuous ECG monitoring (per session)) from the 40 percent PFS Relativity Adjuster. Another commenter requested that CMS consider exempting both CR and PR. Two commenters referred CMS to a recent report by MedPAC which stated that some services are more safely provided in the PBD setting and that limiting payment for these services could limit beneficiary access. These commenters suggested that CMS identify the ambulatory payment classifications for these services and exclude them from the 40 percent PFS Relativity Adjuster. Additionally, these commenters requested that CMS identify payment codes for which payment to freestanding physician offices under the PFS is higher than 40 percent of the OPPS rate and exclude them from the 40 percent PFS Relativity Adjuster. One of these commenters also requested that CMS conduct a comprehensive review of services provided in the physician office and PBD settings to identify other services that should be paid at the OPPS rate to ''preserve beneficiary access.'' Finally, one commenter reported that they compared the non-facility practice expense (PE) national payment amounts to 40 percent of the OPPS rate for the service and discovered 602 HCPCS services for which 40 percent of the OPPS rate is less than the non-facility PE rate. Acknowledging that many of these codes are the imaging codes previously discussed, the commenter stated that the list also included codes for services that are not covered or allowed to be paid in the non-facility setting and for which facility resources are not included in the non-facility PE RVUs. The commenter stated that these procedures should be paid 100 percent of OPPS and not be subject to the PFS Relatively Adjustor because they are not allowed to be performed in physicians' offices. The commenter additionally requested that CMS review a selection of services included in an appendix to the comment, which highlights instances where 40 percent of the OPPS payment rate is less than the non-facility PE payment rate and requests that, where the PFS Relatively Adjustor is less than the non-facility PE payment rate from the MPFS, that CMS pay either 100 percent of the OPPS rate or, at a minimum, use the non-facility PE payment rate as a floor.

Response: We appreciate commenters' many thoughtful responses to our comment solicitation as well as their many nominations of services that they believe should be excluded from the 40 percent PFS Relativity Adjuster based on payment rate comparisons and other non-statutory considerations. While we will take these suggestions into consideration in future rulemaking, we emphasize that our primary rationale for making this change was adherence to the statute which explicitly requires the PFS rate for ICR services be the same as the OPPS rate for CR services.

After consideration of the public comments we received, we are finalizing, without modification, our proposal to exclude ICR from the 40 percent PFS Relativity Adjuster at the code level by modifying the claims processing of HCPCS codes G0422 and G0423 so that 100 percent of the OPPS rate for CR is paid irrespective of the presence of the ''PN'' modifier on the claim.

C. OPPS Payment for Specimen Collection for COVID–19 Tests

In the May 8, 2020 COVID–19 interim final rule with comment period titled ''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'', we created a new E/M code to support COVID–19 testing during the PHE: HCPCS code C9803 (Hospital outpatient clinic visit specimen collection for severe acute respiratory syndrome coronavirus 2 (sars–cov–2) (coronavirus disease [covid–19]), any specimen source) (85 FR 27604). In our review of available HCPCS and CPT codes for the May 8, 2020 COVID–19 IFC, we did not identify a prior code that explicitly described the exact services of symptom assessment and specimen collection that HOPDs were undertaking to facilitate widespread testing for COVID–19. 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 the conclusion of the COVID–19 PHE (85 FR 27604).

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 $24.96 for CY 2023. 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 explained that 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. On May 11, 2023, the COVID–19 PHE concluded.[198] As stated above, we created HCPCS code C9803 to meet the need of the COVID–19 PHE and the resource requirements for HOPDs during the PHE and planned to retire the code following the conclusion of the PHE. While the code will remain active for the remainder of CY 2023 for technical reasons, we do not believe it is necessary for the code remain active in CY 2024 now that the PHE has concluded. Therefore, we proposed to delete HCPCS code C9803 effective January 1, 2024; and we solicited comment on our proposal to delete this code for CY 2024.

We received two comments in support of maintaining the code for purposes of reporting and reimbursement. One commenter requested that if we do retire the code, that we implement a similar code for ongoing nasopharyngeal swab specimen collection. After consideration of the public comments we received, we do not believe it is necessary for the code to remain active in CY 2024 with the conclusion of the COVID–19 PHE. We continue to believe that the utility of HCPCS code C9803 ended when the COVID–19 PHE ended. Therefore, we believe it appropriate to delete HCPCS code C9803 effective January 1, 2024. However, we will continue to explore coding opportunities for nasopharyngeal swab specimen collection, where appropriate.

D. Remote Services

1. Mental Health Services Furnished Remotely by Hospital Staff to Beneficiaries in Their Homes

In the CY 2023 OPPS final rule with comment period (87 FR 72012 through 72017), we finalized creation of three HCPCS C-codes to describe mental health services furnished by hospital staff to beneficiaries in their homes through communications technology. See Table 105 for the C-code numbers and their descriptors.

TABLE 105: C-CODE NUMBERS AND LONG DESCRIPTORS

HCPCS Code	Long Descriptor
C7900	Service for diagnosis, evaluation, or treatment of a mental health or substance use disorder, initial 15-29 minutes, provided remotely by hospital staff who are licensed to provide mental health services under applicable State law(s), when the patient is in their home, and there is no associated professional service
C7901	Service for diagnosis, evaluation, or treatment of a mental health or substance use disorder, initial 30-60 minutes, provided remotely by hospital staff who are licensed to provide mental health services under applicable State law(s), when the patient is in their home, and there is no associated professional service
C7902	Service for diagnosis, evaluation, or treatment of a mental health or substance use disorder, each additional 15 minutes, provided remotely by hospital staff who are licensed to provide mental health services under applicable State law(s), when the patient is in their home, and there is no associated professional service (List separately in addition to code for primary service)

When we created HCPCS codes C7900 through C7902, we did not specify whether they should be used for individual or group services, preferring to keep the coding more general while we gathered information about the use of these new codes. However, we have heard from interested parties that, in instances when a beneficiary is receiving multiple units of group therapy a day, it is administratively burdensome to report and document each unit of time using multiple codes. Instead, interested parties requested that we create a single, untimed code that can be reported when a beneficiary receives multiple hours of group therapy per day. In order to reduce administrative burden and enhance access to these services, we proposed to create a new, untimed, HCPCS C-code describing group therapy. Please see Table 106 for the proposed C-code and long descriptor.

[198] *https://www.hhs.gov/about/news/2023/05/11/hhs-secretary-xavier-becerra-statement-on-end-of-the-covid-19-public-health-emergency.html.*

TABLE 106: PROPOSED C-CODE NUMBER AND LONG DESCRIPTOR

HCPCS	Long Descriptor
C79XX	Group psychotherapy service for diagnosis, evaluation, or treatment of a mental health or substance use disorder provided remotely by hospital staff who are licensed to provide mental health services under applicable State law(s), when the patient is in their home, and there is no associated professional service

As we stated in the CY 2023 OPPS final rule with comment period, when beneficiaries are in their homes and not physically within the hospital, the hospital is not accruing all the costs associated with an in-person service; and the full OPPS rate would not accurately reflect these reduced costs. We believe that the costs associated with hospital clinical staff remotely furnishing a mental health service to a beneficiary who is in their home using communications technology more closely resembles the PFS payment amount for similar services when performed in a facility, which reflects the time and intensity of the professional work associated with performing the mental health service but does not reflect certain practice expense costs, such as clinical labor, equipment, or supplies (87 FR 72015).

In keeping with that methodology, we proposed to assign HCPCS code C79XX to an APC based on the facility payment amount for a clinically similar service, CPT code 90853 (Group psychotherapy (other than of a multiple-family group)) under the PFS. See Table 107 for the proposed SI and APC assignments and payment rates for HCPCS code C79XX.

TABLE 107: PROPOSED CY 2023 SI, APC ASSIGNMENT, AND GEOMETRIC MEAN COST FOR HCPCS CODE C97XX

HCPCS	Short Descriptor	Proposed SI	Proposed Proxy Service	PFS Facility Rate	Proposed APC	APC GMC
C79XX	HOPD mntl hlt, grp	S	90853	$23.38	5821	$28.62

We sought comment on whether HCPCS code C79XX sufficiently describes group psychotherapy to the extent that group psychotherapy would no longer be reported with HCPCS codes C7900–C7902, in which case we would need to refine the code descriptors for HCPCS codes C7900–C7902 to stipulate that they are solely for services furnished to an individual beneficiary. Alternatively, we sought comment on whether or there are circumstances where interested parties believe it would be appropriate to bill for group services using HCPCS codes C7900–C7902. We also sought comment on any further refinements to the code descriptors, valuation, or billing guidance.

We have also heard from interested parties that there is confusion about the presence of the word ''initial'' in the descriptors for HCPCS codes C7900 and C7901 and that this is preventing billing for remote behavioral health services furnished subsequent to either the first 15 to 29 minutes or 30 to 60 minutes. In order to facilitate accurate billing, regardless of whether the remote mental health service is being furnished as an initial or subsequent service, we proposed to revise the code descriptors to remove the word ''initial.'' We also proposed to revise the descriptor for HCPCS code C7902 to limit billing with HCPCS code C7901. See Table 108 for revised code descriptors.

TABLE 108: PROPOSED DESCRIPTORS FOR HCPCS CODES C9700 AND C9701

HCPCS	Proposed Long Descriptor
C7900	Service for diagnosis, evaluation, or treatment of a mental health or substance use disorder, 15-29 minutes, provided remotely by hospital staff who are licensed to provide mental health services under applicable State law(s), when the patient is in their home, and there is no associated professional service
C7901	Service for diagnosis, evaluation, or treatment of a mental health or substance use disorder, 30-60 minutes, provided remotely by hospital staff who are licensed to provide mental health services under applicable State law(s), when the patient is in their home, and there is no associated professional service
C7902	Service for diagnosis, evaluation, or treatment of a mental health or substance use disorder, each additional 15 minutes, provided remotely by hospital staff who are licensed to provide mental health services under applicable State law(s), when the patient is in their home, and there is no associated professional service (List separately in addition to HCPCS code C9701)

The following is a summary of the comments we received and our responses to those comments.

Comment: Most commenters supported our proposal to create to a new, untimed, HCPCS C-code (C79XX) describing group therapy, citing reduced confusion and administrative burden, and ensuring appropriate patient access to the services.

Response: We thank commenters for their support.

Comment: Several commenters opposed the creation of the group therapy code, objecting to our proposal to assign the code to an APC based on the facility payment amount for a similar service (CPT code 90853 Group Psychotherapy (other than of a multiple-family group)) under the PFS. Several other commenters neither supported nor objected to the creation of the group therapy code but expressed concern with basing reimbursement on the facility PFS payment for remote mental health services generally. These commenters disagreed with CMS's assumption that when beneficiaries are in their homes and not physically within the hospital, the hospital is not accruing all the costs associated with an in-person service. These commenters pointed to many factors in support of their contention, including investments in infrastructure, equipment, and technology to provide remote services, the clinical and administrative staff necessary to provide remote services while maintaining access to in-person care, the staff time and resources necessary to make the remote visit run smoothly (scheduling and setting up the appointment, assisting patients with connecting to the appointment, screening patients, making referrals and scheduling follow ups), the fact that salaries and operating costs do not decrease simply because some services are provided remotely and that the only cost savings are for supplies, which are negligible because the services being provided remotely are mental health services. In recognition of these costs, these commenters requested payment for remote mental health services at the full OPPS rate. One commenter supported CMS's conclusion that mental health services provided remotely cost less than mental health services provided in-person, noting that even though the work RVU remains the same, the practice expenses are significantly reduced.

Response: We continue to believe that when beneficiaries are in their homes and not physically within the hospital, that the hospital is not accruing all the costs associated with an in-person service and as such the full OPPS rate would not accurately reflect these costs. However, we do agree that the non-facility payment rate is likely a better reflection of the resources associated with furnishing these services than the facility payment rate. However, as demonstrated in Table 109 below, using the non-facility rate to inform the APC assignment still results in assignment to the same APCs.

TABLE 109: FINAL CY 2024 SI AND APC FOR C7900, C7901, AND C7903

HCPCS	Short Descriptor	Final SI	Final Proxy Code	PFS NF Rate	Final CY 2024 APC	Final CY 2024 APC GMC	Final CY 2024 OPPS Payment Rate
C7900	Hopd mntl hlt, 15-29 min	S	96159	$21.61	5821	$28.08	Refer to OPPS Addendum B
C7901	Hopd mntl hlt, 30-60 min	S	95158	$62.88	5822	$87.30	Refer to OPPS Addendum B
C7903 (placeholder C79XX)	HOPD mntl hlt, grp	S	90853	$25.87	5821	$28.08	Refer to OPPS Addendum B

We appreciate commenters insights and will consider further updates to the payment rates as needed in future rulemaking.

Comment: All commenters supported our proposal to revise the code descriptors C7900 and C7901 to remove the word ''initial.''

Response: We thank commenters for their support.

Comment: One commenter, in response to CMS's request for comment on the HCPCS codes C7900–7902, stated that because the nomenclature and minutes in these codes are similar to other HCPCS codes, the commenter would support keeping the codes as currently written.

Response: We thank the commenter for this input.

Comment: One commenter encouraged CMS to clearly define a beneficiary's home as broadly as possible, in recognition that not all beneficiaries own, rent, or occupy a space that might traditionally be considered a ''home.'' This commenter points out that shelters, tents, parked vehicles, and other settings may well be considered a ''home'' to some or might offer a safe environment that is necessary for the beneficiary to openly engage with their clinician during a mental health disorder, or other, visit.

Response: We appreciate commenter's suggestion and agree that one's home can cover a wide breadth of settings and arrangements. As we have previously explained, our definition of ''home,'' both in general and in terms of a mental healthcare delivery site, is broad and includes temporary lodging such as hotels and homeless shelters (86 FR 65048 and 65049).

Comment: One commenter stated that the new remote mental health services are not fully understood by many providers and therefore not utilized as often as they could be. The commenter expressed concern that there will be significant confusion in the community between these services (which are sometimes used to bill for remote IOP services) and the new IOS services covered by Medicare. The commenter requests that CMS issue informational materials to smaller rural providers (like CAHs) to help them to understand the circumstances under which each service is appropriate and how each option would help them to meet the needs of their patient populations.

Response: We appreciate the commenter's suggestion and will consider the creation of additional informational materials related to remote mental health services.

Comment: One commenter emphasized the importance of CMS providing explicit billing guidance when clinicians in hospitals furnish telehealth services to patients in their homes. The commenter requested that CMS confirm the appropriate billing and payment for telehealth services when the clinician is in the hospital and the patient is in the home and asked several specific billing questions.

Response: We direct the commenter to the CY 2024 PFS final rule for specific information relating to billing for telehealth services furnished to patients in their homes. We will consider additional sub-regulatory clarifications, as needed, in the future.

Comment: One commenter emphasized that remote monitoring tools must play a central role in CMS's efforts to make its OPPS more efficient and effective and encouraged CMS to fully support the use of remote monitoring (both physiologic and therapeutic) through its OPPS policies. This commenter also requested that CMS ensure that critical access hospitals (CAHs) and REHs be able to provide services via the most appropriate and accessible modality, whether live voice/video or asynchronous modalities, including remote monitoring. The commenter

argued that CAHs and REHs should enjoy the same fee-for-service carve out that FQHCs and RHCs already enjoy for Chronic Care Management (CCM), Transitional Care Management (TCM), and Behavioral Health Integration (BHI) services. The commenter urged CMS to act to support the use of Remote Patient Monitoring (RPM) and Remote Therapeutic Management (RTM) by CAHs and REHs. Finally, the commenter notes that CMS has proposed to provide new support for RPM and RTM to FQHCs and RHCs, and requests that the OPPS rules provide similar support for CAHs and REHs.

Response: We appreciate the commenter's input and recommendations with respect to remote monitoring tools and we will consider them for future rulemaking. After consideration of the public comments we received, we are finalizing, without modification, our proposal to create a new, untimed, HCPCS C-code, specifically, C7903, describing group therapy and to assign that code to an APC based on the facility payment amount for a clinically similar service, CPT code 90853 (Group psychotherapy (other than of a multiple-family group)) under the PFS. We are also finalizing our proposal to revise the code descriptors for HCPCS codes C7900 and C7901 to remove the word ''initial'' and HCPCS code C7902 to limit billing with HCPCS code C7901.

2. Periodic In-Person Visits

In the CY 2023 OPPS final rule with comment period (87 FR 72017), we finalized a requirement that payment for mental health services furnished remotely to beneficiaries in their homes using telecommunications technology may only be made if the beneficiary receives an in-person service within 6 months prior to the first time the hospital clinical staff provides the mental health services remotely; and that there must be an in-person service without the use of telecommunications technology within 12 months of each mental health service furnished remotely by the hospital clinical staff. We also finalized that we would permit exceptions to the requirement that there be an in-person service without the use of communications technology within 12 months of each remotely furnished mental health service when the hospital clinical staff member and beneficiary agree that the risks and burdens of an in-person service outweigh the benefits of it. We stated that exceptions to the in-person visit requirement should involve a clear justification documented in the beneficiary's medical record including the clinician's professional judgement that the patient is clinically stable and/or that an in-person visit has the risk of worsening the person's condition, creating undue hardship on the person or their family, or would otherwise result in disengaging with care that has been effective in managing the person's illness. We also finalized that hospitals must document that the patient has a regular source of general medical care and has the ability to obtain any needed point of care testing, including vital sign monitoring and laboratory studies. We finalized that these requirements would not go into effect until the 152nd day after the PHE for COVID–19 ends to maintain consistency with similar policies implemented for professional services paid under the PFS, and for RHCs/FQHCs (87 FR 72018).

Section 4113(d) of the Consolidated Appropriations Act (CAA), 2023 (Pub. L. 117–328), extended the delay in implementing the in-person visit requirements until January 1, 2025, for both professionals billing for mental health services via Medicare telehealth and for RHCs/FQHCs furnishing remote mental health visits. As previously stated, we believe it is important to maintain consistent requirements for these policies across payment systems; therefore, we proposed to delay the in-person visit requirements for mental health services furnished remotely by hospital staff to beneficiaries in their homes until January 1, 2025. The following is a summary of the comments we received and our responses to those comments.

Comment: All commenters supported our proposal to delay the in-person requirements and the majority of those commenters requested that CMS work with Congress to eliminate the in-person requirements altogether. These commenters stated that the in-person requirements should be eliminated because the requirements are arbitrary and not based upon any clinical guidelines or evidence, they create logistical hurdles for patients and providers, they perpetuate stigma related to receiving mental health care, they are problematic for those in rural communities and those with inconsistent transportation accessibility, remote mental health services were overwhelmingly successful during the PHE when there were no in-person visit requirements, and clinicians, rather than the government, should make the determination of the need for an in-person visit on a patient-by-patient basis.

Response: We thank commenters for their support and appreciate their concerns related to the in-person requirements. As acknowledged by commenters, Congressional legislation would be required to eliminate these requirements.

Comment: One of these commenters requested that in future rulemaking CMS consider changing the in-person visit requirements to allow a broader array of practitioners to fulfill the in-person obligation. Another commenter requested that CMS implement a broad exception to the in-person visit requirements criteria based on clinical discretion, as well as an expansive view of the types of in-person visits that can meet the requirements.

Response: We thank commenters for their suggestions and will take them into consideration for future rulemaking. We note, however, that in the CY 2023 final OPPS rule (87 FR 72017), we finalized an exception to the requirement that there be an in-person service within 12 months of each remotely furnished mental health service. This exception may be exercised when the hospital clinical staff member and beneficiary agree that the risks and burdens of an in-person service outweigh the benefits of it and a clear justification for the exception is documented in the beneficiary's medical record, including the clinician's professional judgement that the patient is clinically stable and/or that an in-person visit has the risk of worsening the person's condition, creating undue hardship on the person or their family, or would otherwise result in disengaging with care that has been effective in managing the person's illness. Hospitals must also document that the patient has a regular source of general medical care and has the ability to obtain any needed point of care testing, including vital sign monitoring and laboratory studies.

After consideration of the public comments we received, we are finalizing, without modification, our proposal to delay the in-person visit requirements for mental health services furnished remotely by hospital staff to beneficiaries in their homes until January 1, 2025.

3. Payment for Outpatient Therapy Services, Diabetes Self-Management Training, and Medical Nutrition Therapy When Furnished by Hospital Staff to Beneficiaries in Their Homes Through Communication Technology

The CAA, 2023 extended most flexibilities for Medicare telehealth services, including retention of physical and occupational therapists and speech-language pathologists as telehealth distant site practitioners, through the end of CY 2024. In the CY 2024 PFS proposed rule, we proposed to continue

to make payment for outpatient therapy (physical therapy (PT), occupational therapy (OT), and speech-language pathology (SLP)) services, Diabetes Self-Management Training (DSMT), and Medical Nutrition Therapy (MNT) when furnished via telehealth by qualified employed staff of institutional providers through the end of CY 2024. We note that the proposal includes outpatient therapy, DSMT, and MNT services furnished via telehealth by staff of hospital outpatient departments. For further discussion, please see the CY 2024 PFS final rule. The following is a summary of the comments we received and our responses to those comments.

Comment: All commenters supported our proposal to make payment for outpatient therapy, DSMT, and MNT when furnished via telehealth by qualified employed staff of institutional providers, including staff of hospital outpatient departments, through the end of 2024. One commenter stated that the extension would provide the flexibility needed to offer these outpatient therapy services to patients, especially those who have difficulty traveling to a hospital and otherwise would not have access to these critical services. Another commenter opined that enabling Medicare beneficiaries to engage with their hospital's dietary/nutrition staff from the comfort of their homes allows more frequent and productive communication that helps ensure patients persevere through the difficult dietary and lifestyle changes necessary to manage endemic chronic conditions associated with obesity and malnutrition alike, diabetes in particular. The commenter further stated that permitting hospitals to bill for these services delivered via telehealth helps ensure their availability, especially in rural communities where the local hospital may be the only available provider. Another commenter stated that it finds the inclusion of these therapists as eligible telehealth provider types to be particularly representative of CMS's stated goals of building in health equity and access measures to its program offerings.

Response: We thank commenters for their support and note that additional comments on the proposal to make payment for PT, OT, SLP, DSMT, and MNT when furnished via telehealth by qualified employed staff of institutional providers, including staff of hospital outpatient departments, through the end of 2024 are discussed in the CY 2024 PFS final rule.

Comment: One commenter requested that CMS provide billing instructions to hospitals about how PT, OT, SLP, DSMT, and MNT therapists are allowed to furnish rehabilitation and that hospitals can receive Part B MPFS payment.

Response: We direct the commenter to the CY 2024 PFS final rule for specific information relating to billing for telehealth services furnished to patients in their homes. We will consider additional sub-regulatory clarifications, as needed, in the future.

We refer readers to the CY 2024 PFS final rule for details relating to the final policy for payment for outpatient therapy (PT, OT, and SLP) services, DSMT, and MNT when furnished via telehealth by qualified employed staff of institutional providers, including staff of hospital outpatient departments, through the end of CY 2024.

E. OPPS Payment for Dental Services

1. Background

Section 1862(a)(12) of the Act generally precludes payment under Medicare Parts A or B for any expenses incurred for services in connection with the care, treatment, filling, removal, or replacement of teeth or structures directly supporting teeth. (Collectively here, we will refer to ''the care, treatment, filling, removal, or replacement of teeth or structures directly supporting teeth'' as ''dental services.'') In the CY 2023 Physician Fee Schedule (PFS) final rule (87 FR 69663), we explained that we believe there are instances where dental services are so integral to other medically necessary services that they are not in connection with the care, treatment, filling, removal, or replacement of teeth or structures directly supporting teeth within the meaning of section 1862(a)(12) of the Act. Rather, such dental services are inextricably linked to the clinical success of an otherwise covered medical service, and therefore, are instead substantially related and integral to that primary medical service. To provide greater clarity to our current policies and respond to issues raised by interested parties, in the CY 2023 PFS final rule, we finalized: (1) a clarification of our interpretation of section 1862(a)(12) of the Act to permit payment for dental services that are inextricably linked to, and substantially related and integral to the clinical success of, other covered medical services (hereafter in this discussion, ''inextricably linked to other covered services''); (2) clarification and codification of certain longstanding Medicare Fee-For-Service (FFS) payment policies for inextricably linked dental services; (3) that, beginning for CY 2023, Medicare Parts A and B payment can be made for certain dental services inextricably linked to Medicare-covered organ transplant, cardiac valve replacement, or valvuloplasty procedures; (4) for CY 2024, that Medicare Part A and B payment can be made for certain dental services inextricably linked to Medicare-covered services for treatment of head and neck cancers; and (5) beginning for CY 2023, the establishment of a process to submit for our consideration and review additional dental services that are inextricably linked to other covered medical services (87 FR 69670 and 69671). The CY 2023 PFS final rule specified that Medicare payment for these dental services may be made regardless of whether the services are furnished in an inpatient or outpatient setting. We directed readers to the CY 2023 PFS final rule (87 FR 69663 through 69688) for a full discussion of these policies as well as to the CY 2024 PFS proposed rule for proposals related to dental services.

In the CY 2023 PFS final rule, CMS identified various examples of HCPCS codes, mostly Current Dental Terminology (CDT®) codes, that could be used to describe the types of dental services identified in the CY 2023 PFS final rule for which Medicare payment can be made when coverage and payment policy requirements are met (87 FR 69667). We refer readers to the PFS Relative Value Files that are released quarterly on the CMS website for a comprehensive list of HCPCS codes, including D-codes, that may be payable under the PFS, available at *https://www.cms.gov/medicare/medicare-fee-for-service-payment/physicianfeesched/pfs-relative-value-files.*

We explained that the policies adopted in the CY 2023 PFS final rule allow payment for certain dental services performed in outpatient settings. However, the current dental codes assigned to APCs for CY 2023 do not fully describe the dental services that may be inextricably linked to covered medical services and payable under Medicare Part B. Specifically, for the OPPS for CY 2023, only 57 CDT codes are assigned to APCs and payable under the OPPS when coverage and payment conditions are met. In addition to the small number of CDT codes assigned to APCs for CY 2023, there is also a limited number of CPT codes that may describe dental services, including CPT code 41899 (Unlisted px dentalvlr strux), that are currently assigned to APCs and payable under the OPPS.

In the CY 2023 OPPS/ASC final rule with comment period, we created HCPCS code G0330 to describe facility

services for dental rehabilitation procedure(s) furnished to patients who require monitored anesthesia (*e.g.,* general, intravenous sedation (monitored anesthesia care)) and use of an operating room. We finalized this code based on extensive public comments expressing the need for a coding and payment mechanism to improve access to covered dental procedures under anesthesia, especially dental rehabilitation procedures, an issue that commenters to the CY 2023 OPPS proposed rule explained is caused by barriers to securing sufficient operating room time to furnish these services. We further noted that HCPCS code G0330 must only be used to describe facility fees for dental rehabilitation services that meet Medicare payment and coverage requirements as interpreted in the CY 2023 PFS final rule. We explained that HCPCS code G0330 cannot be used to describe or bill the facility fee for noncovered dental professional services. We assigned HCPCS code G0330 to APC 5871 (Dental Procedures) for CY 2023. We directed readers to the CY 2023 OPPS/ASC final rule with comment period for a full discussion on HCPCS code G0330 (87 FR 71882 and 71883). For CY 2024, we proposed to continue to assign HCPCS code G0330 to APC 5871 (Dental Procedures).

Comment: We received several comments requesting clarification on the billing of HCPCS code G0330 in light of our proposal to price additional dental codes. Commenters stated that CMS should provide guidance as to whether HCPCS code G0330 should also be reported when one or more of the 229 dental codes are performed in an operating room under anesthesia. A few commenters asked whether G0330 should be billed under the OPPS similarly to how we proposed for the code to be billed when the service is performed in an ASC setting.

Response: We appreciate the opportunity to provide clarification regarding billing of HCPCS code G0330 under the OPPS. Under the OPPS, HCPCS code G0330 is payable without requiring the billing of any other code on the same day, so long as the service performed meets all Medicare coverage and payment requirements. We are clarifying that providers should bill any other more specific CPT and/or CDT codes assigned to APCs that describe the service performed, instead of HCPCS code G0330, whenever possible. HCPCS code G0330 should only be billed when no other, more specific code is available to describe the service performed. For instance, if a dentist performs a prophylactic cleaning (CPT code D1110), several imaging services (*e.g.,* D705–D709), and alveoloplasty with extraction (D7310), each of these codes are assigned to APCs, and, therefore, even if the services meet the description of HCPCS code G0330, hospital outpatient departments should only bill the more specific codes without HCPCS code G0330. We believe that as we continue to price additional codes describing dental services, the situations where it is necessary to bill HCPCS code G0330 will be increasingly limited. However, we believe HCPCS code G0330 is still necessary to fill the need for a billing and payment mechanism for dental rehabilitation services performed under monitored anesthesia in an operating room that meets Medicare coverage and payment requirements, but has not been assigned to an APC. Finally, the clarification regarding billing of HCPCS code G0330 provided here only applies to billing and payment under the OPPS. For information regarding the billing and payment for HCPCS code G0330 in the ASC setting, we refer readers to our discussion on this issue in section XIII.D of this final rule with comment period.

Comment: We received several comments expressing concern over the impact of the proposed payment rate for HCPCS code G0330 for CY 2024. One commenter requested that we recalculate the payment rate for the APC. Another commenter stated that because the proposed G0330 payment rate for HCPCS code G0330 is 45 percent lower than the CY 2023 payment rate, and even lower for the ASC payment, the payment rate may be insufficient in light of specialized dental equipment and personnel required to furnish these services in hospital outpatient departments and ASCs. Another commenter stated that the inadequacy of the proposed payment rates for HCPCS code G0330 for both hospital and ASC settings is likely to stymie use of the code. Several commenters urged CMS to not finalize our proposal to continue to assign HCPCS code G0330 to APC 5871 due to concerns over the APC's payment rate. Some commenters requested that CMS finalize an APC reassignment for HCPCS code G0330 from APC 5871 to APC 5164 (Level 4 ENT Procedures) with a proposed payment rate of $3,087.88 for CY 2024. One commenter stated that reassignment to APC 5164 would be consistent with available cost and charge data for dental procedures likely to be reported using HCPCS code G0330. To support their request for reassignment to APC 5164, commenters stated that prior to CMS's establishment of HCPCS code G0330, these same dental rehabilitation procedures were reported using unlisted CPT code 41899, with a geometric mean cost of approximately $2,200, which is within the range of costs for procedures classified into APC 5164. Another commenter stated that CMS's proposal to allow for multiple procedure discounting for HCPCS code G0330 by proposing to assign status indicator ''T'' to the code would further lower the payment rate for services described by the code.

Response: We thank the commenters for their input. First, we note that APC geometric mean costs can change from year to year as a result of data updates and policy changes. In this case, we proposed to assign 229 dental procedures to APCs, with many proposed for assignment to APC 5871, the same APC to which HCPCS code G0330 was proposed to be assigned. Additionally, we proposed to change the APC assignments of some codes that were previously paid under the OPPS based on clinical similarity, including codes describing dental imaging services. We also note, APC 5871 is an APC with a low volume of claims and, therefore, is more prone to volatility in its geometric mean cost and payment rate changes from year to year based on the claims data available for ratesetting. The proposed coding changes, as well as the fact that APC 5871 has a low volume of claims, resulted in an unintentional reduction to APC 5871's geometric mean cost and payment rate for CY 2024. As we explained in our proposal for CY 2024, we encountered various challenges in securing accurate cost information for the hospital outpatient setting for the dental codes we proposed to assign to APC payment rates. We believe that as utilization increases and we receive claims data on the codes that we proposed to assign to various APCs for CY 2024, we will make changes to APC assignments and APC groups, including considering creating additional APC levels and new clinical APCs in future rulemaking, based on clinical and resource needs.

We reiterate that the proposed payment rate for the services assigned to the Dental Procedures APC was the result of our ratesetting process, which we apply consistently to set the payment rates for other clinical APCs. With that said, we are sympathetic to commenters' concerns regarding the reduction in the proposed payment rate for HCPCS code G0330 from CY 2023 to CY 2024, especially without having claims data for the code that would indicate that the proposed payment rate

is appropriate. Based on comments received stating that CPT code 41899 was used to describe the services currently described by HCPCS code G0330 prior to the code's effective date of January 1, 2023, we analyzed the available claims data for surgical claims for CPT code 41899 in CY 2021 to get a benchmark for the geometric mean costs of services that are described by HCPCS code G0330. While CPT code 41899 is an unlisted code describing unlisted procedures on the dentoalveolar structures that may or may not be surgical in nature and performed under the same conditions as described by HCPCS code G0330, we ran a study to isolate the claims performed with monitored anesthesia codes to more closely mimic the conditions required for services billed under HCPCS code G0330. Based on this analysis, we believe that the proposed APC assignment for HCPCS code G0330 for CY 2024 would be inappropriate in terms of estimated resource costs. Therefore, for CY 2024, we are not finalizing the APC assignment of HCPCS code G0330 to APC 5871 as proposed.

Although we believe isolating the surgical claims gives us a better idea of the geometric mean costs of HCPCS code G0330, we also believe that the approximation using surgical services billed with CPT code 41899 will not be as accurate as the claims information we will receive for HCPCS code G0330 in future years. We also note the crosswalk to CPT code 41899 is not a perfect comparator given that it is an unlisted code, which, per our billing instructions, should only be used when there is no other more specific code available. Therefore, we will determine whether the APC assignment we are finalizing for HCPCS code G0330 is appropriate based on claims data received in future years and consider further APC assignment changes in future rulemaking. However, based on the comments received, the fact that we do not have existing claims data for HCPCS code G0330 at this time, and our analysis of surgical claims using CPT code 41899, which demonstrate that the geometric mean costs for surgical claims for CPT code 41899 are notably higher than the proposed payment rate for procedures assigned to APC 5871 for CY 2024, we believe reassigning HCPCS code G0330 from APC 5871 to APC 5164 is appropriate for CY 2024.

After consideration of the public comments we received, we are finalizing an APC reassignment for HCPCS code G0330 from APC 5871 to APC 5164 with status indicator ''J1'' for CY 2024. We refer readers to Addendum B to this final rule with comment period rule for the final CY 2024 APC assignment and associated payment rate for HCPCS code G0330. Addendum B is available via the internet on the CMS website. We also refer readers to Addendum D1 for a definition of status indicators including ''J1.''

2. OPPS Payment for Additional Dental Codes Beginning in CY 2024

To ensure that dental services can be paid under the OPPS when consistent with the policies and clarifications included in the CY 2023 PFS final rule, we proposed to assign additional dental codes to APCs for CY 2024. Specifically, for CY 2024, we proposed to assign 229 additional dental codes to clinical APCs to enable them to be paid for under the OPPS when payment and coverage requirements are met. We explained that assigning additional dental codes to clinical APCs would result in greater consistency in Medicare payment for different sites of service and help ensure patient access to dental services for which payment can be made when performed in the hospital outpatient setting.

Prior to detailing our proposals, we noted two things for readers' awareness. First, OPPS payment will only be made for a dental code that we proposed to assign to an APC for CY 2024 if it is among the types of dental services for which payment can be made as described in the regulation at § 411.15(i)(3)(i). As we have consistently stated in past rules (87 FR 71879) and quarterly change requests to assign new codes to APCs (see, *e.g.,* Pub 100–04 Medicare Claims Processing, Transmittal 11937), the fact that a drug, device, procedure or service is assigned a HCPCS code and a payment rate under the OPPS does not imply coverage by the Medicare program, but indicates only how the product, procedure, or service may be paid if covered by the program. Medicare Administrative Contractors (MACs) determine whether a drug, device, procedure, or other service meets all program requirements and conditions for coverage and payment. Accordingly, we emphasize that HOPDs would only receive payment for a dental service assigned to an APC when the appropriate MAC determines that the service meets the relevant conditions for coverage and payment.

Second, we anticipate that we would continue to assess our policies for OPPS payment for dental services in future rulemaking. We believe that as we collect claims data, gather input from the public and interested parties, and learn more about the services performed in the HOPD setting, we will be able to make more informed decisions regarding payment rates, APC assignments, and status indicators for dental services.

The dental services for which we proposed APC assignments in the CY 2024 OPPS/ASC proposed rule are those dental services described in the CY 2023 PFS final rule for which Medicare Part B payment can be made when they are inextricably linked to other covered services. Based on the dental services identified in that final rule, we generated a list of codes that describe those services for which we believed we needed to propose APC assignments to ensure payment is available under the OPPS. To generate this list, we reviewed the dental codes that were specifically listed as examples of payable dental services in the CY 2023 PFS final rule (87 FR 69676). We also reviewed the clinical vignettes provided in the CY 2023 PFS final rule to identify whether there are other dental codes in addition to the dental code examples already identified for which we should propose APC assignments.

The CY 2023 PFS final rule amended § 411.15(i)(3)(i) to allow for payment under Medicare Part A and Part B for dental services, furnished in an inpatient or outpatient setting, that are inextricably linked to, and substantially related and integral to the success of, certain other covered medical services, including, but not limited to: (1) dental or oral examination as part of a comprehensive workup prior to a Medicare covered organ transplant, cardiac valve replacement, or valvuloplasty procedures; and the necessary diagnostic and treatment services to eliminate an oral or dental infection prior to, or contemporaneously with, the organ transplant, cardiac valve replacement, or valvuloplasty procedure; (2) reconstruction of a dental ridge performed as a result of, and at the same time as, the surgical removal of a tumor; (3) the stabilization or immobilization of teeth in connection with the reduction of a jaw fracture, and dental splints only when used in conjunction with covered treatment of a covered medical condition such as dislocated jaw joints; and (4) the extraction of teeth to prepare the jaw for radiation treatment of neoplastic disease. For CY 2024, we established that Medicare Parts A and B payment may also be made for dental services, such as dental examinations, including necessary treatments, performed as part of a comprehensive workup prior to treatment for head and neck cancers. We included a proposal in the CY 2024 PFS proposed rule to codify this example

under § 411.15(i)(3)(i). We identified dental services described in the regulation at § 411.15(i)(3)(i) and those that may be part of a comprehensive workup prior to treatment for head and neck cancers that could be payable under the OPPS if payment and coverage requirements are met. For example, consistent with § 411.15(i)(3)(i)(A), which describes dental or oral examinations as part of a comprehensive workup prior to a Medicare covered organ transplant, cardiac valve replacement, or valvuloplasty procedure, we identified several codes describing dental examinations for which we proposed APC assignments (*e.g.,* D0120, D0140, D0150, D0160, D0170, D0180, D0191, D0171). Section 411.15(i)(3)(i)(C) describes services for the stabilization or immobilization of the teeth in connection with the reduction of a jaw fracture, and dental splints only when used with a covered treatment of a covered medical condition. We identified an additional 16 dental codes (*e.g.,* D7670–D7671; D4322; D5988) that we believe identify these services and for which we proposed APC assignments.

While it is appropriate for CMS to assign certain dental codes to APCs for payment under the OPPS, we explained that we do not believe that every dental code should be assigned to an APC and made payable under the OPPS. For instance, there are services described by CDT codes that may already be described by existing CPT codes assigned to clinical APCs. When this is the case, we proposed that HOPDs would use the existing CPT codes to bill for the services performed. We also did not propose APC assignments for all dental codes, even if they describe dental services that are payable consistent with the policies and clarifications included in the CY 2023 PFS final rule. This is because under our regulation at 42 CFR 419.22, the following services are not paid under the OPPS (except when packaged as part of a bundled payment): physician services that meet the requirements of 42 CFR 415.102(a); nurse practitioner or clinical nurse specialist services, as defined in section 1861(s)(2)(K)(ii) of the Act; physician assistant services, as defined in section 1861(s)(2)(K)(i) of the Act; and services of an anesthetist as defined in § 410.9. We note that dentists are considered physicians for purposes of Medicare payment policy, including this regulation. There are a number of existing CDT codes that describe the professional services of dentists that could be paid under the PFS (*e.g.,* D9990–D9997), but that we do not believe are appropriate for payment under the OPPS. Therefore, we did not propose to assign CDT codes that describe professional services of dentists and other dental professionals to clinical APCs.

Finally, there are dental codes that we believe would not meet our current interpretation of dental services that may be inextricably linked to other covered medical services. For instance, there are CDT codes that describe removable prosthodontic procedures, including codes that describe complete or partial denture procedures (*e.g.,* D5110; D5120; D5211–D5214). Because denture procedures are not covered medical procedures under Medicare, we did not propose to assign any dental codes describing denture procedures to clinical APCs.

In sum, in consultation with medical experts, we identified 229 dental codes as appropriate for payment under the OPPS when relevant conditions for payment and coverage are met. In addition to the dental codes already assigned to APCs, we proposed to assign the 229 additional dental codes listed in Table 110 below to various clinical APCs for CY 2024:

BILLING CODE 4150–28–P

TABLE 110: DENTAL CODES PROPOSED FOR ASSIGNMENT TO CLINICAL APCS IN CY 2024

HCPCS Code	Description
D0120	Periodic oral evaluation
D0140	Limit oral eval problem focus
D0160	Extensv oral eval prob focus
D0170	Re-eval,est pt,problem focus
D0180	Comp periodontal evaluation
D0191	Assessment of a patient
D0171	Re-eval post-op visit
D1110	Dental prophylaxis adult
D7950	Mandible graft
D7340	Vestibuloplasty ridge extens
D7350	Vestibuloplasty exten graft
D7485	Surg reduct osseoustuberosit
D7310	Alveoplasty w/ extraction
D7311	Alveoloplasty w/extract 1-3
D7510	I&d absc intraoral soft tiss
D7473	Remove torus mandibularis
D7472	Removal of torus palatinus
D7520	I&d abscess extraoral
D7521	Incision/drain abscess extra
D7511	Incision/drain abscess intra
D7550	Removal of sloughed off bone
D7460	Rem nonodonto cyst to 1.25cm
D7461	Rem nonodonto cyst > 1.25 cm
D7272	Tooth transplantation
D7270	Tooth reimplantation
D7670	Closd rductn splint alveolus
D7671	Alveolus open reduction
D7770	Open reduc compd alveolus fx
D7771	Alveolus clsd reduc stblz te
D7874	Tmj arthroscopy disc reposit
D7922	Place intra-socket bio dress
D4323	Splint extra-coronal
D4322	Splint intra-coronal
D5988	Surgical splint
D2140	Amalgam one surface permanen
D2150	Amalgam two surfaces permane
D2160	Amalgam three surfaces perma
D2161	Amalgam 4 or > surfaces perm
D2330	Resin one surface-anterior
D2331	Resin two surfaces-anterior
D2332	Resin three surfaces-anterio

HCPCS Code	Description
D2335	Resin 4/> surf or w incis an
D2390	Ant resin-based cmpst crown
D2391	Post 1 srfc resinbased cmpst
D2392	Post 2 srfc resinbased cmpst
D2393	Post 3 srfc resinbased cmpst
D2394	Post >=4srfc resinbase cmpst
D2410	Dental gold foil one surface
D2420	Dental gold foil two surface
D2430	Dental gold foil three surfa
D2510	Dental inlay metalic 1 surf
D2520	Dental inlay metallic 2 surf
D2530	Dental inlay metl 3/more sur
D2542	Dental onlay metallic 2 surf
D2543	Dental onlay metallic 3 surf
D2544	Dental onlay metl 4/more sur
D2610	Inlay porcelain/ceramic 1 su
D2620	Inlay porcelain/ceramic 2 su
D2630	Dental onlay porc 3/more sur
D2642	Dental onlay porcelin 2 surf
D2643	Dental onlay porcelin 3 surf
D2644	Dental onlay porc 4/more sur
D2650	Inlay composite/resin one su
D2651	Inlay composite/resin two su
D2652	Dental inlay resin 3/mre sur
D2662	Dental onlay resin 2 surface
D2663	Dental onlay resin 3 surface
D2664	Dental onlay resin 4/mre sur
D2710	Crown resin-based indirect
D2712	Crown 3/4 resin-based compos
D2720	Crown resin w/ high noble me
D2721	Crown resin w/ base metal
D2722	Crown resin w/ noble metal
D2740	Crown porcelain/ceramic
D2750	Crown porcelain w/ h noble m
D2751	Crown porcelain fused base m
D2752	Crown porcelain w/ noble met
D2753	Crown porc fused to titanium
D2780	Crown 3/4 cast hi noble met
D2781	Crown 3/4 cast base metal
D2782	Crown 3/4 cast noble metal
D2783	Crown 3/4 porcelain/ceramic
D2790	Crown full cast high noble m
D2791	Crown full cast base metal
D2792	Crown full cast noble metal

HCPCS Code	Description
D2794	Crown-titanium
D2799	Interim crown
D2990	Resin infiltration of lesion
D2910	Recement inlay onlay or part
D2915	Recement cast or prefab post
D2920	Re-cement or re-bond crown
D2921	Reattach tooth fragment
D2929	Prefab porc/ceram crown pri
D2928	Prefab porc/cer crown perm
D2930	Prefab stnlss steel crwn pri
D2931	Prefab stnlss steel crown pe
D2932	Prefabricated resin crown
D2933	Prefab stainless steel crown
D2934	Prefab steel crown primary
D2940	Protective restoration
D2941	Int therapeutic restoration
D2949	Restorative foundation
D2950	Core build-up incl any pins
D2951	Tooth pin retention
D2952	Post and core cast + crown
D2953	Each addtnl cast post
D2954	Prefab post/core + crown
D2957	Each addtnl prefab post
D2955	Post removal
D2960	Labial veneer resin direct
D2961	Labial veneer resin indirect
D2962	Labial veneer porc indirect
D2971	Add proc construct new crown
D2975	Coping
D2980	Crown repair
D2981	Inlay repair
D2982	Onlay repair
D2983	Veneer repair
D1354	Int caries med app per tooth
D4210	Gingivectomy/plasty 4 or mor
D4211	Gingivectomy/plasty 1 to 3
D4212	Gingivectomy/plasty rest
D4230	Ana crown exp 4 or> per quad
D4231	Ana crown exp 1-3 per quad
D4240	Gingival flap proc w/ planin
D4241	Gngvl flap w rootplan 1-3 th
D4245	Apically positioned flap
D4249	Crown lengthen hard tissue
D4261	Osseous surg 1 to 3 teeth

HCPCS Code	Description
D4265	Bio mtrls to aid soft/os reg
D4266	Guided tiss regen resorble
D4267	Guided tiss regen nonresorb
D4274	Mesial/distal wedge proc
D4275	Non-auto graft 1st tooth
D4276	Con tissue w pedicle graft
D4277	Soft tissue graft firsttooth
D4278	Soft tissue graft addl tooth
D4283	Auto tissue graft addl tooth
D4285	Non-auto graft addl tooth
D4341	Periodontal scaling & root
D4342	Periodontal scaling 1-3teeth
D4346	Scaling gingiv inflammation
D4355	Full mouth debridement
D4381	Localized delivery antimicro
D4910	Periodontal maint procedures
D4920	Unscheduled dressing change
D4921	Gingival irrigation per quad
D4999	Unspecified periodontal proc
D3110	Pulp cap direct
D3120	Pulp cap indirect
D3220	Therapeutic pulpotomy
D3221	Gross pulpal debridement
D3222	Part pulp for apexogenesis
D3230	Pulpal therapy anterior prim
D3240	Pulpal therapy posterior pri
D3310	End thxpy, anterior tooth
D3320	End thxpy, premolar tooth
D3330	End thxpy, molar tooth
D3331	Non-surg tx root canal obs
D3332	Incomplete endodontic tx
D3333	Internal root repair
D3346	Retreat root canal anterior
D3347	Retreat root canal premolar
D3348	Retreat root canal molar
D3351	Apexification/recalc initial
D3352	Apexification/recalc interim
D3353	Apexification/recalc final
D3355	Pulpal regeneration initial
D3356	Pulpal regeneration interim
D3357	Pulpal regeneration complete
D3410	Apicoectomy – anterior
D3421	Root surgery premolar
D3425	Root surgery molar

HCPCS Code	Description
D3426	Root surgery ea add root
D3428	Bone graft peri per tooth
D3429	Bone graft peri each addl
D3430	Retrograde filling
D3431	Biological materials
D3432	Guided tissue regeneration
D3450	Root amputation
D3470	Intentional replantation
D3471	Surg rep root res anterior
D3472	Surg rep root res premolar
D3473	Surg rep root res molar
D3501	Surg exp root surf anterior
D3502	Surg exp root surf premolar
D3503	Surg exp root surf molar
D3910	Isolation- tooth w rubb dam
D3911	Intraorifice barrier
D3920	Tooth splitting
D3921	Decor or submerg erupt tooth
D3950	Canal prep/fitting of dowel
D0210	Intraor comprehensive series
D0220	Intraoral periapical first
D0230	Intraoral periapical ea add
D0273	Bitewings - three images
D0310	Dental saliography
D0320	Dental tmj arthrogram incl i
D0321	Other tmj images by report
D0322	Dental tomographic survey
D0330	Panoramic image
D0340	2d cephalometric image
D0350	Oral/facial photo images
D0364	Cone beam ct capt & interp
D0365	Cone beam ct interprete man
D0366	Cone beam ct interprete max
D0367	Cone beam ct interp both jaw
D0368	Cone beam ct interprete tmj
D0369	Max mri capture & interprete
D0370	Max ultrasound capt & interp
D0371	Sialoendoscopy capt & interp
D0380	Cone beam ct capture limited
D0381	Cone beam ct capt mandible
D0382	Cone beam ct capt maxilla
D0383	Cone beam ct both jaws
D0384	Cone beam ct capture tmj
D0385	Max mri image capture

HCPCS Code	Description
D0386	Max ultrasound image capture
D0701	Pano radio image
D0702	2d cephal radio image
D0703	2d oral/facial photo image
D0705	Extra oral post radio image
D0706	Intraoral occlus radio image
D0707	Intraoral periap radio image
D0708	Intraoral bite radio image
D0709	Intraoral comp image capture
D0393	Trtmnt simulation 3d image
D0394	Digital sub 2 or more images
D0395	Fusion 2 or more 3d images

We requested comments on the list of 229 dental codes that we proposed to assign to APCs for OPPS payment for CY 2024. We also requested comments on any additional dental codes that may fall within the scope of dental services for which payment is permitted as explained in the CY 2023 PFS final rule and provided in § 411.14(i)(3)(i), and for which payment should be made available under the OPPS when payment and coverage requirements are met.

Comment: Commenters supported our proposal to assign 229 dental codes to various APCs and considered it a positive step towards increased access to dental services for Medicare beneficiaries. Commenters requested that CMS continue to expand Medicare coverage of dental services. Many commenters expressed support for the dental proposals regarding Medicare payment for dental services in the CY 2024 PFS proposed rule. Other commenters suggested additional covered medical services for which they believe Medicare should pay for dental care.

Response: We appreciate the support from commenters but want to make a few clarifications on the policy proposal. First, we are clarifying that our proposal to assign additional dental codes to APCs is not a coverage determination. Billed services will only be paid under the OPPS when the applicable payment and coverage requirements are met. That said, we appreciate commenters' support for our proposal to assign additional dental codes to APCs, to enable payment when Medicare coverage and payment requirements are met. The comments received on the payment proposals in the CY 2024 PFS proposed rule are outside of the scope of this final rule with comment period. We direct readers to the discussion of dental services in the CY 2024 PFS proposed and final rules (88 FR 52371 through 52384) for more information on Medicare payment for dental services.

Comment: We received one comment requesting CMS assign an additional 18 CDT codes to APCs for CY 2024. The commenter explained that it would be appropriate to assign the 18 additional codes to APCs because they may be necessary to treat oral or dental infections for patients with certain acute conditions.

Response: We thank the commenter for their suggestion. We reviewed the list of codes recommended and believe some of the codes commenters suggested identify services that would be payable consistent with the dental payment policies specified in the CY 2023 PFS final rule, provided conditions for payment and coverage are met. Specifically, we believe some of the codes recommended for APC assignment describe dental services that may be considered medically necessary diagnostic and treatment services immediately necessary to eliminate or eradicate an oral or dental infection prior to, or contemporaneously with, certain Medicare-covered medical services specified in the CY 2023 PFS final rule, including organ transplant, cardiac valve replacement, or valvuloplasty procedures (42 CFR 411.15). The recommended codes that we believe are consistent with the dental payment policies specified in the CY 2023 PFS final rule are the following: CDT codes D7251 (Coronectomy), D7280 (Exposure of unerupted tooth), D7410 (Rad exc lesion up to 1.25 cm), D7411 (Excision benign lesion>1.25c), D7412 (Excision benign lesion compl), D7413 (Excision malig lesion≤1.25c), D7414 (Excision malig lesion>1.25cm), D7415 (Excision malig les complicat), D7440 (Malig tumor exc to 1.25 cm), D7441 (Malig tumor >1.25 cm), D7450 (Rem odontogen cyst to 1.25cm), D7451 (Rem odontogen cyst >1.25 cm), D7530 (Removal fb skin/areolar tiss), and D7540 (Removal of fb reaction). We note that Medicare would only pay for these services when all payment and coverage requirements are met but we are finalizing APC assignments for these codes to make payment available in circumstances when those requirements are met. We would need additional information on how certain codes the commenter recommended for APC assignment, including CDT codes D7471 (Rem exostosis any site), D7283 (Place device impacted tooth), D7320 (Alveoplasty w/o extraction), and D7321 (Alveoloplasty not w/extracts), are consistent with the dental payment policies provided in the CY 2023 PFS final rule, and will revisit the issue in future rulemaking. We refer readers to Addendum B to this final rule with comment period for the finalized CY 2024 APC assignments and associated payment rates for the dental codes. Addendum B is available via the internet on the CMS website.

Comment: Some commentors requested additional information regarding how CMS arrived at its dental proposal. One commenter stated that CMS did not specify the criteria used to determine which dental procedures to assign to APCs.

Response: We thank the commenters for their feedback but disagree that we did not specify how we determined which dental procedures to assign to APCs for CY 2024. The dental services we proposed to assign to APCs in the CY 2024 OPPS/ASC proposed rule are those dental services described in the CY 2023 PFS final rule for which Medicare Part B payment can be made when they are inextricably linked to

other covered services. As we stated in our proposal, we generated a list of codes to assign to APCs based on the specific dental services and clinical vignettes provided in the CY 2023 PFS final rule. This list was reviewed by our medical experts to ensure that the codes identified would be appropriate for payment under the OPPS when relevant conditions for payment and coverage are met.

After consideration of the public comments we received, we are finalizing our initial list of proposed dental codes for assignment to clinical APCs as well as assigning additional dental codes to APCs for CY 2024. Specifically, we are assigning the following CDT codes to APCs for CY 2024: D7251, D7280, D7410, D7411, D7412, D7413, D7414, D7415, D7440, D7441, D7450, D7451, D7530, and D7540. Table 111 contains the list of dental codes assigned to a clinical APC for CY 2024. We note that the assignment of these codes to APCs is not a determination of Medicare coverage or payment. We refer readers to Addendum B to this final rule with comment period for the finalized CY 2024 APC assignments and associated payment rates for the dental codes. Addendum B is available via the internet on the CMS website.

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TABLE 111: DENTAL CODES FINALIZED FOR ASSIGNMENT TO CLINICAL APCS IN CY 2024

HCPCS Code	Description
D0120	Periodic oral evaluation
D0140	Limit oral eval 1ubmerg focus
D0160	Extensv oral eval prob focus
D0170	Re-eval,est pt,problem focus
D0180	Comp periodontal evaluation
D0191	Assessment of a patient
D0171	Re-eval post-op visit
D1110	Dental prophylaxis adult
D7950	Mandible graft
D7340	Vestibuloplasty ridge extens
D7350	Vestibuloplasty exten graft
D7485	Surg reduct osseoustuberosit
D7310	Alveoplasty w/ extraction
D7311	Alveoloplasty w/extract 1-3
D7510	I&d absc intraoral soft tiss
D7473	Remove torus mandibularis
D7472	Removal of torus palatinus
D7520	I&d abscess extraoral
D7521	Incision/drain abscess extra
D7511	Incision/drain abscess intra
D7550	Removal of sloughed off bone
D7460	Rem nonodonto cyst to 1.25cm
D7461	Rem nonodonto cyst > 1.25 cm
D7272	Tooth transplantation
D7270	Tooth reimplantation
D7670	Closd rductn splint alveolus
D7671	Alveolus open reduction
D7770	Open reduc compd alveolus fx
D7771	Alveolus clsd reduc stblz te
D7874	Tmj arthroscopy disc reposit
D7922	Place intra-socket bio dress
D4323	Splint extra-coronal
D4322	Splint intra-coronal
D5988	Surgical splint
D2140	Amalgam one surface permanen
D2150	Amalgam two surfaces permane
D2160	Amalgam three surfaces perma
D2161	Amalgam 4 or > surfaces perm
D2330	Resin one surface-anterior
D2331	Resin two surfaces-anterior
D2332	Resin three surfaces-anterio

HCPCS Code	Description
D2335	Resin 4/> surf or w incis an
D2390	Ant resin-based cmpst crown
D2391	Post 1 srfc resinbased cmpst
D2392	Post 2 srfc resinbased cmpst
D2393	Post 3 srfc resinbased cmpst
D2394	Post >=4srfc resinbase cmpst
D2410	Dental gold foil one surface
D2420	Dental gold foil two surface
D2430	Dental gold foil three surfa
D2510	Dental inlay metalic 1 surf
D2520	Dental inlay metallic 2 surf
D2530	Dental inlay metl 3/more sur
D2542	Dental onlay metallic 2 surf
D2543	Dental onlay metallic 3 surf
D2544	Dental onlay metl 4/more sur
D2610	Inlay porcelain/ceramic 1 su
D2620	Inlay porcelain/ceramic 2 su
D2630	Dental onlay porc 3/more sur
D2642	Dental onlay porcelin 2 surf
D2643	Dental onlay porcelin 3 surf
D2644	Dental onlay porc 4/more sur
D2650	Inlay composite/resin one su
D2651	Inlay composite/resin two su
D2652	Dental inlay resin 3/mre sur
D2662	Dental onlay resin 2 surface
D2663	Dental onlay resin 3 surface
D2664	Dental onlay resin 4/mre sur
D2710	Crown resin-based indirect
D2712	Crown 3/4 resin-based compos
D2720	Crown resin w/ high noble me
D2721	Crown resin w/ base metal
D2722	Crown resin w/ noble metal
D2740	Crown porcelain/ceramic
D2750	Crown porcelain w/ h noble m
D2751	Crown porcelain fused base m
D2752	Crown porcelain w/ noble met
D2753	Crown porc fused to titanium
D2780	Crown 3/4 cast hi noble met
D2781	Crown 3/4 cast base metal
D2782	Crown 3/4 cast noble metal
D2783	Crown 3/4 porcelain/ceramic
D2790	Crown full cast high noble m
D2791	Crown full cast base metal
D2792	Crown full cast noble metal

HCPCS Code	Description
D2794	Crown-titanium
D2799	Interim crown
D2990	Resin infiltration of lesion
D2910	Recement inlay onlay or part
D2915	Recement cast or prefab post
D2920	Re-cement or re-bond crown
D2921	Reattach tooth fragment
D2929	Prefab porc/ceram crown pri
D2928	Prefab porc/cer crown perm
D2930	Prefab stnlss steel crwn pri
D2931	Prefab stnlss steel crown pe
D2932	Prefabricated resin crown
D2933	Prefab stainless steel crown
D2934	Prefab steel crown primary
D2940	Protective restoration
D2941	Int therapeutic restoration
D2949	Restorative foundation
D2950	Core build-up incl any pins
D2951	Tooth pin retention
D2952	Post and core cast + crown
D2953	Each addtnl cast post
D2954	Prefab post/core + crown
D2957	Each addtnl prefab post
D2955	Post removal
D2960	Labial veneer resin direct
D2961	Labial veneer resin indirect
D2962	Labial veneer porc indirect
D2971	Add proc construct new crown
D2975	Coping
D2980	Crown repair
D2981	Inlay repair
D2982	Onlay repair
D2983	Veneer repair
D1354	Int caries med app per tooth
D4210	Gingivectomy/plasty 4 or mor
D4211	Gingivectomy/plasty 1 to 3
D4212	Gingivectomy/plasty rest
D4230	Ana crown exp 4 or> per quad
D4231	Ana crown exp 1-3 per quad
D4240	Gingival flap proc w/ planin
D4241	Gngvl flap w rootplan 1-3 th
D4245	Apically positioned flap
D4249	Crown lengthen hard tissue
D4261	Osseous surg 1 to 3 teeth

HCPCS Code	Description
D4265	Bio mtrls to aid soft/os reg
D4266	Guided tiss regen resorble
D4267	Guided tiss regen nonresorb
D4274	Mesial/distal wedge proc
D4275	Non-auto graft 1st tooth
D4276	Con tissue w pedicle graft
D4277	Soft tissue graft firsttooth
D4278	Soft tissue graft addl tooth
D4283	Auto tissue graft addl tooth
D4285	Non-auto graft addl tooth
D4341	Periodontal scaling & root
D4342	Periodontal scaling 1-3teeth
D4346	Scaling gingiv inflammation
D4355	Full mouth debridement
D4381	Localized delivery antimicro
D4910	Periodontal maint procedures
D4920	Unscheduled dressing change
D4921	Gingival irrigation per quad
D4999	Unspecified periodontal proc
D3110	Pulp cap direct
D3120	Pulp cap indirect
D3220	Therapeutic pulpotomy
D3221	Gross pulpal debridement
D3222	Part pulp for apexogenesis
D3230	Pulpal therapy anterior prim
D3240	Pulpal therapy posterior pri
D3310	End thxpy, anterior tooth
D3320	End thxpy, premolar tooth
D3330	End thxpy, molar tooth
D3331	Non-surg tx root canal obs
D3332	Incomplete endodontic tx
D3333	Internal root repair
D3346	Retreat root canal anterior
D3347	Retreat root canal premolar
D3348	Retreat root canal molar
D3351	Apexification/recalc initial
D3352	Apexification/recalc interim
D3353	Apexification/recalc final
D3355	Pulpal regeneration initial
D3356	Pulpal regeneration interim
D3357	Pulpal regeneration complete
D3410	Apicoectomy – anterior
D3421	Root surgery premolar
D3425	Root surgery molar

HCPCS Code	Description
D3426	Root surgery ea add root
D3428	Bone graft peri per tooth
D3429	Bone graft peri each addl
D3430	Retrograde filling
D3431	Biological materials
D3432	Guided tissue regeneration
D3450	Root amputation
D3470	Intentional replantation
D3471	Surg rep root res anterior
D3472	Surg rep root res premolar
D3473	Surg rep root res molar
D3501	Surg exp root surf anterior
D3502	Surg exp root surf premolar
D3503	Surg exp root surf molar
D3910	Isolation- tooth w rubb dam
D3911	Intraorifice barrier
D3920	Tooth splitting
D3921	Decor or submerg erupt tooth
D3950	Canal prep/fitting of dowel
D0210	Intraor comprehensive series
D0220	Intraoral periapical first
D0230	Intraoral periapical ea add
D0273	Bitewings - three images
D0310	Dental saliography
D0320	Dental tmj arthrogram incl i
D0321	Other tmj images by report
D0322	Dental tomographic survey
D0330	Panoramic image
D0340	2d cephalometric image
D0350	Oral/facial photo images
D0364	Cone beam ct capt & interp
D0365	Cone beam ct interprete man
D0366	Cone beam ct interprete max
D0367	Cone beam ct interp both jaw
D0368	Cone beam ct interprete tmj
D0369	Max mri capture & interprete
D0370	Max ultrasound capt & interp
D0371	Sialoendoscopy capt & interp
D0380	Cone beam ct capture limited
D0381	Cone beam ct capt mandible
D0382	Cone beam ct capt maxilla
D0383	Cone beam ct both jaws
D0384	Cone beam ct capture tmj
D0385	Max mri image capture

HCPCS Code	Description
D0386	Max ultrasound image capture
D0701	Pano radio image
D0702	2d cephal radio image
D0703	2d oral/facial photo image
D0705	Extra oral post radio image
D0706	Intraoral occlus radio image
D0707	Intraoral periap radio image
D0708	Intraoral bite radio image
D0709	Intraoral comp image capture
D0393	Trtmnt simulation 3d image
D0394	Digital sub 2 or more images
D0395	Fusion 2 or more 3d images
D7251	Coronectomy
D7280	Exposure of unerupted tooth
D7410	Rad exc lesion up to 1.25 cm
D7411	Excision benign lesion>1.25c
D7412	Excision benign lesion compl
D7413	Excision malig lesion<=1.25c
D7414	Excision malig lesion>1.25cm
D7415	Excision malig les complicat
D7440	Malig tumor exc to 1.25 cm
D7441	Malig tumor > 1.25 cm
D7450	Rem odontogen cyst to 1.25cm
D7451	Rem odontogen cyst > 1.25 cm
D7530	Removal fb skin/areolar tiss
D7540	Removal of fb reaction

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3. APC Assignments for Additional Dental Codes

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. Accordingly, when considering the appropriateness of an APC assignment for a code, we consider the clinical characteristics and resource costs of the service described by the code compared to other services in a clinical APC.

Consistent with our existing processes, we were able to crosswalk many of the dental codes to existing CPT codes assigned to APCs for purposes of assessing clinical similarity. For instance, we crosswalked certain tissue graft procedures (*e.g.,* D4270) to CPT code 41870 (gum graft). Because both are surgical procedures where gum tissue near the area of recession is used to cover and protect the exposed tooth root, the codes are clinically similar and we believe are appropriate for grouping within the same clinical APC (that is, APC 5163 (Level 3 ENT Procedures)). We also found clinical similarities between several dental imaging services and the services assigned to the various levels of the Imaging without Contrast APC series (that is, APCs 5521 (Level 1, Imaging without Contrast); 5522 (Level 2, Imaging without Contrast); and 5523 (Level 3, Imaging without Contrast)). For example, we crosswalked D0210 (Intraor complete film series) to CPT code 70320 (Full mouth x-ray of teeth) and therefore proposed to assign D0210 to APC 5523 based on the crosswalk analysis.

With regard to resource similarity, because the 229 dental codes we proposed to assign to APCs for CY 2024 were not previously paid under the OPPS, we do not have existing claims information to inform proposed APC placements based on resource costs. We considered gathering cost information from several non-Medicare data sources to aid in assigning the dental codes to APCs. For instance, we considered requesting cost information from the Department of Veterans Affairs (VA). However, the VA's dental reimbursement rates are proprietary and are not publicly available.

We also considered requesting data from State Medicaid agencies but found the available data too inconsistent and limited to be useful given that payment rates vary between states. Additionally, not every State Medicaid Agency provides the same dental benefits, so not every state would have cost information for each of the dental codes we propose for OPPS payment. Lastly, while many State Medicaid Agencies provide robust information on the dental benefits covered for Medicaid beneficiaries in their state, the fee schedules published by State Medicaid Agencies most likely include payments to practitioners only and would not be informative for our purposes of assigning payment rates under the OPPS.

Finally, we considered analyzing private insurance claims from third-party databases but determined that the

cost information available would also not be relevant for OPPS ratesetting. For example, because most dental services covered by private insurance are provided in the office setting, there is a very limited number of claims that would be relevant for OPPS ratesetting purposes. Of the limited dental claims performed in the hospital setting, we learned that many of the dental services are performed in combination with several other services; therefore, it would be extremely difficult to isolate the facility fee payment for the dental services performed.

Although specific cost information is informative for making proposed APC assignments, it is not essential. For example, each quarter, after consultation with clinical experts, CMS assigns new CPT codes for which no cost information is available to APCs using crosswalk code analyses. Similar to our process for assigning new codes to APCs, we used a crosswalk code analysis and consulted with clinical experts to propose appropriate APC assignments for the 229 dental codes. In our conversations with the clinical experts, we discussed the clinical aspects of each dental service and learned about the resources, including supplies, used to perform each dental service, in order to more accurately identify crosswalk codes and propose APC assignments for them. We solicited comments regarding the proposed APC assignments for the dental codes for CY 2024. We refer readers to Addendum B to the CY 2024 OPPS/ASC proposed rule for the proposed CY 2024 APC assignments and associated payment rates for the dental codes. Addendum B is available via the internet on the CMS website.

Comment: One commenter asked for clarification on which crosswalks were used to determine the proposed APC assignments, and for data validation on these crosswalks. The commenter provided two examples of proposed APC assignments that they believed did not reflect relative clinical complexity and resource use. Specifically, the commenter disagreed with the proposed APC assignment for CDT code D4240 (Gingival flap proc w/planin) because they believed that the clinical intensity, resource utilization, and supply costs for CDT code D4240 would be expected to be greater than CDT code D4210 (Gingivectomy/plasty 4 or mor), which was proposed to be assigned to a higher paying APC. Similarly, the commenter disagreed with the proposed APC assignment for CDT code D7210 (Rem imp tooth w mucoper flp) because they believed that the clinical intensity, and resource use would be similar to those for CDT code D7310 (Alveoplasty w/ extraction), which was proposed to be assigned to a higher paying APC.

Response: We appreciate the opportunity to provide additional information on our proposed APC assignments for dental services for CY 2024. Our proposals for APC assignments for the 229 dental codes were made using a process that is consistent with our processes for assigning non-dental codes and services for which we do not have pricing information to clinical APCs. As we stated in our proposal, we do not yet have claims data or pricing information available for the dental codes we proposed to assign to APCs for CY 2024. As is our policy for all new HCPCS codes for which we lack pricing information, we proposed to assign the dental codes to existing APCs based on input from a variety of sources, including, but not limited to, review of the clinical similarity of the service to existing procedures including by using CPT crosswalk analyses, input from CMS medical advisors, and review of all other information available to us. The OPPS is a prospective payment system that provides payment for groups of services that share clinical and resource use characteristics. Therefore, we proposed to assign the dental codes to various APCs based on our evaluation of their clinical and resource similarities to other codes using the information available to us. Regarding releasing the crosswalks for all 229 dental codes we proposed to assign to APCs for CY 2024, it is not our policy to release crosswalks for every single code we assign to APCs in either our quarterly updates or in annual rulemaking. Additionally, as we have stated, CPT crosswalk analyses are just one method we use to assign codes to APCs for which we have no pricing information, and therefore, releasing CPT crosswalk codes would not fully explain our reasons for proposing to assign every dental code to a clinical APC.

Regarding the specific examples of inaccurate proposed APC assignments and the explanations provided by the commenter regarding resource and clinical similarities to codes in different clinical APCs than proposed, we agree with the commenter's concerns. Therefore, based on the commenter's arguments explaining the clinical and resource similarities to codes assigned to other clinical APCs than what was proposed we will finalize APC assignments according to the commenter's suggestions.

Comment: We received comments requesting that a dentist or dental specialist serve on the Advisory Panel on Hospital Outpatient Payment to be able to issue recommendations to CMS on dental issues brought forth to the Panel, including the appropriate APC assignments for dental services.

Response: We welcome nominations for representatives of providers to serve on the Advisory Panel on Hospital Outpatient Payment through the MEARIS™ module. We direct readers and interested parties to the CMS website for additional information regarding the purpose, responsibilities of the Advisory Panel on Hospital Outpatient Payment, and member requirements at: *https://www.cms.gov/medicare/regulations-guidance/advisory-committees/hospital-outpatient-payment.*

Comment: We received a comment from an organization representing the interests of people with disabilities expressing concern that our CY 2024 dental proposal may have the impact of ultimately prohibiting people with disabilities, particularly those residing in rural communities or who are otherwise unable to access a hospital outpatient department, from getting the dental procedures they need for their health and wellbeing.

Response: We appreciate the comment. It is unclear whether the commenter's concern was that the proposal to assign additional dental codes to APCs or the proposed payment rates for certain dental codes would have the negative effects described in their comment. Nonetheless, we take the concerns raised by the commenter seriously but reiterate that we believe our proposal to set payment rates for over 200 dental services, which would allow for payment under the OPPS when Medicare payment and coverage requirements are met, will improve access to dental services for Medicare beneficiaries, including beneficiaries with disabilities. As we stated in the CY 2023 PFS final rule (87 FR 69675), the policy changes for payment under Medicare Parts A and B for dental services that meet the conditions specified in that rule have the potential to advance health equity for people who are medically underserved. Finally, CMS will continue to consider how our dental policies may impact beneficiaries with disabilities.

Comment: We received two comments requesting that we remain vigilant and aware of unintended consequences that may occur if we were to finalize the proposed APC assignments for dental codes in the CY 2024 OPPS proposed rule. One commenter stated that CMS should diligently monitor the impacts the proposed APC assignments would have on APCs. Another commenter

cautioned CMS that if the OPPS payment rate for dental services is higher than other settings of care, our policies may have the unintended effect of shifting procedures that have traditionally been done in a dentist's office to the hospital outpatient setting. The commenter encouraged CMS to ensure that we are not creating a financial incentive to shift dental care services to the hospital outpatient department.

Response: We understand and appreciate the commenters' concerns and agree that the potential for higher payments in the hospital outpatient setting may incentivize providing dental care in the hospital outpatient department setting rather than dental offices. In an effort to control costs and promote more efficient care, our proposal for CY 2024 would package payment and implement multiple procedure discounting for almost every code that was proposed to be assigned to an APC. As we do every year, we will review the APC assignments for all services and items paid under the OPPS, including dental services, and make changes as appropriate. We anticipate that we will make adjustments in APC code assignments and APC groups to more accurately pay for dental services in future rulemaking based on claims data we collect. Finally, we encourage interested parties to continue to communicate their concerns and ideas with CMS so that we may address adverse incentives.

Comment: We received one comment requesting additional changes to the proposed APC assignments for dental codes. The commenter submitted a list of over 40 dental codes for which they requested different APC assignments than the ones we proposed. The commenter included CPT crosswalks for some of the dental codes to justify their suggested APC assignment changes, but not all. The commenter also did not provide a justification or their reasoning for why their suggested APC assignments were appropriate.

Response: We thank the commenter for their suggestions. However, based on the comment received, we do not have sufficient information to make the suggested APC assignment changes because minimal or sometimes no justification for the changes was provided. For example, additional information, including why a certain CPT crosswalk was chosen as well as the clinical or resource appropriateness of the suggested APC assignment change is necessary for us to assess the suggested APC assignments.

After consideration of the public comments we received, we are finalizing our proposed APC assignments for the dental codes as proposed with slight modifications. Specifically, for CY 2024, we are reassigning CDT code D7210 from APC 5871 to APC 5163, and CDT code D4240 to APC 5164. We refer readers to Addendum B to this final rule with comment period for the finalized CY 2024 APC assignments and status indicators for the dental codes. Addendum B is available via the internet on the CMS website.

4. Packaged Payment and Associated Status Indicators for Dental Codes

For CY 2024, we proposed to package payments for dental services when they are performed with another covered dental or medical service to promote clinical resource efficiencies, a strategic goal of the OPPS. Given our understanding of the nature of dental practice and in consultation with our clinical experts, we explained that we believe packaged payments are appropriate for dental services paid under the OPPS. We noted that we are aware that it is common for several dental services to be performed together, or alongside other medical services, and submitted on one claim. Unlike medical specialties where often only one procedure is performed at a time, it is our understanding that it is common for a patient to undergo several surgical and non-surgical dental procedures on multiple teeth in one day, or for dental services to be performed contemporaneously with other medical services. For example, there are several non-invasive, non-surgical dental services, including a dental exam or X-ray, which would most likely be performed together with other more invasive dental services in the HOPD setting, rather than on their own. Because a dental exam or X-ray is likely to be performed in addition to other more invasive dental services in the HOPD setting, we stated we believe packaging payment for dental codes describing dental exams and X-rays (*e.g.,* D0380–D0386) when performed with another service is appropriate and would further our strategic goal of encouraging hospitals to furnish services most efficiently and to manage their resources with maximum flexibility. We explained that we also are aware that there are several dental services that are performed as part of a primary service, and therefore, we believe would also result in resource efficiencies if paid under the OPPS as a packaged payment. For example, CDT codes D3110 (pulp cap-direct (excluding final restoration)) and D3120 (pulp cap-indirect (excluding final restoration)) are typically performed as part of a restorative procedure (*e.g.,* a crown or amalgam). Thus, we stated that we believe it is appropriate to propose to package payment for CDT codes D3110 and D3120 with payment for the associated restorative procedures.

We believe our proposal to package payment for dental services under the OPPS is consistent with existing packaging payment principles in the OPPS. The OPPS regularly 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. We believe applying these principles to the furnishing of dental services in the OPPS is appropriate and would incentivize clinical resource efficiencies.

In addition to proposing to package payment for dental services to promote clinical resource efficiencies, there are also several dental services that would nevertheless be packaged under our regulation at 42 CFR 419.2(b). For example, payment for dental services described by add-on codes, like CDT code D2953 (each addtnl cast post) would be packaged under the OPPS consistent with § 419.2(b)(18). Therefore, we proposed to package payment for CDT code D2953 with the procedures with which it is performed. We refer readers to the regulation at § 419.2(b) for a full list of items and services for which payment is packaged or conditionally packaged.

For CY 2024, we proposed packaging payment for dental services under the OPPS by assigning the dental codes to packaged status indicators. We believe there are clinical resource efficiencies to be gained by packaging payments rather than separately paying for each dental service performed. We refer readers to Addendum B to the CY 2024 OPPS/ASC proposed rule for the proposed CY 2024 status indicators for the dental codes. Addendum B is available via the internet on the CMS website. For more information on all of the proposed status indicators for CY 2024, including explanations of the payment status for each proposed status indicator, we refer readers to Addendum D1 to the CY 2024 OPPS/ASC proposed rule.

Comment: We received one comment supporting the proposal to assign ''N'' and ''Q1'' status indicators for certain dental services. The commenter stated that they believed the codes identified to be packaged with a primary service were appropriate.

Response: We thank the commenter for their support of our proposal to

assign ''N'' and ''Q1'' status indicators to certain dental codes.

Comment: We received one comment regarding finalizing proposed status indicator ''T'' for HCPCS code G0330. The commenter stated that since HCPCS code G0330 is used to report the performance of multiple procedures that otherwise would be separately billable, it is inappropriate to apply the multiple surgical procedure discount by assigning status indicator ''T'' to hospital dental rehabilitation claims.

Response: For CY 2024, we are not finalizing the APC assignment for HCPCS code G0330 as proposed. Based on our discussion of the final policy in this final rule with comment period, we are assigning HCPCS code G0330 to APC 5164 with status indicator ''J1.'' As stated in Addendum D1 to this final rule with comment period, services that are assigned a status indicator ''J1'' are paid under the OPPS. All covered Part B services on the same claim as a service with status indicator ''J1'' are packaged with the primary ''J1'' on the claim, with certain exceptions. We direct readers to Addendum D1 to this final rule with comment period for more information on the ''J1'' status indicator.

Comment: A few commenters stated that they did not support assigning status indicators that would package payments for any of the dental codes we proposed to assign to APCs due to concerns that packaged payments may not be appropriate for dental services and may result in lower payments.

Response: We disagree with commenters and continue to believe that packaging payment for certain dental services is appropriate. As stated in our proposal, there are certain packaging principles that are applied to all services paid under the OPPS, whether dental or medical. Additionally, we believe packaging payments will promote clinical resource efficiencies. We direct readers to our discussion on packaged payments for dental services in this final rule with comment for more information.

Comment: One commenter stated that there may be significant room for interpretation in terms of packaging. The commenter also stated they did not believe that when a dentist performs dental procedures described by add-on codes, like CPT code D2953 (each addtnl cast post), on the same patient that other dentists are similarly engaging in the same activity.

Response: We believe that the commenter is trying to explain that they do not believe providing a single payment for multiple services, including those described by add-on codes, would be appropriate because when multiple services are performed by multiple dentists on the same patient, the dentists are furnishing separate services, which should be paid for individually. First, we are clarifying that the OPPS is the Medicare payment system for hospital outpatient department services, not for the services of individual physicians, dentists, or other practitioners. Medicare payment for physicians' services is made through the PFS to the physicians, health care practitioners, and other suppliers that furnish these services. Second, we reiterate that it is our policy to package payment for most add-on codes, whether dental or medical, as these are codes that describe a procedure or service always performed in addition to a primary service or procedure. Since whenever CPT code D2953 is performed, it would always be performed with a primary service, its payment would always be packaged even though it may not be furnished every time the primary service is performed. Finally, we direct the commenter to section XI ''CY 2024 Payment Status and Comment Indicators'' of this final rule with comment period for a discussion of the various status indicators, including the packaged status indicator ''N,'' used under the OPPS. The complete list of the final status indicators and their definitions is provided in Addendum D1 to this final rule with comment period.

After consideration of the public comments we received, we are finalizing our proposal to package payment for certain dental services under the OPPS. We refer readers to Addendum B to this final rule with comment period for the finalized CY 2024 APC assignments and status indicators for the dental codes. Addendum B is available via the internet on the CMS website.

In summary, we are finalizing the following dental policy changes for CY 2024. First, after consideration of the public comments we received, we are finalizing the proposed list of dental codes for assignments to APCs for CY 2024 as well as some of the additional codes commenters suggested we make payable under the OPPS when coverage and payment requirements are met. Specifically, in addition to the codes we proposed to assign to APCs for CY 2024, we are assigning the following additional CDT codes to APCs for CY 2024: D7251, D7280, D7410, D7411, D7412, D7413, D7414, D7415, D7440, D7441, D7450, D7451, D7530, and D7540. We note that the assignment of these codes to APCs is not a determination of coverage or Medicare payment.

Second, we are finalizing our proposed APC assignments for the dental codes as proposed with slight modifications. Specifically, for CY 2024, we are assigning CDT code D7210 to APC 5163 and assigning CDT code D4240 to APC 5164, rather than finalizing their proposed APC assignments. Additionally, we are finalizing an APC reassignment for HCPCS code G0330 from APC 5871 to APC 5164 for CY 2024. We refer readers to Addendum B to this final rule with comment period for the finalized CY 2024 APC assignments and status indicators for the dental codes. Addendum B is available via the internet on the CMS website.

Finally, we are finalizing our proposal to package payments for certain dental services under the OPPS. We refer readers to Addendum B to this final rule with comment period for the specific finalized CY 2024 APC assignments and status indicators for the dental codes. Addendum B is available via the internet on the CMS website.

F. Use of Claims and Cost Report Data for CY 2024 OPPS and ASC Payment System Ratesetting Due to the PHE

As described in section I.A of the CY 2024 OPPS/ASC proposed rule, section 1833(t) of the Act requires the Secretary to annually review and update the payment rates for services payable under the Hospital OPPS. Specifically, section 1833(t)(9)(A) of the Act requires the Secretary to review not less often than annually and to revise the groups, the relative payment weights, and the wage and other adjustments described in paragraph (2) of the Act 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.

When updating the OPPS payment rates and system for each rulemaking cycle, we primarily use two sources of information: the outpatient Medicare claims data and Healthcare Cost Report Information System (HCRIS) cost report data. The claims data source is the Outpatient Standard Analytic File, which includes final action Medicare outpatient claims for services furnished in a given calendar year. For the OPPS ratesetting process, our goal is to use the best available data for ratesetting to accurately estimate the costs associated with furnishing outpatient services and to set appropriate payment rates. Ordinarily, the best available claims data are the data from 2 years prior to the calendar year that is the subject of rulemaking. For the CY 2024 OPPS/ASC

proposed rule ratesetting, the best available claims data would typically be the CY 2022 calendar year outpatient claims data processed through December 31, 2022. The cost report data source is typically the Medicare hospital cost report data files from the most recently available quarterly HCRIS file as we begin the ratesetting process. The best available cost report data used in developing the OPPS relative weights would ordinarily be from cost reports beginning three fiscal years prior to the year that is the subject of the rulemaking. For CY 2024 OPPS ratesetting, that would be cost report data from HCRIS extracted in December 2022, which would contain many cost reports ending in FY 2020 and 2021 based on each hospital's cost reporting period.

As discussed in the CY 2022 OPPS/ASC final rule with comment period, the standard hospital data we would have otherwise used for purposes of CY 2022 ratesetting included significant effects from the COVID–19 PHE, which led to a number of concerns with using this data for CY 2022 ratesetting (86 FR 63751 through 63754). In section X.E of the CY 2022 OPPS/ASC proposed rule (86 FR 42188 through 42190), we noted a number of changes in the CY 2020 OPPS claims data we would ordinarily have used for ratesetting, likely as a result of the PHE. These changes included overall aggregate decreases in claims volume (particularly those associated with visits); significant increases in HCPCS code Q3014 (Telehealth originating site facility fee) in the hospital outpatient claims; and increases in certain PHE-related services, such as HCPCS code C9803, which describes COVID–19 specimen collection, and services assigned to APC 5801 (Ventilation Initiation and Management). As a result of the effects, we observed from COVID–19 PHE-related factors in our claims and cost report data, as well as the increasing number of Medicare beneficiaries vaccinated against COVID–19, which we believed might make the CY 2022 outpatient experience closer to CY 2019 rather than CY 2020, we believed that CY 2020 data were not the best overall approximation of expected outpatient hospital services in CY 2022. Instead, we believed that CY 2019 data, as the most recent complete calendar year of data prior to the COVID–19 PHE, were a better approximation of expected CY 2022 hospital outpatient services. Therefore, in the CY 2022 OPPS/ASC final rule with comment period, we established a policy of using CY 2019 claims data and cost reports prior to the PHE in ratesetting for the CY 2022 OPPS with certain limited exceptions, such as where CY 2019 data were not available (86 FR 63753 and 63754).

For the CY 2023 OPPS proposed rule ratesetting, we conducted a review similar to the one we conducted for the CY 2022 OPPS ratesetting to determine the degree to which the effects of the COVID–19 PHE had continued or subsided in our claims data as well as what claims and cost report data would be appropriate for CY 2023 OPPS ratesetting. In general, we saw that the PHE had limited effect on the service and aggregate levels of volume as well as changes in the site of service of care, suggesting that, while clinical and billing patterns had not quite returned to their pre-PHE levels, they were beginning to do so.

For the CY 2023 OPPS/ASC final rule, while the effects of the COVID–19 PHE remained at both the aggregate and service levels for certain services, as discussed in that final rule with comment period (87 FR 48795 through 48798) and in FY 2023 IPPS proposed rule (87 FR 28123 through 28125), we recognized that future COVID–19 variants may have potentially varying effects. Therefore, we explained that we believed it was reasonable to assume that there would continue to be some effects of the COVID–19 PHE on the outpatient claims that we use for OPPS ratesetting, similar to the CY 2021 claims data. As a result, we proposed and finalized the use of CY 2021 claims for CY 2023 OPPS ratesetting.

We also used cost report data for the CY 2023 OPPS/ASC final rule (87 FR 72021) from the same set of cost reports we originally used in the CY 2021 OPPS/ASC final rule for ratesetting, which included cost reporting periods beginning in CY 2018 in most cases. We typically would have used the most updated available cost reports available in HCRIS in determining the CY 2023 OPPS/APC relative weights, which would have included cost reports with reporting periods that overlap with parts of CY 2020. However, noting that we observed significant impact at the service level when incorporating these cost reports into ratesetting and the effects on billing/clinical patterns, we finalized a policy to continue to use the same set of cost reports that we used in developing CY 2022 OPPS ratesetting.

For CY 2024 OPPS rulemaking, we continue to observe some differences at the aggregate and service level volumes in the CY 2022 claims data, relative to the pre-PHE period. However, we believe that it is reasonable to assume that there will be minor variations as a result of the COVID–19 PHE in claims data we use for ratesetting for the foreseeable future. As we have found that the effects are less pronounced, even relative to CY 2021 claims data used in CY 2023 OPPS ratesetting, we anticipate that most of the changes we observe represent a moderate continued return to pre-PHE volume and ongoing changes in clinical practice. As a result, we believe the CY 2022 claims data are appropriate for setting CY 2024 OPPS rates.

For CY 2024, we also evaluated the impact of using our standard update for cost reports. If we were to resume our typical process of using the most updated cost reports available, we would predominantly use cost report data from CY 2021, with some portion of the cost reports including cost reporting periods from prior years. While there are some differences compared to pre-PHE data, we generally observed limited impacts. Similar to the claims data approach, we believe it is reasonable to assume there will continue to be a limited influence of the COVID–19 PHE on the cost report data. However, as we continue to receive more updated cost report data, we believe that data will better reflect changes in provider charge and cost reporting structures. Given these factors, we believe that using the most recent cost report data available and resuming our regular cost report update process is appropriate for CY 2024 OPPS ratesetting.

As a result of our expectation that the CY 2022 claims that we would typically use are appropriate for establishing the CY 2024 OPPS rates, we proposed to use the CY 2022 claims for the CY 2024 OPPS/ASC ratesetting process. In addition, we proposed to resume our typical cost report update process of including the most recently available cost report data (primarily including cost reports with cost reporting periods including CY 2021). For the reasons previously discussed, we generally do not propose any modifications to our usual OPPS ratesetting methodologies with regard to the use of updated claims and cost report data to account for the impact of COVID–19 on the ratesetting data.

We did not receive any public comments on our proposal, and we are finalizing our proposal without modification to resume our typical data update process, using CY 2022 claims data and the most recently available cost report data, in the CY 2024 OPPS ratesetting process.

G. Comment Solicitation on Payment for High-Cost Drugs Provided by Indian Health Service and Tribal Facilities

In the CY 2000 OPPS final rule (65 FR 18433), CMS implemented the prospective payment system for hospital outpatient services furnished to Medicare beneficiaries, as set forth in section 1833(t) of the Act. In this rule, we noted that the Outpatient Prospective Payment System (OPPS) applies to covered hospital outpatient services furnished by all hospitals participating in the Medicare program with a few exceptions. We identified one of these exceptions as ''outpatient services provided by hospitals of the Indian Health Service (IHS).'' While we stated that these services would ''continue to be paid under separately established rates which are published annually in the **Federal Register**,'' we indicated that our intent was ''to develop a plan that will help these facilities transition to the [O]PPS and will consult with the IHS to develop this plan.'' In the CY 2002 OPPS final rule (66 FR 59855), we finalized our revision to § 419.20 (Hospitals subject to the hospital outpatient prospective payment system) by adding paragraph (b)(4), which specifies that hospitals of the IHS are excluded from the OPPS. However, we reiterated that this exclusion would only be in place until we developed a plan to include IHS hospitals under the OPPS.

In the intervening years, IHS and tribal facilities have been paid under the separately established All-Inclusive Rate (AIR). On an annual basis, the IHS calculates and publishes, in the **Federal Register**, calendar year reimbursement rates. Due to the higher cost of living in Alaska, separate rates are calculated for Alaska and the lower 48 States. For CY 2023, the Medicare Outpatient per Visit Rate is $620 for the lower 48 States and $801 for Alaska.

IHS and tribal facilities have continued to expand the breadth of services that they provide to their communities. Increasingly, this has meant providing higher-cost drugs along with more complex and expensive services. While the majority of IHS and tribal facilities appear to be well served by the AIR, there are specialty facilities where the AIR might not be an adequate representation of the Medicare share of costs. If providing a drug or service costs a specialty facility exponentially more than the payment they receive through the AIR, it may not be financially feasible for these facilities to provide that drug or service. For example, the cost of providing expensive cancer drugs or oncology services could greatly exceed payment a specialty IHS facility receives through the AIR. We are concerned that, if payments under the AIR are inadequate for high-cost drugs, this could potentially threaten the viability of the few IHS and tribal hospital outpatient specialty programs currently in operation and provide less incentive to IHS hospitals and tribal facilities not currently offering specialty services to begin doing so.

Consequently, we sought comment on a number of potential policies to address payment to IHS and tribal facilities for certain high-cost drugs and services. We sought comment on whether Medicare should pay separately for high-cost drugs provided by IHS and tribal facilities. We requested input on the following:

- What universe of drugs would be appropriate for separate payment? How could CMS maintain that list and add or remove drugs from it?
- Would paying separately for all drugs over a certain cost threshold be easier to operationalize than paying separately for a specified list of drugs, while achieving the same policy objective? If so, what would be an appropriate cost threshold and how should it be updated?
- What would be the appropriate payment rate for any separately paid drugs? How should these rates be updated and should these rates be updated on an annual basis?
- Would the standard Average Sales Price (ASP) plus 6 percent payment methodology rate be too high of a payment rate if tribal and IHS facilities are able to acquire drugs at a discounted rate through the Federal Supply Schedule? Would a payment rate equivalent to the acquisition cost of the drug through the Federal Supply Schedule be a more appropriate approximation of the cost of these drugs?
- Should IHS remove the cost of any separately paid drugs from the calculation of the AIR? If the cost of these drugs was not removed from the AIR, would the government be paying twice for these drugs?
- How would IHS and tribal facilities bill for separately paid drugs? Could they use the UB–04 form like standard OPPS hospitals?

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. We sought comment on whether an outlier policy might be an appropriate mechanism for addressing high-cost drugs and services provided by IHS and tribal facilities.

We welcomed input from interested parties on these policy ideas and any additional payment approaches that would enhance our ability to provide equitable payment for high-cost drugs and services provided by IHS and tribal facilities.

Comment: We received a total of nine comments in response to this comment solicitation, including from a tribal facility, organizations representing IHS and tribal healthcare providers, pharmaceutical companies, and other interested parties. All of the commenters supported establishing a payment methodology that would allow IHS and Tribal healthcare facilities to receive separate payment outside of the AIR for oncology drugs and services whose costs exceed the AIR.

Commenters discussed the different payment approaches that would cover the cost of oncology drugs and services above the AIR payment rate. The preferred approach of the commenters was to treat the AIR payment amount as a payment threshold. If the cost of a drug or service is less than the AIR, the provider would be paid the AIR. If the cost of the drug or service is more than the AIR, then the provider would receive separate payment for the drug or service. Commenters noted that this payment approach is currently being used for drugs receiving payment through Arizona Medicaid (AHCCCS) for IHS and tribal facilities located in Arizona. The commenters explained that the AHCCCS payment methodology was established through a state plan amendment to the AHCCCS program that was approved by CMS.

There was less enthusiasm for other possible payment approaches to cover the costs of high-cost oncology drugs and services. One commenter opposed establishing a fixed list of medications that would be eligible for separate payment because of frequent changes in treatment and therapy approaches and the entry of new drugs onto the market. Instead, the commenter would support separate payment for defined classes of drugs using HCPCS coding that would remain stable over several years. The commenter noted that this payment approach would not accommodate separate payment for radiation oncology services. The commenter also was skeptical about using outlier payments for high-cost oncology drugs and services. They stated that while this approach may cover costs that are not currently covered by the AIR, the high threshold to initiate an outlier payment and the limited additional payment would still leave IHS and Tribal

facilities who provide high-cost oncology drugs and other high-cost services with significant uncompensated expenditures.

Multiple commenters requested that separately payable drugs furnished by IHS and tribal facilities be paid at a rate of ASP + 6 percent rather than using the Federal Supply Schedule rate. Commenters assert that the IHS is chronically underfunded and that paying ASP + 6 percent for high-cost drugs could help with remedying those funding issues.

Commenters also wanted to ensure the integrity of the AIR if there is separate payment for high-cost oncology drugs and other high-cost services. They did not support applying offsets to the AIR to avoid double payment to IHS and tribal healthcare providers for separately payable high-cost oncology drugs or for high-cost services that may receive separate payment.

Response: We appreciate the suggestions and feedback from the interested parties who responded to this comment solicitation. We will consider the public comments for potential future rulemaking.

H. Technical Changes to Hospital Billing for Marriage and Family Therapist Services and Mental Health Counselor Services

Section 4121(a) of Division FF, Title IV, Subtitle C of the Consolidated Appropriations Act of 2023 (CAA, 2023) (Pub. L. 117–328, December 29, 2022), Coverage of Marriage and Family Therapist Services and Mental Health Counselor Services under Part B of the Medicare Program, provides for Medicare coverage of and payment for the services of mental health care professionals who meet the qualifications for marriage and family therapists (MFTs) and mental health counselors (MHCs) when billed by these professionals.

Specifically, section 4121(a)(1) of the CAA, 2023 amended section 1861(s)(2) of the Act by adding a new benefit category under Medicare Part B in new subparagraph (II) to include marriage and family therapist services (as defined in an added section 1861(lll)(1) of the Act) and mental health counselor services (as defined in an added section 1861(lll)(3) of the Act).

Section 4121(a)(2) of the CAA, 2023 added a new subsection (lll) to section 1861 of the Act, which defines marriage and family therapist services, marriage and family therapist (MFT), mental health counselor services, and mental health counselor (MHC). Section 1861(lll)(1) of the Act defines ''marriage and family therapist services'' as services furnished by an MFT for the diagnosis and treatment of mental illnesses (other than services furnished to an inpatient of a hospital), which the MFT is legally authorized to perform under State law (or the State regulatory mechanism provided by State law) of the State in which such services are furnished, as would otherwise be covered if furnished by a physician or as an incident to a physician's professional service. Section 1861(lll)(2) of the Act defines the term MFT to mean an individual who:

- Possesses a master's or doctor's degree which qualifies for licensure or certification as a MFT pursuant to State law of the State in which such individual furnishes marriage and family therapist services;
- Is licensed or certified as a MFT by the State in which such individual furnishes such services;
- After obtaining such degree has performed at least 2 years of clinical supervised experience in marriage and family therapy; and
- Meets such other requirements as specified by the Secretary.

Section 1861(lll)(3) of the Act defines ''mental health counselor services'' as services furnished by a mental health counselor (MHC) for the diagnosis and treatment of mental illnesses (other than services furnished to an inpatient of a hospital), which the MHC is legally authorized to perform under State law (or the State regulatory mechanism provided by the State law) of the State in which such services are furnished, as would otherwise be covered if furnished by a physician or as incident to a physician's professional service. Section 1861(lll)(4) of the Act defines MHC as an individual who:

- Possesses a master's or doctor's degree which qualifies for licensure or certification as a mental health counselor, clinical professional counselor, or professional counselor under State law of the State in which such individual furnishes MHC services;
- Is licensed or certified as a mental health counselor, clinical professional counselor, or professional counselor by the State in which the services are furnished;
- After obtaining such degree has performed at least 2 years of clinical supervised experience in mental health counseling; and
- Meets such other requirements as specified by the Secretary.

In the CY 2024 Physician Fee Schedule proposed rule, we proposed to create two new regulation sections at §§ 410.53 and 410.54 to codify the coverage provisions for MFTs and MHCs, respectively. We proposed a number of changes (88 FR 52361 through 52364) to implement the amendments made by section 4121 of CAA, 2023. Generally, these amendments added MFTs and MHCs as types of non-physician practitioners who can enroll in Medicare and bill for their professional services to diagnose and treat mental illnesses and specified that payment is made for these services at 80 percent of the lesser of the actual charges for the services or 75 percent of the amount determined under the PFS for services of a clinical psychologist (CP).

We received public comments in response to the OPPS proposed rule regarding section 4121 of the CAA, 2023. The following is a summary of the comments we received and our responses.

Comment: Several commenters requested that CMS amend the regulations at § 419.22 to add the services of MFTs and MHCs to the list of services that are not paid for under the Hospital Outpatient Prospective Payment System (OPPS) (except when packaged as part of a bundled payment) in order to clarify that MHC and MFT services are excluded from payment under the OPPS. This subject regulation at § 419.22 lists those services that are authorized by Medicare law to be paid under payment systems other than the OPPS, such as the Physician Fee Schedule (PFS), the Skilled Nursing Facility Prospective Payment System (SNF PPS), and the End Stage Renal Disease Prospective Payment System (ESRD PPS).

Response: We thank the commenters for bringing this inadvertent omission to our attention. As noted above, we proposed a number of changes (88 FR 52361 through 52364) to implement the amendments made by section 4121 of the CAA, 2023. Generally, these amendments added MFTs and MHCs as types of non-physician practitioners who can enroll in Medicare and bill for their professional services to diagnose and treat mental illnesses and specified that payment is made for these services at 80 percent of the lesser of the actual charges for the services or 75 percent of the amount determined under the PFS for services of a clinical psychologist (CP).

In proposing to implement section 4121, we inadvertently did not discuss excluding MFT and MHC services from payment under the hospital outpatient prospective payment system (OPPS). Services paid under fee schedules or other payment systems, including the professional services of physicians or nonphysician practitioners, are not paid

under the OPPS (69 FR 65685). The regulation at 42 CFR 419.22 lists the services excluded from payment under the OPPS and includes services of qualified psychologists, as defined in section 1861(ii) of the Act. Because MHC and MFT services are professional services of nonphysician practitioners for which payment is made under the PFS at 75 percent of the amount of payment for services of a psychologist, we believe that in implementing the amendments to the Act made by section 4121 of the CAA, 2023, we must also exclude these services from payment under the OPPS. Accordingly, we are amending the regulation at 42 CFR 419.22 to add the services of MFTs as defined in 1861(lll)(1) and the services of MHCs as defined in section 1861(lll)(3) to the list of hospital services excluded from payment under the OPPS, at new sections (w) and (x), respectively.

Comment: A few commenters requested that the regulation at 42 CFR 410.27, which permits certain hospital services to be furnished incident to a physician or nonphysician practitioner's service, be updated to expand the definition of ''nonphysician practitioner'' to include MFTs and MHCs.

Response: We thank the commenters for bringing this inadvertent omission to our attention. We are amending the regulation at 42 CFR 410.27(g) to revise the definition of ''nonphysician practitioner'' to include MFTs and MHCs, consistent with section 4121 of the CAA, 2023, and the amendments to the regulations at §§ 410.53 and 410.54 that we are adopting in the CY 2024 PFS final rule.

After consideration of the public comments, we are amending the regulations at §§ 410.27 and 419.22, as described above.

XI. CY 2024 OPPS Payment Status and Comment Indicators

A. CY 2024 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 whether particular OPPS policies apply to the code.

For CY 2024, we proposed to change the definition of status indicator ''P'' from ''Partial Hospitalization'' to ''Partial Hospitalization or Intensive Outpatient Program'' in order to account for the proposed payment of intensive outpatient services beginning January 1, 2024, as discussed in section VIII.B of the CY 2024 OPPS/ASC proposed rule. We did not propose to make any other changes to the existing definitions of status indicators that were listed in Addendum D1 to the CY 2023 OPPS/ASC final rule with comment period, which is available on the CMS website at: *https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient/regulations-notices.*

We solicited public comments on the proposed definitions of the OPPS payment status indicators for 2024. We did not receive any public comments on our proposal, and we are finalizing our proposal to change the definition of status indicator ''P'' from ''Partial Hospitalization'' to ''Partial Hospitalization or Intensive Outpatient Program''.

The complete list of CY 2024 payment status indicators and their definitions is displayed in Addendum D1 to this final rule with comment period, which is available on the CMS website at: *https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient/regulations-notices.*

The CY 2024 payment status indicator assignments for APCs and HCPCS codes are shown in Addendum A and Addendum B, respectively, to this final rule with comment period, which are available on the CMS website at: *https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient/regulations-notices.*

B. CY 2024 Comment Indicator Definitions

We proposed to use four comment indicators for the CY 2024 OPPS/ASC. These comment indicators, ''CH,'' ''NC,'' ''NI,'' and ''NP,'' are in effect for CY 2023; and we proposed to continue their use in CY 2024. The proposed CY 2024 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 CY 2024 OPPS/ASC 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 OPPS comment indicators for CY 2024 are listed in Addendum D2 to this final rule with comment period, which is available on the CMS website at: *https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient/regulations-notices.*

We explained that we believe that the existing CY 2024 definitions of the OPPS/ASC comment indicators continue to be appropriate for CY 2024. Therefore, we proposed to use those definitions without modification for CY 2024. We solicited public comments on our proposed definitions of the OPPS/ASC comment indicators for 2024.

We did not receive any public comments on our proposal and are finalizing those definitions without modification for CY 2024.

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 2023 report.

A. OPPS Payment Rates Update

The March 2023 MedPAC ''Report to the Congress: Medicare Payment Policy,'' recommended that Congress update Medicare OPPS payment rates by the amount specified in current law plus 1 percent. We refer readers to the March 2023 report for a complete discussion of this recommendation.[199]

[199] Medicare Payment Advisory Committee. March 2023 Report to the Congress. Chapter 3: Hospital inpatient and outpatient services, p.57. Available at: *https://www.medpac.gov.*

We appreciate MedPAC's recommendation and, as discussed further in section II.B of the CY 2024 OPPS/ASC proposed rule, we proposed to increase the OPPS payment rates by the amount specified in current law. Comments received from MedPAC for other OPPS policies are discussed in the applicable sections of this final rule with comment period.

B. Medicare Safety Net Index

The March 2023 MedPAC ''Report to the Congress: Medicare Payment Policy,'' recommended that Congress should begin a transition to redistribute disproportionate share hospital and uncompensated care payments through the Medicare Safety-Net Index (MSNI). Additionally, MedPAC recommended that Congress add $2 billion to the MSNI pool of funds and distribute such funds through a percentage add-on to payments under the IPPS and OPPS.

In light of these recommendations, and in particular those concerning safety net hospitals, in the CY 2024 OPPS/ASC proposed rule, we stated that we look forward to working with Congress and sought comments on approaches CMS could take. We did not receive any public comments in response to our comment solicitation regarding MedPAC's MSNI recommendation.

C. ASC Cost Data

In the March 2023 MedPAC ''Report to the Congress: Medicare Payment Policy,'' MedPAC reiterated its longstanding recommendation 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. MedPAC suggested that such cost data would allow CMS to examine whether an existing Medicare price index is an appropriate proxy for ASC costs or whether an ASC-specific market basket should be developed, stating both the CPI–U and hospital market basket update likely do not reflect an ASC's cost structure. MedPAC contended that it is feasible for small facilities, such as ASCs, to provide cost information since other small facilities, such as home health agencies, hospices, and rural health clinics, currently furnish cost data to CMS. Further, ASCs in Pennsylvania submit cost and revenue data annually to a state agency to estimate margins for those ASCs, and that, as businesses, ASCs keep records of their costs for filing taxes and other purposes.[200]

While we recognize that the submission of cost data could place additional administrative burden on most ASCs, and we did not propose any cost reporting requirements for ASCs in the CY 2024 OPPS/ASC proposed rule, as in previous years, we sought public comment on 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. Such cost data would be beneficial in establishing an ASC-specific market basket index for updating payment rates under the ASC payment system. We did not receive any public comments on our comment solicitation regarding methods to mitigate the burden of ASC cost reporting and data collection. Comments received from MedPAC for other ASC payment system policies are discussed in the applicable sections of this final rule with comment period.

XIII. Updates to the Ambulatory Surgical Center (ASC) Payment System

A. Background, 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 and 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 to 2023 OPPS/ASC final rules with comment period (76 FR 74378 and 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; 84 FR 61370 through 61410; 85 FR 86121 through 86179; 86 FR 63761 through 63815; and 87 FR 72054 through 72096).

B. ASC Treatment of New and Revised Codes

1. Background on Process for New and Revised HCPCS Codes

We update the lists 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 systems (§ 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 paid for 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

[200] Medicare Payment Advisory Committee. March 2023 Report to the Congress. Chapter 5: Ambulatory surgical center services, p.163. Available at: *https://www.medpac.gov/wp-content/uploads/2023/03/Ch5_Mar23_MedPAC_Report_To_Congress_SEC.pdf.*

updates occur in a regular, predictable, and timely manner.

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. Level I is comprised of CPT (Current Procedural Terminology) codes, a numeric and alphanumeric coding system maintained by the 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 2024 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 the proposed rule (and respond to those comments in this final rule with comment period) or whether we will be soliciting public comments in this CY 2024 OPPS/ASC final rule with comment period (and responding to those comments in the CY 2025 OPPS/ASC final rule with comment period).

2. April 2023 HCPCS Codes Proposed Rule Comment Solicitation

For the April 2023 update, there were no new CPT codes; however, there were several new Level II HCPCS codes. In the April 2023 ASC quarterly update (Transmittal 11927, dated March 24, 2023, CR 13143), we added several new Level II HCPCS codes to the list of covered ancillary services. Table 54 (New Level II HCPCS Codes for Ancillary Services Effective April 1, 2023) of the CY 2024 OPPS/ASC proposed rule (88 FR 49745) displayed the new Level II HCPCS codes that were implemented April 1, 2023. These new codes that were effective April 1, 2023, were assigned to comment indicator ''NP'' in Addendum BB to the proposed rule to indicate that the codes were assigned to an interim APC assignment and that comments would be accepted on their interim APC assignments. In addition, we note that the entire ASC addenda, which consist of the addenda listed below, are available via the internet on the CMS website, specifically, at *https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient/regulations-notices:*

- ASC Addendum AA: ASC Covered Surgical Procedures (Including Surgical Procedures for Which Payment is Packaged)
- ASC Addendum BB: Covered Ancillary Services Integral to Covered Surgical Procedures (Including Ancillary Services for Which Payment is Packaged)
- ASC Addendum DD1: ASC Payment Indicators (PI)
- ASC Addendum DD2: ASC Comment Indicators (CI)
- ASC Addendum EE: Surgical Procedures Excluded from Payment in ASCs
- ASC Addendum FF: ASC Device Offset Percentages
- Addendum O: Long Descriptors for New Category I CPT Codes, Category III CPT Codes, C-codes, and G-Codes Effective January 1, 2024

We invited public comments on the proposed payment indicators for the new HCPCS codes that were recognized as ASC covered ancillary services in April 2023 through the quarterly update CRs, and as listed in Table 112 (New Level II HCPCS Codes for Ancillary Services Effective April 1, 2023). The new codes that were effective April 1, 2023, were assigned to comment indicator ''NP'' in ASC Addendum BB to the CY 2024 OPPS/ASC proposed rule to indicate that the codes are assigned to interim payment indicators and comments would be accepted on their interim assignments. We proposed to finalize the payment indicators in this CY 2024 OPPS/ASC final rule with comment period. We did not receive any comments on the proposed ASC payment indicator assignments for the new Level II HCPCS codes implemented in April 2023 and are finalizing the proposed ASC payment indicator assignments for these codes.

We note that several of the temporary drug HCPCS C-codes have been replaced with permanent drug HCPCS J-codes. Their replacement codes are also listed in Table 112. In addition, although in prior years we included the final ASC payment indicators in the coding tables in the preamble, because we include the same information in the ASC addenda, we have not included them in Table 112. Therefore, readers are advised to refer to the ASC addenda for the final ASC payment indicators and payment rates for all codes reported under the ASC payment system. The list of ASC payment indicators and definitions used under the ASC payment system can be found in the ASC addenda. We note that the ASC addenda (AA, BB, DD1, DD2, EE, and FF) are available via the internet on the CMS website.

TABLE 112: NEW LEVEL II HCPCS CODES FOR ASC COVERED ANCILLARY SERVICES EFFECTIVE APRIL 1, 2023

April 2023 HCPCS Code	CY2024 HCPCS Code	CY 2024 Long Descriptor
C9145	C9145	Injection, aprepitant, (aponvie), 1 mg
C9146	J9063	Injection, mirvetuximab soravtansine-gynx, 1 mg
C9147	J9347	Injection, tremelimumab-actl, 1 mg
C9148	J9380	Injection, teclistamab-cqyv, 0.5 mg
C9149	J9381	Injection, teplizumab-mzwv, 5 mcg
J0208	J0208	Injection, sodium thiosulfate, 100 mg
J0218	J0218	Injection, olipudase alfa-rpcp, 1 mg
J1449	J1449	Injection, eflapegrastim-xnst, 0.1 mg
J1747	J1747	Injection, spesolimab-sbzo, 1 mg
J2403	J2403	Chloroprocaine hcl ophthalmic, 3% gel, 1 mg
J9294	J9294	Injection, pemetrexed (hospira) not therapeutically equivalent to j9305, 10 mg
J9296	J9296	Injection, pemetrexed (accord) not therapeutically equivalent to j9305, 10 mg
J9297	J9297	Injection, pemetrexed (sandoz), not therapeutically equivalent to j9305, 10 mg
Q4265	Q4265	Neostim tl, per square centimeter
Q4266	Q4266	Neostim membrane, per square centimeter
Q4267	Q4267	Neostim dl, per square centimeter
Q4268	Q4268	Surgraft ft, per square centimeter
Q4269	Q4269	Surgraft xt, per square centimeter
Q4270	Q4270	Complete sl, per square centimeter
Q4271	Q4271	Complete ft, per square centimeter
Q5127	Q5127	Injection, pegfilgrastim-fpgk (stimufend), biosimilar, 0.5 mg
Q5128	Q5128	Injection, ranibizumab-eqrn (cimerli), biosimilar, 0.1 mg
Q5130	Q5130	Injection, pegfilgrastim-pbbk (fylnetra), biosimilar, 0.5 mg

3. July 2023 HCPCS Codes Proposed Rule Comment Solicitation

In the July 2023 ASC quarterly update (Transmittal 12099, Change Request 13216, dated June 22, 2023, which was subsequently rescinded and replaced with Transmittal 12122, Change Request 13216, dated July 5, 2023), we added several separately payable CPT and Level II HCPCS codes to the list of covered surgical procedures and covered ancillary services. Table 55 (New HCPCS Codes for Covered Surgical Procedures and Covered Ancillary Services Effective July 1, 2023) of the CY 2024 OPPS/ASC proposed rule (88 FR 49746) displayed the new HCPCS codes that were effective July 1, 2023. We invited public comments on the proposed payment indicators for these Level II HCPCS codes, and indicated that the proposed comment indicators, payment indicators, and payment rates for these codes were listed in Addendum AA and Addendum BB of the proposed rule. These new codes that were effective July 1, 2023, were assigned to comment indicator ''NP'' in ASC Addendum AA and Addendum BB to the CY 2024 OPPS/ASC proposed rule to indicate that the codes were assigned to an interim payment indicators and

comments would be accepted on their interim assignments. We further stated that we proposed to finalize the payment indicators in this CY 2024 OPPS/ASC final rule with comment period. We note that several of the temporary drug HCPCS C-codes have been replaced with HCPCS J-codes and HCPCS Q-codes. Their replacement codes are also listed in Table 113. In addition, in prior years we included the final ASC payment indicators the coding preamble tables, however, because the same information can be found in Addendum AA and Addendum BB, we are no longer including them in Table 113. Therefore, readers are advised to refer to the ASC addenda for the final ASC payment indicators and payment rates for all codes reported under the ASC payment system.

We did not receive any comments on the proposed ASC payment indicator assignments for the new Level II HCPCS codes that were added to the list of covered surgical procedures and ancillary services implemented in July 2023. Therefore, we are finalizing the proposed ASC payment indicator assignments for the codes.

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TABLE 113: NEW HCPCS CODES FOR COVERED SURGICAL PROCEDURES AND COVERED ANCILLARY SERVICES EFFECTIVE JULY 1, 2023

July 2023 HCPCS Code	CY2024 HCPCS Code	CY 2024 Long Descriptor
0793T	0793T	Percutaneous transcatheter thermal ablation of nerves innervating the pulmonary arteries, including right heart catheterization, pulmonary artery angiography, and all imaging guidance
0797T	0797T	Transcatheter insertion of permanent dual-chamber leadless pacemaker, including imaging guidance (eg, fluoroscopy, venous ultrasound, right atrial angiography, right ventriculography, femoral venography) and device evaluation (eg, interrogation or programming), when performed; right ventricular pacemaker component (when part of a dual-chamber leadless pacemaker system)
0800T	0800T	Transcatheter removal of permanent dual-chamber leadless pacemaker, including imaging guidance (eg, fluoroscopy, venous ultrasound, right atrial angiography, right ventriculography, femoral venography), when performed; right ventricular pacemaker component (when part of a dual-chamber leadless pacemaker system)
0803T	0803T	Transcatheter removal and replacement of permanent dual-chamber leadless pacemaker, including imaging guidance (eg, fluoroscopy, venous ultrasound, right atrial angiography, right ventriculography, femoral venography) and device evaluation (eg, interrogation or programming), when performed; right ventricular pacemaker component (when part of a dual-chamber leadless pacemaker system)
0809T	0809T	Arthrodesis, sacroiliac joint, percutaneous or minimally invasive (indirect visualization), with image guidance, placement of transfixing device(s) and intra-articular implant(s), including allograft or synthetic device(s)
C9151	J2781	Injection, pegcetacoplan, intravitreal,1 mg
J1440	J1440	Fecal microbiota, live - jslm, 1 ml
J1576	J1576	Injection, immune globulin (panzyga), intravenous, non-lyophilized (e.g., liquid), 500 mg
J1961	J1961	Injection, lenacapavir, 1 mg
J2329	J2329	Injection, ublituximab-xiiy, 1mg
J2427	J2427	Injection, paliperidone palmitate extended release (invega hafyera, or invega trinza), 1 mg
J7213	J7213	Injection, coagulation factor ix (recombinant), ixinity, 1 i.u.
J9056	J9056	Injection, bendamustine hydrochloride (vivimusta), 1 mg
J9058	J9058	Injection, bendamustine hydrochloride (apotex), 1 mg
J9059	J9059	Injection, bendamustine hydrochloride (baxter), 1 mg
J9063	J9063	Injection, mirvetuximab soravtansine-gynx, 1 mg

J9259	J9259	Injection, paclitaxel protein-bound particles (american regent) not therapeutically equivalent to j9264, 1 mg
J9322	J9322	Injection, pemetrexed (bluepoint) not therapeutically equivalent to J9305, 10 mg
J9323	J9323	Injection, pemetrexed ditromethamine, 10 mg
J9347	J9347	Injection, tremelimumab-actl, 1 mg
J9350	J9350	Injection, mosunetuzumab-axgb, 1 mg
J9380	J9380	Injection, teclistamab-cqyv, 0.5 mg
J9381	J9381	Injection, teplizumab-mzwv, 5 mcg
Q5129	Q5129	Injection, bevacizumab-adcd (vegzelma), biosimiliar, 10 mg

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4. October 2023 HCPCS Codes Final Rule Comment Solicitation

For CY 2024, consistent with our established policy, we proposed in the CY 2024 OPPS/ASC proposed rule (88 FR 49747) that the Level II HCPCS codes that would be effective October 1, 2023, would be flagged with comment indicator ''NI'' in Addendum BB in the CY 2024 OPPS/ASC final rule with comment period to indicate that we have assigned the codes to interim ASC payment indicators for CY 2024. In the October 2023 ASC quarterly update (Transmittal 12229, Change Request 13353, dated August 31, 2023), we added several separately payable Level II HCPCS codes to the list of covered surgical procedures and covered ancillary services. Table 114 below list the codes that were effective October 1, 2023. We note that several of the temporary C-codes have been replaced with permanent J-codes effective January 1, 2024. We are inviting public comments on this final rule with comment period on the interim payment indicators, which would be finalized in the CY 2025 OPPS/ASC final rule with comment period. We note these same codes will be subject to comment in the CY 2025 OPPS/ASC proposed rule with comment period, which would be finalized in the CY 2025 OPPS/ASC final rule with comment period.

TABLE 114: NEW HCPCS CODES FOR COVERED SURGICAL PROCEDURES AND COVERED ANCILLARY SERVICES EFFECTIVE OCTOBER 1, 2023

October 2023 HCPCS Code	CY 2024 HCPCS Code	CY 2024 Long Descriptor
C9152	J0402	Injection, aripiprazole, (abilify asimtufii), 1 mg
C9153	J0184	Injection, amisulpride, 1 mg
C9154	J0576	Injection, buprenorphine extended-release (brixadi), 1 mg
C9155	J9321	Injection, epcoritamab-bysp, 0.16 mg
C9156	A9608	Flotufolastat F 18, diagnostic, 1 millicurie
C9157	J1304	Injection, tofersen, 1 mg
C9158	J2799	Injection, risperidone, (uzedy), 1 mg
C9789	C9789	Instillation of anti-neoplastic pharmacologic/biologic agent into renal pelvis, any method, including all imaging guidance, including volumetric measurement if performed
C9790	C9790	Histotripsy (ie, non-thermal ablation via acoustic energy delivery) of malignant renal tissue, including image guidance
J0349	J0349	Injection, rezafungin, 1 mg
J0801	J0801	Injection, corticotropin (acthar gel), up to 40 units
J0802	J0802	Injection, corticotropin (ani), up to 40 units
J2781	J2781	Injection, pegcetacoplan, intravitreal, 1 mg
J7519	J7519	Injection, mycophenolate mofetil, 10 mg
J9345	J9345	Injection, retifanlimab-dlwr, 1 mg

5. January 2024 HCPCS Codes

a. New Level II HCPCS Codes Final Rule Comment Solicitation

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 C and G-codes listed in Addendum O to the CY 2024 OPPS/ASC 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 were unable to include them in the OPPS/ASC proposed rule; however, the codes are flagged with comment indicator ''NI'' in ASC Addendum AA and Addendum BB to this final rule with comment period to indicate that we are assigning them an interim payment status, which is subject to public comment. Therefore, as we stated in the CY 2024 OPPS/ASC proposed rule, these Level II HCPCS codes that will be effective January 1, 2024 are included in this final rule with comment period and will also be released to the public through in the January 2024 ASC Update CR and the CMS HCPCS website. We are inviting public comments in this final rule with comment period on the payment indicator assignments, which would be finalized in the CY 2025 OPPS/ASC final rule with comment period. Similar to the codes effective October 1, 2023, these new Level II HCPCS codes that will be effective January 1, 2024, will be subject to comment in the CY 2025 OPPS/ASC proposed rule with comment period, which would be finalized in the CY 2025 OPPS/ASC final rule with comment period.

b. New CY 2024 CPT Codes Proposed Rule Comment Solicitation

For the CY 2024 ASC update, we received the CPT codes that will be effective January 1, 2024, from the AMA in time to be included in the CY 2024 OPPS/ASC proposed rule. The new, revised, and deleted CPT codes were included in Addendum AA and Addendum BB to the CY 2024 OPPS/

ASC proposed rule, which is available via the internet on the CMS website. We note that the new and revised CPT codes were assigned to comment indicator ''NP'' in ASC Addendum AA and Addendum BB of the CY 2024 OPPS/ASC 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 the current calendar year with a proposed payment indicator assignment. We stated that we would accept comments and finalize the payment indicators in this CY 2024 OPPS/ASC final rule with comment period. Further, we reminded readers that the CPT code descriptors that appeared 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 CY 2024 CPT codes in Addendum O to the CY 2024 OPPS/ASC proposed rule so that the public could comment on our proposed payment indicator assignments. The 5-digit placeholder codes were listed in Addendum O to the CY 2024 OPPS/ASC proposed rule, specifically under the column labeled ''CY 2024 OPPS/ASC Proposed Rule 5-Digit Placeholder Code.'' We also stated that we would include the final CPT code numbers in this CY 2024 OPPS/ASC final rule with comment period.

We did not receive any comments on the proposed ASC payment indicators for the new CPT codes effective January 1, 2024, so we are finalizing these codes as proposed.

Finally, in Table 115, 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 payment system.

TABLE 115: COMMENT AND FINALIZATION TIMEFRAMES FOR NEW AND REVISED ASC-RELATED HCPCS CODES

ASC Quarterly Update CR	Type of Code	Effective Date	Comments Sought	When Finalized
April 2023	HCPCS (CPT and Level II codes)	April 1, 2023	CY 2024 OPPS/ASC proposed rule	CY 2024 OPPS/ASC final rule with comment period
July 2023	HCPCS (CPT and Level II codes)	July 1, 2023	CY 2024 OPPS/ASC proposed rule	CY 2024 OPPS/ASC final rule with comment period
October 2023	HCPCS (CPT and Level II codes)	October 1, 2023	CY 2024 OPPS/ASC final rule with comment period	CY 2025 OPPS/ASC final rule with comment period
January 2024	CPT Codes	January 1, 2024	CY 2024 OPPS/ASC proposed rule	CY 2024 OPPS/ASC final rule with comment period
	Level II HCPCS Codes	January 1, 2024	CY 2024 OPPS/ASC final rule with comment period	CY 2025 OPPS/ASC final rule with comment period

6. ASC Payment and Comment Indicators

a. Background

In addition to the payment indicators that we introduced in the August 2, 2007 ASC 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 with comment period 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 (these addenda 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 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.

In the CY 2021 OPPS/ASC final rule with comment period, we finalized the addition of 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 (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.

b. Final ASC Payment and Comment Indicators for CY 2024

For CY 2024, we proposed new and revised Category I and III CPT codes as well as new and revised Level II HCPCS codes. Final Category I and III CPT codes that are new and revised for CY 2024 and any new and existing Level II HCPCS codes with substantial revisions to the code descriptors for CY 2024, compared to the CY 2023 descriptors, are included in ASC Addenda AA and BB to the proposed rule and labeled with comment indicator ''NP'' to indicate that these CPT and Level II HCPCS codes were open for comment as part of the CY 2024 OPPS/ASC proposed rule.

For CY 2024, we proposed to add two ASC payment indicators for new proposed dental codes. Section XIII.D of the proposed rule described the proposed addition of dental codes to the ASC CPL and ancillary services list for CY 2024. We proposed to add specific dental payment indicators for more streamlined claims processing of the new dental codes, as these codes would require different billing mechanisms than non-dental procedures currently on the CPL. Separate payment indicators would allow MACs to more quickly and easily distinguish how these codes need to be processed. Proposed ASC payment indicators ''D1'' and ''D2'' are for the new dental codes that would be paid in CY 2024 and subsequent calendar years and would be added to Addendum DD1 (which is available via the internet on the CMS website) to indicate potentially payable dental services and procedures in the ASC setting. The first proposed payment indicator is ''D1''—''Ancillary dental service/item; no separate payment made.'' The ''D1'' indicator would indicate an ancillary dental procedure that would be performed integral to a separately payable dental surgical procedure with a payment indicator of ''D2.'' The second proposed payment indicator is ''D2''—''Non office-based dental procedure added in CY 2024 or later.'' The ''D2'' payment indicator would indicate a separately payable dental surgical procedure that would be subject to the multiple procedure reduction but would not be designated as an office-based covered surgical procedure. Section XIII.D.2 of the proposed rule described how these payment indicators would be used in claims processing for dental services. We solicited comment on these proposed new payment indicators, including whether their descriptors are appropriate, and any considerations interested parties believe we should consider when structuring payment for the procedures for which we propose to use payment indicators D1 and D2.

We did not receive any public comments on our proposals, and we are finalizing them as proposed without modification. We refer readers to Addenda DD1 and DD2 of this CY 2024 OPPS/ASC final rule (these addenda are available via the internet on the CMS website) for the complete list of ASC payment and comment indicators finalized for the CY 2024 update.

C. Payment Policies Under the ASC Payment System

1. Final 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 have retained payment indicator ''A2'' because it is used to identify procedures that are exempted from the application of the office-based designation.

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. As detailed in section XIII.C.3.b of this CY 2024 OPPS/ASC final rule, we update the payment amounts for office-based procedures (payment indicators ''P2,'' ''P3,'' and ''R2'') using the most recent available MPFS and OPPS data. We compare the estimated current year 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 is lower and, therefore, would be the current year payment rate for the procedure under

our final policy for the revised ASC payment system (§ 416.171(d)).

The rate calculation established for device-intensive procedures (payment indicator ''J8'') is structured so only the service (non-device) portion of the rate is subject to the ASC conversion factor. We update the payment rates for device-intensive procedures to incorporate the most recent device offset percentages calculated under the ASC standard ratesetting methodology, as discussed in section XIII.C.4 of this final rule.

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 is 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 have continued to provide separate payment since CY 2014 and assign the current ASC payment indicators associated with these procedures.

b. Update to ASC Covered Surgical Procedure Payment Rates for CY 2024

We proposed to update ASC payment rates for CY 2024 and subsequent years using the established rate calculation methodologies under § 416.171 and using our definition of device-intensive procedures, as discussed in section XIII.C.4 of this final rule. As the proposed OPPS relative payment weights are generally based on geometric mean costs, we proposed that the ASC payment system will generally use the geometric mean cost to determine proposed relative payment weights under the ASC standard methodology. We proposed to continue to use the amount calculated under the ASC standard ratesetting methodology for procedures assigned payment indicators ''A2'' and ''G2.''

We proposed 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 to identify device-intensive procedures using the methodology discussed in section XIII.C.4 of this final rule. Therefore, we proposed to update the payment amount for the service portion (the non-device portion) of the device-intensive procedures using the standard ASC ratesetting methodology and the payment amount for the device portion based on the proposed CY 2024 device offset percentages that have been calculated using the standard OPPS APC ratesetting methodology. We proposed that payment for office-based procedures would be at the lesser of the proposed CY 2024 MPFS nonfacility PE RVU-based amount or the proposed CY 2024 ASC payment amount calculated according to the ASC standard ratesetting methodology.

As we did for CYs 2014 through 2023, for CY 2024, we proposed 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'') will be assigned the current ASC payment indicators associated with those procedures and will continue to be paid separately under the ASC payment system.

We did not receive any comments on the broader rate calculation methodologies for these procedures and we are finalizing our proposed policies without modification to calculate the CY 2024 payment rates for ASC covered surgical procedures according to our established rate calculation methodologies under § 416.171 and our device-intensive payment policy, as discussed in section XIII.C.4. of this CY 2024 OPPS/ASC final rule with comment period. For covered office-based surgical procedures, the payment rate is the lesser of the final CY 2024 MPFS nonfacility PE RVU-based amount or the final CY 2024 ASC payment amount calculated according to the ASC standard ratesetting methodology. The final payment indicators and rates set forth in this final rule with comment period are based on a comparison using the PFS PE RVUs and the conversion factor effective January 1, 2024. For a discussion of the PFS rates, we refer readers to the CY 2024 PFS final rule with comment period.

c. Final Payment for ASC Add-On Procedures Eligible for Complexity Adjustments Under the OPPS

In this section, we discuss the policy to provide increased payment under the ASC payment system for combinations of certain ''J1'' service codes and add-on procedure codes that are eligible for a complexity adjustment under the OPPS.

(1) OPPS C–APC Complexity Adjustment Policy

Under the OPPS, complexity adjustments are utilized to provide increased payment for certain comprehensive services. As discussed in section II.A.2.b of this final rule, we apply a complexity adjustment by promoting qualifying paired ''J1'' service code combinations or paired code combinations of ''J1'' services and add-on codes from the originating Comprehensive APC (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. A ''J1'' status indicator refers to a hospital outpatient service paid through a C–APC. We package payment for all add-on codes, which are codes that describe a procedure or service always performed in addition to a primary service or procedure, into the payment for the C–APC. However, certain combinations of primary service codes and add-on codes may qualify for a complexity adjustment.

We apply complexity adjustments when the paired code combination represents a complex, costly form or version of the primary service when the frequency and cost thresholds are met. The frequency threshold is met when there are 25 or more claims reporting the code combination, and the cost threshold is met when there is a violation of the 2 times rule, as specified in section 1833(t)(2) of the Act and described in section III.A.2.b of this final rule, in the originating C–APC. These paired code combinations that meet the frequency and cost threshold criteria represent those that exhibit materially greater resource requirements than the primary service. 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 that are either assigned to status indicator ''J1'' or add-on codes to determine if there are paired code

combinations that meet the complexity adjustment criteria. Once we have determined that a particular combination of ''J1'' services, or combinations of a ''J1'' service and add-on code, 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 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 C–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).

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 the primary service code reported with the add-on code is not reassigned to the next higher cost C–APC. We list the final complexity adjustments for ''J1'' and add-on code combinations for CY 2024, along with all of the other final complexity adjustments, in Addendum J to this final rule (which is available via the internet on the CMS website at *https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient/regulations-notices*).

(2) CY 2024 ASC Special Payment Policy for OPPS Complexity-Adjusted C–APCs

Comprehensive APCs cannot be adopted in the ASC payment system due to limitations of the ASC claims processing systems. Thus, we do not use the OPPS comprehensive services ratesetting methodology in the ASC payment system. Under the standard ratesetting methodology used for the ASC payment system, comprehensive ''J1'' claims that exist under the OPPS are treated the same as other claims that contain separately payable procedure codes. As comprehensive APCs do not exist under the ASC payment system, there is not a process similar to the OPPS complexity adjustment policy in the ASC payment system to provide higher payment for more complex code combinations. In the ASC payment system, when multiple procedures are performed together in a single operative session, most covered surgical procedures are subject to a 50-percent reduction for the lower-paying procedure (72 FR 66830). This multiple procedure reduction gives providers additional payment when they perform multiple procedures during the same session, while still encouraging providers to provide necessary services as efficiently as possible. Add-on procedure codes are not separately payable under the ASC payment system and are always packaged into the ASC payment rate for the procedure. Unlike the multiple procedure discounting process used for other surgical procedures in the ASC payment system, providers do not receive any additional payment when they perform a primary service with a service corresponding to an add-on code in the ASC payment system.

Before CY 2023 rulemaking, we received suggestions from commenters requesting that we explore ways to increase payment to ASCs when services corresponding to add-on codes are performed with procedures, as certain code combinations may represent increased procedure complexity or resource intensity when performed together. For example, in the CY 2022 OPPS/ASC final rule with comment period, one commenter suggested that we modify the device-intensive criteria to allow packaged procedures that trigger a complexity adjustment under the OPPS to be eligible for device-intensive status under the ASC payment system (86 FR 63775). Based on our internal data review and assessment at that time, our response to that comment noted that we did not believe any changes were warranted to our packaging policies under the ASC payment system but that we would consider it in future rulemaking.

In the CY 2023 OPPS/ASC final rule with comment period, we evaluated the differences in payment in the OPPS and ASC settings for code pairs that included a primary procedure and add-on codes that were eligible for complexity adjustments under the OPPS and also performed in the ASC setting. When we compared the OPPS complexity-adjusted payment rate of these primary procedure and add-on code combinations to the ASC payment rate for the same code combinations, we found that the average rate of ASC payment as a percent of OPPS payment for these code combinations was significantly lower than 55 percent. We recognized that this payment differential between the C–APC-assigned code combinations eligible for complexity adjustments under the OPPS and the same code combinations under the ASC payment system could potentially create financial disincentives for providers to offer these services in the ASC setting, which could potentially result in Medicare beneficiaries encountering difficulties accessing these combinations of services in ASC settings. As noted above, our policy did not include additional payment for services corresponding to add-on codes, unlike our payment policy for multiple surgical procedures performed together, for which we provide additional payment under the multiple procedure reduction. However, these primary procedure and add-on code combinations that would be eligible for a complexity adjustment under the OPPS represented a more complex and costly version of the service, and we believed that providers not receiving additional payment under the ASC payment system to compensate for that increased complexity could lead to providers not being able to provide these services in the ASC setting, which could result in barriers to beneficiary access.

In order to address this issue, in the CY 2023 OPPS/ASC final rule with comment period (87 FR 72079 and 72080), we finalized a new ASC payment policy that would apply to certain code combinations in the ASC payment system where CMS would pay for those code combinations at a higher payment rate to reflect that the code combination is a more complex and costlier version of the procedure performed, similar to the way in which the OPPS APC complexity adjustment is applied to certain paired code combinations that exhibit materially greater resource requirements than the primary service. We finalized adding new regulatory text at § 416.172(h) to codify this policy.

We finalized that combinations of a primary procedure code and add-on codes that are eligible for a complexity adjustment under the OPPS (as listed in OPPS Addendum J) would be eligible for this payment policy in the ASC setting. Specifically, we finalized that the ASC payment system code combinations eligible for additional payment under this policy would consist of a separately payable surgical procedure code and one or more packaged add-on codes from the ASC Covered Procedures List (CPL) and ancillary services list. Add-on codes were assigned payment indicator ''N1''

(Packaged service/item; no separate payment made), as listed in the ASC addenda.

Regarding eligibility for this special payment policy, we finalized that we would assign each eligible code combination a new C-code, which we will refer to as an ''ASC complexity adjustment code,'' that describes the primary and the add-on procedure(s) performed. C-codes are unique temporary codes and are only valid for claims for HOPD and ASC services and procedures. Under our policy, we add these ASC complexity adjustment codes to the ASC CPL and the ancillary services list, and when ASCs bill an ASC complexity adjustment code, they receive a higher payment rate that reflects that the code combination is a more complex and costlier version of the primary procedure performed. We anticipated that the ASC complexity adjustment codes eligible for this payment policy would change slightly each year, as the complexity adjustment assignments change under the OPPS; and we expect we would add new ASC complexity adjustment codes each year accordingly. In the CY 2023 OPPS/ASC final rule with comment period (87 FR 72079 and 72080), we finalized new ASC complexity adjustment codes to add to the ASC CPL, which were listed in the ASC addenda. We also finalized adding new regulatory text at § 416.172(h)(1), titled ''Eligibility,'' to codify this policy.

We finalized the following payment methodology for this policy, which we reflected in new § 416.172(h)(2), titled ''Calculation of payment.'' The ASC complexity adjustment codes are subject to all ASC payment policies, including the standard ASC payment system ratesetting methodology, meaning, they are treated the same way as other procedure codes in the ASC setting. For example, the multiple procedure discounting rules would apply to the primary procedure in cases where the services corresponding to the ASC complexity adjustment code are performed with another separately payable covered surgical procedure in the ASC setting. We finalized using the OPPS complexity-adjusted C–APC rate to determine the ASC payment rate for qualifying code combinations, similar to how we use OPPS APC relative weights in the standard ASC payment system ratesetting methodology. Under the ASC payment system, we used the OPPS APC relative payment weights to update the ASC relative payment weights for covered surgical procedures since ASCs do not submit cost reports. We then scaled those ASC relative weights for the ASC payment system to ensure budget neutrality. To calculate the ASC payment rates for most ASC covered surgical procedures, we multiplied the ASC conversion factor by the ASC relative payment weight. A more detailed discussion of this methodology is provided in the in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66828 through 66831).

We also finalized using the OPPS complexity-adjusted C–APC rate for each corresponding code combination to calculate the OPPS relative weight for each corresponding ASC complexity adjustment code, which we believed would appropriately reflect the complexity and resource intensity of these ASC procedures being performed together. For ASC complexity adjustment codes that are not assigned device-intensive status (discussed below), we multiply the OPPS relative weight by the ASC budget neutrality adjustment (or ASC weight scalar) to determine the ASC relative weight. We then multiply the ASC relative weight by the ASC conversion factor to determine the ASC payment rate for each ASC complexity adjustment code. In short, we apply the standard ASC ratesetting process to the ASC complexity adjustment codes. We finalized adding new § 416.172(h)(2)(i) to codify this policy.

As discussed in section XIII.C.1.b of the CY 2023 OPPS/ASC final rule with comment period (87 FR 44708), certain ASC complexity adjustment codes under our policy may include a primary procedure that also qualifies for device-intensive status under the ASC payment system. For primary procedures assigned device-intensive status that are a component of an ASC complexity adjustment code created under the proposal, we believe it is appropriate for the ASC complexity adjustment code to retain the device-intensive status of the primary procedure as well as the device portion (or device offset amount) of the primary procedure and not the device offset percentage. For example, if the primary procedure has a device offset percentage of 31 percent (a device offset percentage of greater than 30 percent would be needed to qualify for device-intensive status) and a device portion (or device offset amount) of $3,000, ASC complexity adjustment codes that included this primary procedure would be assigned device-intensive status and a device portion of $3,000 to be held constant with the OPPS. We apply our standard ASC payment system ratesetting methodology to the non-device portion of the OPPS complexity-adjusted APC rate of the ASC complexity adjustment codes; that is, we apply the ASC budget neutrality adjustment and ASC conversion factor. We believe assigning device-intensive status and transferring the device portion from the primary procedure's ASC payment rate to the ASC complexity adjustment code's ASC payment rate calculation is consistent with our treatment of device costs and determining device-intensive status under the ASC payment system and is an appropriate methodology for determining the ASC payment rate. The non-device portion would be the difference between the device portion of the primary procedure and the OPPS complexity-adjusted APC payment rate for the ASC complexity adjustment code based on the ASC standard ratesetting methodology. Although this may yield results where the device offset percentage is not greater than 30 percent of the OPPS complexity-adjusted APC payment rate, we believe this is an appropriate methodology to apply where primary procedures assigned device-intensive status are a component of an ASC complexity adjustment code. As is the case for all device-intensive procedures, we apply the ASC standard ratesetting methodology to the OPPS relative weights of the non-device portion for any ASC complexity adjustment code eligible for payment under the proposal. That is, we would multiply the OPPS relative weight by the ASC budget neutrality adjustment and the ASC conversion factor and sum that amount with the device portion to calculate the ASC payment rate. We finalized adding new § 416.172(h)(2)(ii) to codify this policy.

In order to include these ASC complexity adjustment codes in the budget neutrality calculations for the ASC payment system, we estimated the potential utilization for these ASC complexity adjustment codes. We do not have claims data for packaged codes in the ASC setting because ASCs do not report packaged codes under the ASC payment system. Therefore, we finalized estimating CY 2023 ASC utilization based upon how often these combinations are performed in the HOPD setting. Specifically, we used the ratio of the primary procedure volume to add-on procedure volume from CY 2021 OPPS claims and applied that ratio against ASC primary procedure utilization to estimate the increased spending as a result of our proposal for budget neutrality purposes. We believed this method would provide a reasonable estimate of the utilization of these code combinations in the ASC setting, as it is based on the specific code combination utilization in the OPPS. We anticipated that we would continue this estimation

process until we have sufficient claims data for the ASC complexity adjustment codes that can be used to more accurately calculate code combination utilization in ASCs, likely for the CY 2025 rulemaking.

For CY 2024, we proposed to continue the special payment policy and methodology for OPPS complexity-adjusted C–APCs that was finalized in the CY 2023 OPPS/ASC final rule with comment period (87 FR 72078 through 72080). The full list of the final ASC complexity adjustment codes for CY 2024 can be found in the ASC addenda and the supplemental policy file, which also includes both the existing ASC complexity adjustment codes and proposed additions, is published on the CMS website at *https://www.cms.gov/medicare/medicare-fee-for-service-payment/ascpayment/asc-regulations-and-notices.* Because the complexity adjustment assignments change each year under the OPPS, the proposed list of ASC complexity adjustment codes eligible for the proposed payment policy has changed slightly from the previous year.

Comment: Commenters who commented on to this policy were supportive of continuing the ASC complexity adjustment policy and urged CMS to finalize the proposal for CY 2024. They noted this policy was important in mitigating financial disincentives to perform critical services in the ASC and improving patient access.

Response: We thank the commenters for their support.

Comment: Several commenters disagreed with the C-code creation and descriptors and requested CMS delete these codes or change the descriptors to be consistent with the current CPT code descriptors. Commenters stated this could cause inaccurate reporting, inconvenience, and safety risk to patients in the OPPS setting.

Response: We note that there appears to be a misunderstanding. We created these C-codes solely for the ASC setting to allow for special complexity adjustments in this setting due to the limitations of the ASC claims processing systems. These codes cannot be billed in the OPPS setting, as they are assigned status indicator ''E1'' (Not paid by Medicare when submitted on outpatient claims (any outpatient bill type)).

Comment: Some commenters were concerned that the CY 2024 OPPS/ASC final rule would have fewer ASC complexity adjustment codes, relative to CY 2023. They recommended CMS continue to explore how the inherent costs of add-on services provided in the ASC could be more appropriately reflected in reimbursement, where add-on procedures could be unpackaged for clinical reasons, and how the ASC complexity adjustment policy can be applied more broadly to ensure appropriate payment in the ASC.

Response: We thank the commenters for their input. We will take these suggestions into consideration for future rulemaking.

After consideration of the public comments we received, we are finalizing the ASC special payment policy for OPPS complexity-adjusted C–APCs, as proposed. The final C codes for CY 2024 can be found in ASC Addendum AA.

d. Final Low Volume APCs and Limit on ASC Payment Rates for Procedures Assigned to Low Volume APCs

As stated in section XIII.D.1.b of the CY 2024 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. In the CY 2022 OPPS/ASC final rule with comment period (86 FR 63743 through 63747), we adopted a universal Low Volume APC policy for CY 2022 and subsequent calendar years. Under our policy, we expanded the low volume adjustment policy that is applied to procedures assigned to New Technology APCs to also apply to clinical and brachytherapy APCs. Specifically, a clinical APC or brachytherapy APC with fewer than 100 claims per year would be designated as a Low Volume APC. For items or services assigned to a Low Volume APC, we use up to 4 years of claims data to establish a payment rate for the APC as we currently do for low volume services assigned to New Technology APCs. The payment rate for a Low Volume APC or a low volume New Technology procedure would be based on the highest of the median cost, arithmetic mean cost, or geometric mean cost calculated using multiple years of claims data.

Based on claims data available for the CY 2024 OPPS/ASC proposed rule, we proposed to designate four clinical APCs and five brachytherapy APCs as Low Volume APCs under the ASC payment system (88 FR 49753). The four clinical APCs and five brachytherapy APCs shown in Table 57 of the CY 2024 OPPS/ASC proposed rule (88 FR 49753) met our criteria of having fewer than 100 single claims in the claims year (CY 2022 for the CY 2024 OPPS/ASC proposed rule) and therefore, we proposed that they would be subject to our universal Low Volume APC policy and the APC cost metric would be based on the greater of the median cost, arithmetic mean cost, or geometric mean cost using up to 4 years of claims data. Eight of the nine APCs were designated as low volume APCs in CY 2023. In addition, based on data for the CY 2024 OPPS/ASC proposed rule, APC 2642 (Brachytx, stranded, C–131) met our criteria to be designated a Low Volume APC, and we proposed to designate it as such for CY 2024.

We did not receive any public comments on our proposal to assign the 4 clinical APCs and 5 brachytherapy APCs as Low Volume APCs under the ASC payment system. Based on claims data available for this final rule with comment period, we are finalizing our proposal to designate the 4 clinical APCs and 5 brachytherapy APCs shown in Table 116 as Low Volume APCs under the ASC payment system, because they continue to meet our criteria of having fewer than 100 single claims in the relevant claims year (2022). The APC cost metric for these APCS is based on the greatest of the median cost, arithmetic mean cost, or geometric mean cost using up to 4 years of claims data, as proposed.

TABLE 116: COST STATISTICS FOR FINAL LOW VOLUME APCS STANDARD (ASC) RATESETTING METHODOLOGY FOR CY 2024

APC	APC Description	CY 2022 Claims Available for Ratesetting	Geometric Mean Cost without Low Volume APC Designation	Final Median Cost	Final Arithmetic Mean Cost	Final Geometric Mean Cost	Final CY 2024 APC Cost
2632	Iodine I-125 sodium iodide	0	---*	$31.74	$61.83	$41.06	$61.83
2635	Brachytx, non-str, HA, P-103	21	$97.56	$58.38	$60.78	$54.74	$60.78
2636	Brachy linear, non-str, P-103	1	$60.16	$22.17	$55.57	$32.95	$55.57
2642	Brachytx, stranded, C-131	82	$121.08	$76.36	$100.23	$79.27	$100.23
2647	Brachytx, NS, Non-HDRIr-192	2	$415.40	$201.69	$358.12	$166.75	$358.12
5244	Level 4 Blood Product Exchanges and Related Services	2	$9,420.45	$41,345.37	$37,634.66	$30,857.68	$41,345.37
5494	Level 4 Intraocular Procedures	8	$12,945.59	$12,458.11	$12,279.01	$11,685.91	$12,458.11
5495	Level 5 Intraocular Procedures	70	$3,463.28	$3,241.74	$3,813.82	$3,160.33	$3,813.82
5496	Level 6 Intraocular Procedures	12	$12,351.69	$17,388.10	$16,543.62	$14,492.80	$17,388.10

* For this CY 2024 OPPS/ASC final rule, there were no CY 2022 claims that contain the HCPCS code assigned to APC 2632 (HCPCS code A9527) that were available for CY 2024 OPPS/ASC ratesetting.

2. 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 and 68458), we further clarified our policy regarding the payment indicator assignment for 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 the CY 2022 OPPS/ASC proposed rule (86 FR 42083)). Thus, our policy generally aligns ASC payment bundles with those under the OPPS (72 FR 42495). In all cases, in order for ancillary items and services also to be paid, the 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 the CY 2022 OPPS/ASC final rule with comment period, for CY 2022, we finalized a policy to unpackage and pay separately at ASP plus 6 percent for the cost of non-opioid pain management drugs and biologicals that function as a supply when used in a surgical procedure as determined by CMS under § 416.174 (86 FR 63483).

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, 42508, and 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 and 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 and 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. Final Payment for Covered Ancillary Services for CY 2024

We did not receive any public comments on and are finalizing our proposal 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 final CY 2024 OPPS and ASC payment rates and subsequent years' payment rates. We did not receive any public comments on and are also finalizing our proposal to continue to set the CY 2024 ASC payment rates and subsequent years' payment rates for brachytherapy sources and separately payable drugs and biologicals equal to the OPPS payment rates for CY 2024 and subsequent years' payment rates.

Covered ancillary services and their final payment indicators for CY 2024 are listed in Addendum BB of this final 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 rate under the ASC standard rate setting methodology and the PFS proposed rates (similar to our office-based payment policy), the final payment indicators and rates set forth in this final rule with comment period are based on a comparison using the final PFS rates effective January 1, 2024. For a discussion of the PFS rates, we refer readers to the CY 2024 PFS final rule.

3. Covered Surgical Procedures Designated as Office-Based Procedures

a. 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 with 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 ASC standard ratesetting 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 nonoffice-based, after taking into account updated volume and utilization data.

b. CY 2024 Final Office-Based Procedures

In developing this CY 2024 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 of this rule), including their potential designation as office-based. Historically, we would also review the most recent claims volume and utilization data (CY 2022 claims) and the clinical characteristics for all covered surgical procedures that are currently assigned a payment indicator in CY 2023 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 2022 OPPS/ASC final rule with comment period (86 FR 63769 through 63773).

In our CY 2022 OPPS/ASC final rule with comment period (86 FR 63770), we discussed that we, historically, review the most recent claims volume and utilization data and clinical characteristics for all covered surgical procedures that were assigned a payment indicator of ''G2'' for CY 2021. For the CY 2022 OPPS/ASC final rule with comment period, the most recent claims volume and utilization data was CY 2020 claims. However, given our concerns with the use of CY 2020 claims data as a result of the COVID–19 PHE as further discussed in the CY 2022 OPPS/ASC final rule with comment period (86 FR 63751 through 63754), we adopted a policy to not review CY 2020 claims data and did not assign permanent office-based designations to covered surgical procedures that were assigned a payment indicator of ''G2'' in CY 2021 (86 FR 63770 and 63771).

As discussed further in section X.D of the CY 2023 OPPS/ASC proposed rule (87 FR 44680 through 44682), in our review of the CY 2021 outpatient claims available for ratesetting for this CY 2023 OPPS proposed rule, we observed that many outpatient service volumes have partially returned to their pre-PHE levels; and it is reasonable to assume that there will continue to be some effects of the COVID–19 PHE on the outpatient claims that we use for OPPS ratesetting. As a result, we proposed to use the CY 2021 claims for CY 2023 OPPS ratesetting. Similarly, in the CY 2023 OPPS/ASC proposed rule (87 FR 44705 through 44708), we proposed to resume our historical practice and review the most recent claims and utilization data, in this case data from CY 2021 claims, for determining office-based assignments under the ASC payment system.

Our review of the CY 2022 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 the identification of two surgical procedures that we believed met 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 the services are of a level of complexity consistent with other procedures performed routinely in physicians' offices. The CPT codes that we proposed to permanently designate as office-based for CY 2024 are listed in Table 117.

TABLE 117: ASC COVERED SURGICAL PROCEDURES PROPOSED TO BE NEWLY DESIGNATED AS PERMANENTLY OFFICE-BASED FOR CY 2024

CY 2023 CPT/HCPCS Code	Long Descriptor	Final CY 2023 ASC Payment Indicator	Proposed CY 2024 ASC Payment Indicator*
0448T	Removal of implantable interstitial glucose sensor with creation of subcutaneous pocket at different anatomic site and insertion of new implantable sensor, including system activation	G2	P2*
38232	Bone marrow harvesting for transplantation; autologous	G2	R2*

* Payment indicators were based on a comparison of the proposed rates according to the ASC standard ratesetting methodology and the CY 2024 PFS proposed rates. For a discussion of the proposed PFS rates, we refer readers to the CY 2024 PFS proposed rule.

Comment: A few commenters do not support the assignment of CPT code 15275 ((Application of skin substitute graft to face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet, and/or multiple digits, total wound surface area up to 100 sq cm; first 25 sq cm or less wound surface area)) to a permanent office-based designation. Commenters did not believe was appropriate to assign office-based status to a code in which items are packaged in the OPPS and ASC but not packaged in the physician office, as payment is typically less in the physician office setting. Commenters requested CMS assign CPT code 15275 to a non office-based surgical procedure payment indicator ''G2''.

Response: We are not accepting the commenters' recommendation. We assign procedures to be permanently designated as office-based based on physician claims that report the procedure across all settings of care, both inpatient and outpatient. If the office-based utilization exceeds 50

percent of total utilization across all settings of care and total utilization exceeds 50 claims, we propose such procedures be permanently designated as office-based unless the procedure otherwise may be designated as device-intensive. As we stated in the CY 2023 OPPS/ASC final rule with comment period (87 FR 72060), the volume for this procedure in the physician office setting was more than sufficient to make a permanent office-based designation to CPT code 15275 under our current policy.

After consideration of the comments we received, we are finalizing our proposal, without modification, to permanently designate the procedures in Table 118 as office-based procedures.

TABLE 118: ASC COVERED SURGICAL PROCEDURES TO BE NEWLY DESIGNATED AS PERMANENTLY OFFICE-BASED FOR CY 2024

CY 2024 CPT/HCPCS Code	Long Descriptor	Final CY 2023 ASC Payment Indicator	Final CY 2024 ASC Payment Indicator*
0448T	Removal of implantable interstitial glucose sensor with creation of subcutaneous pocket at different anatomic site and insertion of new implantable sensor, including system activation	G2	P2*
38232	Bone marrow harvesting for transplantation; autologous	G2	R2*

* Payment indicators were based on a comparison of the final rates according to the ASC standard ratesetting methodology and the CY 2024 PFS final rates. For a discussion of the final PFS rates, we refer readers to the CY 2024 PFS final rule.

As discussed in the August 2, 2007 ASC final rule (72 FR 42533 through 42535), we finalized our policy to designate certain new surgical procedures as temporarily office-based until adequate claims data are available to assess their predominant sites of service, whereupon if we confirm their office-based nature, the procedures are permanently assigned to the list of office-based procedures. In the absence of claims data, we 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.

We reviewed CY 2022 volume and utilization data for nine surgical procedures designated as temporarily office-based in the CY 2023 OPPS/ASC final rule with comment period and temporarily assigned one of the office-based payment indicators, specifically ''P2,'' ''P3,'' or ''R2.'' As shown in Table 119, for four of the nine surgical procedures, there were greater than 50 claims available and the volume and utilization data indicated these four procedures were performed predominantly in the office setting. Therefore, we proposed to no longer designate the four procedures as temporarily office-based but to permanently designate these procedures as office-based and assign one of the office-based payment indicators, specifically ''P2,'' ''P3,'' or ''R2.''

Additionally, for one of the nine surgical procedures, there were greater than 50 claims available; and the volume and utilization data indicated that this procedure—CPT code 64454 (Injection(s), anesthetic agent(s) and/or steroid; genicular nerve branches, including imaging guidance, when performed)—is not performed predominantly in the office setting. Therefore, as shown in Table 59, we proposed to no longer designate this procedure as temporarily office-based. For CY 2024, we proposed to assign this procedure a payment indicator of ''G2'' (Non office-based surgical procedure added in CY 2008 or later; payment based on OPPS relative payment weight).

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TABLE 119: ASC COVERED SURGICAL PROCEDURES PROPOSED TO BE NO LONGER DESIGNATED AS TEMPORARILY OFFICE-BASED FOR CY 2024

CY 2024 CPT/HCPCS Code	Long Descriptor	Final CY 2023 ASC Payment Indicator	Proposed CY 2024 ASC Payment Indicator*
0402T	Collagen cross-linking of cornea, including removal of the corneal epithelium, when performed, and intraoperative pachymetry, when performed	R2	R2*
0512T	Extracorporeal shock wave for integumentary wound healing, including topical application and dressing care; initial wound	R2	R2*
64454	Injection(s), anesthetic agent(s) and/or steroid; genicular nerve branches, including imaging guidance, when performed	P3	G2
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 were based on a comparison of the final rates according to the ASC standard ratesetting methodology and the CY 2024 PFS final rates. For a discussion of the final PFS rates, we refer readers to the CY 2024 PFS final rule.

We did not receive any public comments on our proposal to no longer designate the procedures listed in Table 120 as temporarily office-based and permanently designate these procedures as office-based procedures. Therefore, we are finalizing our proposal, without modification, to designate the procedures shown in Table 120 as permanently office-based for CY 2024.

TABLE 120: CY 2024 PAYMENT INDICATORS FOR ASC COVERED SURGICAL PROCEDURES DESIGNATED AS PERMANENTLY OFFICE-BASED

CY 2024 CPT/HCPCS Code	Long Descriptor	Final CY 2023 ASC Payment Indicator	Final CY 2024 ASC Payment Indicator*
0402T	Collagen cross-linking of cornea, including removal of the corneal epithelium, when performed, and intraoperative pachymetry, when performed	R2	R2*
0512T	Extracorporeal shock wave for integumentary wound healing, including topical application and dressing care; initial wound	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 were based on a comparison of the final rates according to the ASC standard ratesetting methodology and the CY 2024 PFS final rates. For a discussion of the final PFS rates, we refer readers to the CY 2024 PFS final rule.

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For four of the nine procedures that were designated as temporarily office-based in the CY 2023 OPPS/ASC final rule with comment period and temporarily assigned one of the office-based payment indicators, specifically ''P2,'' ''P3,'' or ''R2,'' there were fewer than 50 claims; therefore, there was an insufficient amount to determine if the office setting was the predominant setting of care for these procedures. Therefore, as shown in Table 121, we proposed to continue to designate such procedures as temporarily office-based for CY 2024 and assign one of the office-based payment indicators.

For CY 2024, we proposed to designate three new CY 2024 CPT codes for ASC covered surgical procedures as temporarily office-based—CPT codes 67516 (CPT placeholder code 6X000), 64598 (CPT placeholder code 64XX4), and 0864T (CPT placeholder code X170T). After reviewing the clinical characteristics, utilization, and volume of related procedure codes or predecessor codes, we determined that the predecessor code for CPT placeholder code 67516 (Suprachoroidal space injection of pharmacologic agent (separate procedure)) is CPT code 0465T (Suprachoroidal injection of a pharmacologic agent (does not include supply of medication)), which was designated as an office-based procedure. Additionally, CPT placeholder code 64598 (Revision or removal of neurostimulator electrode array, peripheral nerve, with integrated neurostimulator) is most similar to CPT code 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), which is also designated as temporarily office-based. Lastly, CPT placeholder code 0864T (Low-intensity extracorporeal shock wave therapy involving corpus cavernosum, low energy) is most similar to CPT code 0101T (Extracorporeal shock wave involving musculoskeletal system, not otherwise specified) which is designated as an office-based surgical procedure. Therefore, as shown in Table 121, we proposed to designate these three new CPT codes as temporarily office-based for CY 2024.

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TABLE 121: PROPOSED CY 2024 PAYMENT INDICATORS FOR NEW AND EXISTING ASC COVERED SURGICAL PROCEDURES DESIGNATED AS TEMPORARILY OFFICE-BASED

CY 2024 CPT/HCPCS Code	Long Descriptor	Final CY 2023 ASC Payment Indicator	Proposed CY 2024 ASC Payment Indicator*
0581T	Ablation, malignant breast tumor(s), percutaneous, cryotherapy, including imaging guidance when performed, unilateral	R2	R2*
67516	Suprachoroidal space injection of pharmacologic agent (separate procedure)	NA	P3*
64598	Revision or removal of neurostimulator electrode array, peripheral nerve, with integrated neurostimulator	NA	R2*
65785	Implantation of intrastromal corneal ring segments	P2	P3*
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 (e.g., retinopathy of prematurity), photocoagulation or cryotherapy	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*
0864T	Low-intensity extracorporeal shock wave therapy involving corpus cavernosum, low energy	NA	R2*

* Payment indicators were based on a comparison of the final rates according to the ASC standard ratesetting methodology and the CY 2024 PFS final rates. For a discussion of the final PFS rates, we refer readers to the CY 2024 PFS final rule.

Comment: One commenter supported our proposal to assign a temporary office-based designation to CPT code 0864T (Low-intensity extracorporeal shock wave therapy involving corpus cavernosum, low energy).

Response: We appreciate the commenter's support of our office-based designation for CPT code 0864T.

After consideration of the public comment we received, we are finalizing our proposal to designate the procedures shown in Table 122 as temporarily office-based for CY 2024.

The procedures for which the final office-based designation for CY 2024 is temporary are indicated by an asterisk in Addendum AA to this final rule (which is available via the internet on the CMS website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ASCPayment/ASC-Regulations-and-Notices).*

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TABLE 122: FINAL CY 2024 PAYMENT INDICATORS ASC COVERED SURGICAL PROCEDURES DESIGNATED AS TEMPORARILY OFFICE-BASED

CY 2024 Placeholder Code	Long Descriptor	Final CY 2023 ASC Payment Indicator	Final CY 2024 ASC Payment Indicator*
0581T	Ablation, malignant breast tumor(s), percutaneous, cryotherapy, including imaging guidance when performed, unilateral	R2	R2*
67516	Suprachoroidal space injection of pharmacologic agent (separate procedure)	NA	P3*
64598	Revision or removal of neurostimulator electrode array, peripheral nerve, with integrated neurostimulator	NA	R2*
65785	Implantation of intrastromal corneal ring segments	P2	P3*
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 (e.g., retinopathy of prematurity), photocoagulation or cryotherapy	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*
0864T	Low-intensity extracorporeal shock wave therapy involving corpus cavernosum, low energy	NA	R2*

* Payment indicators were based on a comparison of the final rates according to the ASC standard ratesetting methodology and the CY 2024 PFS final rates. For a discussion of the final PFS rates, we refer readers to the CY 2024 PFS final rule.

4. Device-Intensive ASC Covered Surgical Procedures

a. 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.

b. CY 2024 Final Device Intensive Procedures

In the CY 2019 OPPS/ASC final rule with comment period (83 FR 59040 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. The device offset percentage is the percentage of device costs within a procedure's total costs. 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 or insertable 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 and involve 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 the 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 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 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).

In the CY 2022 OPPS/ASC final rule with comment period (86 FR 63773 through 63775), we modified our approach to assigning device-intensive status to surgical procedures under the ASC payment system. First, we adopted a policy of assigning device-intensive status to procedures that involve surgically inserted or implanted, high-cost, single-use devices if their device offset percentage exceeds 30 percent under the ASC standard ratesetting methodology, even if the procedure is not designated as device-intensive under the OPPS. Second, we adopted a policy that if a procedure is assigned device-intensive status under the OPPS, but has a device offset percentage below the device-intensive threshold under the standard ASC ratesetting methodology, the procedure will be assigned device-intensive status under the ASC payment system with a default device offset percentage of 31 percent. The policies were adopted to provide consistency between the OPPS and ASC payment system and provide a more appropriate payment rate for surgical procedures with significant device costs under the ASC payment system.

In the CY 2023 OPPS/ASC final rule with comment period (87 FR 72078 through 72080), we finalized our policy to create certain C-codes, or ASC complexity adjustment codes that describe certain combinations of a primary covered surgical procedure as well as a packaged (payment indicator = ''N1'') procedure that are otherwise eligible for a complexity adjustment under the OPPS (as listed in Addendum J). Each ASC complexity adjustment code's APC assignment is based on its corresponding OPPS complexity adjustment code's APC assignment. In the CY 2023 OPPS/ASC final rule with comment period, we stated our belief that it would be appropriate for these ASC complexity adjustment codes to qualify for device-intensive status under the ASC payment system if the primary procedure of the code was also designated as device-intensive. Under our current policy, the ASC complexity adjustment code would retain the device portion of the primary procedure (also called the ''device offset amount'') and not the device offset percentage. Therefore, for device-intensive ASC complexity adjustment codes, we set the device portion of the combined procedure equal to the device portion of the primary procedure and calculate the device offset percentage by dividing the device portion by the ASC complexity adjustment code's APC payment rate. Further, we apply our standard ASC payment system ratesetting methodology to the non-device portion of the ASC complexity adjustment code's APC payment rate; that is, we multiply the OPPS relative weight by the ASC budget neutrality adjustment and the ASC conversion factor and sum that amount with the device portion to calculate the ASC payment rate.

We did not propose any changes related to designating surgical procedures as device-intensive under the ASC payment system for CY 2024.

Comment: Some commenters recommended that we refrain from wage-adjusting the device portion of device-intensive procedures by the wage index for that particular area and only wage-adjust non device portions of the ASC payment rate. The commenters contend that wage-adjusting 50 percent of the ASC payment rate by the wage index for a particular area can reduce ASC payment rates below the cost of certain devices.

Response: We appreciate the commenters' recommendation. We did not propose such a change to our application of the ASC wage index but, as we stated in the CY 2019 OPPS/ASC final rule with comment period (83 FR 59042), such a policy would increase payment for providers with a relatively low wage index (that is, a wage index value of less than 1) and decrease it for providers with a relatively high wage index (that is, a wage index value of greater than 1). We will consider the feasibility of this change and take this comment into consideration for future rulemaking.

Comment: One commenter requested that we consider a modification to our established policy that would allow the continuation of the default device offset of 31 percent for procedures for which there were fewer than 100 claims used to calculate the device offset percentage.

Response: We appreciate the commenter's request. We are concerned that such a policy would inaccurately assign device-intensive status to procedures that would otherwise consistently be ineligible for device-intensive assignment. While we do not believe at this time that continuing the default device offset percentage over available claims data for procedures for which there are fewer than 100 claims would be an improvement to our methodology for determining device offset amounts and device-intensive status for such procedures; however, we will take this comment into consideration for future rulemaking.

Comment: Commenters requested that we assign device-intensive status to the following procedures:

- CPT code 0581T (Ablation, malignant breast tumor(s), percutaneous, cryotherapy, including imaging guidance when performed, unilateral)
- CPT code 31242 (Nasal/sinus endoscopy, surgical; with destruction by radiofrequency ablation, posterior nasal nerve)
- CPT code 52284 (Cystourethroscopy, with mechanical urethral dilation and urethral therapeutic drug delivery by drug-coated balloon catheter for urethral stricture or stenosis, male, including fluoroscopy, when performed)
- CPT code 53854 (Transurethral destruction of prostate tissue; by radiofrequency generated water vapor thermotherapy)
- HCPCS code C9757 (Laminotomy (hemilaminectomy), with decompression of nerve root(s), including partial facetectomy, foraminotomy and excision of herniated intervertebral disc, and repair of annular defect with implantation of bone anchored annular closure device, including annular defect measurement, alignment and sizing assessment, and image guidance; 1 interspace, lumbar);
- HCPCS code C9761 (Cystourethroscopy, with ureteroscopy and/or pyeloscopy, with lithotripsy, and ureteral catheterization for steerable vacuum aspiration of the kidney, collecting system, ureter, bladder, and urethra if applicable (must use a steerable ureteral catheter)

Response: Based on CY 2022 claims data available for this final rule, the procedures requested by commenters do not have device offset percentages that exceed the 30-percent threshold required for device-intensive status under the OPPS or ASC payment system and, therefore, are not eligible to be assigned device-intensive status.

Comment: Commenters supported the proposed device offset percentages for the following procedures:

- CPT code 0627T (Percutaneous injection of allogeneic cellular and/or tissue-based product, intervertebral disc, unilateral or bilateral injection, with fluoroscopic guidance, lumbar; first level)
- CPT code 0671T (Insertion of anterior segment aqueous drainage device into the trabecular meshwork, without external reservoir, and without concomitant cataract removal, one or more)
- CPT code 66989 (Extracapsular cataract removal with insertion of intraocular lens prosthesis (1-stage procedure), manual or mechanical technique (*e.g.,* irrigation and aspiration or phacoemulsification), complex, requiring devices or techniques not generally used in routine cataract surgery (*e.g.,* iris expansion device, suture support for intraocular lens, or primary posterior capsulorrhexis) or performed on patients in the amblyogenic developmental stage; with insertion of intraocular (*e.g.,* trabecular meshwork, supraciliary, suprachoroidal) anterior segment aqueous drainage device, without extraocular reservoir, internal approach, one or more)
- CPT code 66991(Extracapsular cataract removal with insertion of intraocular lens prosthesis (1 stage procedure), manual or mechanical technique (*e.g.,* irrigation and aspiration or phacoemulsification); with insertion of intraocular (*e.g.,* trabecular meshwork, supraciliary, suprachoroidal) anterior segment aqueous drainage device, without extraocular reservoir, internal approach, one or more)
- CPT code 58356 (Endometrial cryoablation with ultrasonic guidance, including endometrial curettage, when performed)
- CPT code 31242 (Nasal/sinus endoscopy, surgical; with destruction by radiofrequency ablation, posterior nasal nerve)
- CPT code 31243 (Nasal/sinus endoscopy, surgical; with destruction by cryoablation, posterior nasal nerve)
- CPT code 31295 (Nasal/sinus endoscopy, surgical, with dilation (*e.g.,* balloon dilation); maxillary sinus ostium, transnasal or via canine fossa)
- HCPCS code C9757 (Laminotomy (hemilaminectomy), with decompression of nerve root(s), including partial facetectomy, foraminotomy and excision of herniated intervertebral disc, and repair of annular defect with implantation of bone anchored annular closure device, including annular defect measurement, alignment and sizing assessment, and image guidance; 1 interspace, lumbar);
- HCPCS code C9781 (Arthroscopy, shoulder, surgical; with implantation of subacromial spacer (*e.g.,* balloon), includes debridement (*e.g.,* limited or extensive), subacromial decompression, acromioplasty, and biceps tenodesis when performed)

Response: We appreciate the commenters' support. We are finalizing our proposed device offset amounts for CPT codes 0627T, 0671T, 66989, 66991, 58356, 31242, 31243, 31295 and HCPCS codes C9757 and C9781. For final CY 2024 device offset percentages based on available claims data for this final rule with comment period, we refer readers to Addendum FF of this final rule with comment period.

Comment: Two commenters requested that we increase the device offset for CPT code 0629T (Percutaneous injection of allogeneic cellular and/or tissue-based product, intervertebral disc, unilateral or bilateral injection, with ct guidance, lumbar; first level) to be in alignment with CPT code 0627T (Percutaneous injection of allogeneic cellular and/or tissue-based product, intervertebral disc, unilateral or bilateral injection, with fluoroscopic guidance, lumbar; first level) as both procedures use the same device.

Response: We thank the commenters for their suggestion. We stated in the CY 2023 OPPS/ASC final rule with comment period (87 FR 71941) that we did not have any claims data for CPT code 0629T to determine a device offset percentage. Under our current policy, we may assign an alternative device offset percentage if we have claims data from a clinically similar procedure code that uses the same device; however, since we have claims data for CPT code 0629T to determine a device offset percentage under the ASC payment system, we are not accepting the commenters' recommendation.

Comment: One commenter requested that we increase the device offset amount for CPT code 30469 (Repair of nasal valve collapse with low energy, temperature-controlled (*i.e.,* radiofrequency) subcutaneous/submucosal remodeling), and asked that we align the device offset amount with the valuation that CMS has adopted for the cost of the VivAer Stylus device under the 2024 Physician Fee Schedule.

Response: We are not accepting the commenter's recommendation. While we do not have claims data to determine a device offset percentage for CPT code 30469, in the absence of available claims data, predecessor code data, or a clinically similar code that utilizes the same device, our established policy is to assign a default device offset percentage of 31 percent for procedures that we believe have significant device costs and that otherwise meet our device-intensive criteria. We believe our proposed default device offset percentage of 31 percent for CPT code 30469 for CY 2024 provides a reasonable and appropriate device offset amount until claims data become available.

Comment: Several commenters requested that we assign the new CPT codes 0816T (Open insertion or replacement of integrated neurostimulation system for bladder dysfunction including electrode(s) (*e.g.,* array or leadless), and pulse generator or receiver, including analysis, programming, and imaging guidance, when performed, posterior tibial nerve; subcutaneous) and 0817T (Open insertion or replacement of integrated neurostimulation system for bladder dysfunction including electrode(s) (*e.g.,* array or leadless), and pulse generator or receiver, including analysis, programming, and imaging guidance, when performed, posterior tibial nerve; subfascial) to the same device offset percentage as CPT code 64590, instead of the default 31 percent. The commenters state that the services described by these codes were previously billed using CPT code 64590 (Insertion or replacement of peripheral or gastric neurostimulator pulse generator or receiver, direct or inductive coupling).

Response: We are not accepting the commenters' recommendation. While we may assign device-intensive status to new procedures that have significant device costs, we generally assign the default device offset percentage of 31 percent of total procedure costs until such claims data becomes available. However, if there is available claims data from the predecessor code of a new procedure or claims data from a clinically similar procedure that uses the same device, our current policy allows us to use this proxy claims data to establish a device offset percentage in lieu of the default 31 percent. We do not agree that CPT code 64590 was the predecessor code for either CPT code 0816T and 0817T and believe that CPT code 64999 (Unlisted procedure,

nervous system) was the CPT code previously used when reporting the procedures described by the new CPT codes 0816T and 0817T. CPT code 64999 does not exceed our device-intensive threshold under the OPPS or ASC payment system, and, since this CPT code can be used for various types of unlisted surgical procedures of the nervous system, we do not believe this procedure would be an accurate reflection of the device costs of CPT code 0816T and 0817T. Since 0816T and 0817T do not have claims data from a predecessor code or a similar code that uses the same device, we are finalizing our proposal to assign the default 31 percent device offset percentage for CY 2024.

Comment: One commenter requested that we assign HCPCS code C9734 (Focused ultrasound ablation/therapeutic intervention, other than uterine leiomyomata, with magnetic resonance (mr) guidance) to payment indicator ''J8'' and the default device offset of 31 percent.

Response: We are finalizing the addition of HCPCS code C9734 to the ASC CPL for CY 2024. After reviewing the clinical characteristics of the procedure, we agree with the commenter that HCPCS C9734 meets the requirements to be assigned device-intensive status. Therefore, we are accepting the commenter's recommendation and are assigning device-intensive status with a default device offset percentage of 31 percent to HCPCS code C9734 and assigning a payment indicator of ''J8,'' which indicates a device-intensive procedure, for CY 2024.

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. ASC payment is reduced 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 amount of 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 device-intensive covered surgical 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 appends the HCPCS ''FB'' modifier on the line in the claim with the procedure to implant or insert the device. The contractor reduces 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.

In the CY 2019 OPPS/ASC final rule with comment period (83 FR 59043 and 59044) 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 CY 2019 and subsequent calendar years. Therefore, we finalized our proposal 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 2022 and subsequent calendar years (86 FR 63775 through 63776). Specifically, for CY 2022 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 did not receive any comments on our policies related to no/cost full credit or partial credit devices, and we are continuing our existing policies for CY 2024.

5. Requirement in the Physician Fee Schedule CY 2024 Proposed Rule for HOPDs and ASCs To Report Discarded Amounts of Certain Single-Dose or Single-Use Package Drugs

Section 90004 of the Infrastructure Investment and Jobs Act (Pub. L. 117–9, November 15, 2021) (''the Infrastructure Act'') amended section 1847A of the Act to re-designate subsection (h) as subsection (i) and insert a new subsection (h), which requires manufacturers to provide a refund to CMS for certain discarded amounts from a refundable single-dose container or single-use package drug. The CY 2024 PFS proposed rule includes proposals to operationalize section 90004 of the Infrastructure Act, including a proposal that impacts hospital outpatient departments (HOPDs) and ambulatory surgical centers (ASCs). Similar to our CY 2023 notice in the OPPS/ASC proposed rule (87 FR 71988), we wanted to ensure interested parties were aware of these proposals and knew to refer to the CY 2024 Physician Fee Schedule proposed rule for a full description of the proposed policy. Interested parties were asked to submit comments on any proposals to implement section 90004 of the Infrastructure Act to the CY 2024 PFS proposed rule. Public comments on these proposals are addressed in the CY 2024 PFS final rule with comment period. We note that this same notice appears in section V.C of this final rule.

As explained in the CY 2024 OPPS/ASC proposed rule (88 FR 49759), because the CY 2024 PFS proposed rule discussed and proposed to codify certain billing requirements for HOPDs and ASCs, we explained that we wanted to ensure interested parties were aware of them and knew to refer to that rule for a full description of the proposed policy. Interested parties were asked to submit comments on this and any other proposals to implement section 90004 of the Infrastructure Act in response to the CY 2024 PFS proposed rule. We stated that public comments on the proposals would be addressed in the CY 2024 PFS final rule.

We thank commenters for their feedback. For final details on this policy, we refer readers to the CY 2024 PFS final rule.

6. Payment Amount and Beneficiary Coinsurance for Part B Rebatable Drugs

On August 16, 2022, the Inflation Reduction Act of 2022 (IRA) (Pub. L. 117–169) was signed into law. Section 11101 of the IRA requires a Part B inflation rebate for a Part B rebatable drug if the Medicare payment amount, which is generally ASP plus 6 percent, if the drug rises at a rate that is faster than the rate of inflation. It also establishes changes to the Medicare payment rate and beneficiary coinsurance for such drugs under the ASC payment system. We refer the reader to the discussion of this policy and changes to the regulatory text, which are discussed in further detail in section II.H.I of this final rule.

D. Additions to ASC Covered Surgical Procedures and Covered Ancillary Services Lists

1. 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 also be safely performed in an ASC, a CAH, or an HOPD, and to review and update the list of ASC covered surgical procedures at least every two 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 regulations at §§ 416.2 and 416.166, covered surgical procedures furnished on or after January 1, 2022, are surgical procedures that meet the general standards specified in § 416.166(b) and are not excluded under the general exclusion criteria specified in § 416.166(c). Specifically, under § 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.

Section 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 § 419.22(n); (7) can only be reported using a CPT unlisted surgical procedure code; or (8) are otherwise excluded under § 411.15.

In the CY 2019 OPPS/ASC final rule with comment period (83 FR 59029 and 59030), we defined 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 determined met the general standards established in previous years for addition to the ASC CPL.

For a detailed discussion of the history of our policies for adding surgical procedures to the ASC CPL, we refer readers to the CY 2021, CY 2022, and CY 2023 OPPS/ASC final rules with comment period (85 FR 86143 through 86145; 86 FR 63777 through 63805, 87 FR 72068 through 72076).

2. Final Changes to the List of ASC Covered Surgical Procedures for CY 2024

Our current policy, which includes consideration of the general standards and exclusion criteria we have historically used to determine whether a surgical procedure should be added to the ASC CPL, is intended to ensure that surgical procedures added to the ASC CPL can be performed safely in the ASC setting on the typical Medicare beneficiary. In the CY 2023 OPPS/ASC final rule with comment period, we received requests to add dental surgeries furnished in the ASC setting to the ASC CPL (87 FR 71882). In response to these public comments, we noted that if a dental service is covered under Medicare Part B and meets the criteria for the ASC CPL (set forth at 42 CFR 416.166), then it could be added to the ASC CPL, and that we would take additional dental procedures into consideration for future rulemaking. For CY 2024, we conducted a review of procedures that currently are paid under the OPPS and not included on the ASC CPL. We also assessed procedures against our regulatory safety criteria at § 416.166. Based upon this review, we proposed to update the ASC CPL by adding 26 dental surgical procedures to the list for CY 2024, as shown in Table 123 below.

After reviewing the clinical characteristics of these procedures, as well as consulting with stakeholders and multiple 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. These procedures are clinically similar to procedures in the CPT surgical range that we determined met the general standards for addition to the ASC CPL. These procedures are not excluded from being included on the ASC CPL because they do not generally result in extensive blood loss, require major or prolonged invasion of body cavities, commonly require systemic thrombolytic therapy, or directly involve major blood vessels; are not generally emergent or life-threatening in nature or designated as requiring inpatient care; or can only be reported using a CPT unlisted surgical procedure code or are otherwise excluded under Medicare. Therefore, we believed these procedures may all be appropriately performed in an ASC and proposed to include them on the ASC CPL for CY 2024.

We note that there are statutory and regulatory limitations regarding Medicare coverage and payment for dental services. Section 1862(a)(12) of the Act generally precludes Medicare Part A or Part B payment for services in connection with the care, treatment, filling, removal, or replacement of teeth or structures directly supporting teeth (collectively referred to in this section as ''dental services''). The regulation at § 411.15(i) similarly prohibits payment for dental services. In the CY 2023 PFS final rule (87 FR 69663), we explained that there are certain instances where dental services are so integral to other medically necessary services that they are not in connection with dental services within the meaning of section 1862(a)(12) of the Act. Rather, such dental services are inextricably linked to, and substantially related to the clinical success of, other covered services (hereafter in this section, ''inextricably linked''). To provide greater clarity to current policies, the CY 2023 PFS final rule finalized: (1) a clarification of our interpretation of section 1862(a)(12) of the Act to permit payment for dental services that are inextricably linked to other covered services; (2) clarification and codification of certain longstanding Medicare FFS payment policies for dental services that are inextricably linked to other covered services; (3) that, beginning for CY 2023, Medicare Parts A and B payment can be made for certain dental services inextricably linked to Medicare-covered organ transplant, cardiac valve replacement, or valvuloplasty procedures; and, (4) beginning for CY 2024, that Medicare Parts A and B payment can be made for certain dental services inextricably linked to Medicare-covered services for treatment of head and neck cancers (87 FR 69670 and 69671). For the ASC setting, services must meet all applicable Medicare conditions for coverage and payment to be paid by Medicare, including those as specified under the CY 2023 PFS final rule (87 FR 69687 and 69688) and § 411.15(i)(3). Medicare payment may be made in the ASC setting for dental services for which payment may be made under Medicare Part B, paid under the OPPS, and that meet the ASC CPL criteria. The fact that a drug, device, procedure, or service is assigned a HCPCS code and a payment rate under the ASC payment system indicates only how the product, procedure, or service may be paid if covered by the program. MACs will be involved in the final decision regarding whether a drug, device, procedure, or other service meets all program requirements and conditions for coverage and payment. Therefore, even if a code describing a dental service has an associated payment rate on the ASC CPL, Medicare will only make payment for the service if it meets applicable requirements. We also clarify that adding dental procedures to the ASC CPL does not serve as a coverage determination for dental services under general anesthesia. We direct readers to the CY 2024 PFS proposed rule for additional discussion of Medicare coverage and payment for dental services, which is available on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html.*

HCPCS code G0330 covers facility services for dental rehabilitation procedure(s) performed on a patient who requires monitored anesthesia (*e.g.,* general, intravenous sedation (monitored anesthesia care)) and use of an operating room. While G0330 has a broader code descriptor than most of the dental codes proposed to be added to the ASC CPL, we proposed to add G0330 to the ASC CPL. We also proposed that it can only be billed when accompanied by at least one covered ancillary dental service on a specific and definitive list of CDT codes, which can be found in ASC Addendum BB with payment indicator ''D1.'' [201] Performance of at least one of these covered ancillary services is integral to each of the surgical procedures that correspond to G0330. For example, if a patient requires a full mouth debridement to enable a comprehensive periodontal evaluation and diagnosis on a subsequent visit, as described by covered ancillary code CDT code D4355 (Full mouth debridement to enable a comprehensive periodontal evaluation and diagnosis on a subsequent visit), or to enable excision of a gum lesion, as described by CPT 41827 (Excision of lesion or tumor (except listed above), dentoalveolar structures; with complex repair), and this procedure needs to be performed under anesthesia due to patient-specific circumstances, the ASC would bill G0330 with covered ancillary code D4355 to perform the debridement under anesthesia or G0330 with covered ancillary code 41827 to perform the excision service under anesthesia. Additionally, as previously noted, when G0330 is billed on a claim, MACs would determine whether payment can be made for the procedure under § 411.15(i)(3), and whether the procedure was reasonable and

[201] See section XIII.B.6.b for a detailed discussion of payment indicators ''D1'' and ''D2.''

medically necessary before providing payment for the procedure. This claims processing mechanism is discussed in further detail in the covered ancillary services section (section XIII.D.2 of this final rule). Procedures assigned to payment indicator ''D2,'' other than HCPCS code G0330, are not required to be billed with a covered ancillary procedure assigned to payment indicator ''D1'' in order to receive payment for the procedure.

We continue to focus on maximizing patient access to care by adding procedures to the ASC CPL when appropriate. While expanding the ASC CPL offers benefits, such as preserving the capacity of hospitals to treat more acute patients and promoting site neutrality, we also believe that any additions to the CPL should be added in a carefully calibrated fashion to ensure that the procedure is safe to be performed in the ASC setting for a typical Medicare beneficiary. We expect to continue to gradually expand the ASC CPL, as medical practice and technology continue to evolve and advance in future years. We encourage stakeholders to submit procedure recommendations to be added to the ASC CPL, particularly if there is evidence that these procedures meet our criteria and can be safely performed in the ASC setting.

Comment: Commenters supported the proposed addition of 26 dental procedures, noting that access to medically necessary oral health care may be critical to successful outcomes for patients with certain acute conditions. A subset of these commenters requested that CMS extend payment to all inextricably linked and medically necessary dental surgical services paid under the PFS and OPPS to the ASC CPL to better ensure access across settings and reduce administrative burden. One commenter requested that non-surgical dental procedures be added to the CPL to increase access.

Response: We thank commenters for their support and their feedback. We anticipate that we will continue to assess our policies for ASC payment for dental services in future rulemaking. We believe that as we collect data, gather input from the public and interested parties, and learn more about the services performed in the ASC setting, we will be able to make more informed decisions regarding policies for dental services. We encourage interested parties to continue to communicate their concerns and ideas with CMS so that we may address adverse incentives in the health care system.

Comment: A few interested parties expressed disappointment that CMS did not propose any surgical codes suggested by ASCs prior to proposed rulemaking. These commenters felt there was ambiguity and a lack of transparency in the addition of procedures, with CMS not required to provide specific rationales, guidance around supporting documentation, or more clarity on the typical Medicare beneficiary definition. These commenters also requested more information on the pre-proposed rule recommendation process, asking for supporting information and guidance to be published as soon as possible.

Response: We appreciate this input from commenters. After evaluating the procedure recommendations and supporting evidence received during the public comment period, we are adding 11 additional surgical codes to the ASC CPL, as reflected in the Table 123 below. As part of our evaluation process, we assess recommended procedures against the specific list of ASC CPL criteria at 42 CFR 416.166, examining clinical data on these procedures from multiple sites of services, reviewing the literature and experiential data provided in public comments, and examining claims volume to ensure that procedures are not expected to pose a significant risk to beneficiary safety when performed in an ASC. We also provide rationales for codes we do not add to the CPL by procedure category in the final rule each year. We will continue to monitor clinical data on these services in the ASC setting and address any new trends in future rulemaking. We remain open to engaging with interested parties on ways we can make the ASC CPL evaluation process more transparent.

Regarding the pre-proposed rule recommendation process, we have fully developed an online module, which is currently undergoing the Paperwork Reduction Act (PRA) process.[202] [203] We anticipate that this module will be live on January 1, 2024, as discussed in the CY 2023 OPPS/ASC final rule (87 FR 72076).

Comment: Most commenters on this policy recommended specific codes to be added to the ASC CPL including total shoulder arthroplasty, prostate ablations, cardiac ablations, endoscopic sleeve gastroplasty, and dental procedures. We received over 200 procedure recommendations for the CPL, listed in Table 124, below. There were multiple letters from orthopedic providers requesting total shoulder arthroplasty be added to the CPL, based on claims of safe and routine performance in ASCs with good outcomes, high patient satisfaction, and financial savings.

Response: We thank commenters for their recommendations. We individually assessed each of the recommended procedures, evaluating clinical data on these procedures from multiple sites of service, reviewing the literature and experiential data provided in public comments, and examining claims volume to determine whether these procedures meet each of the regulatory criteria at 42 CFR 416.166.

Based on our review of the clinical characteristics of the procedures and their similarity to other procedures that are currently on the ASC CPL, we believe that 11 procedures (HCPCS code C9734 and CPT codes 21194, 21195, 23470, 23472, 27702, 27006, 29868, 33289, 37192, 60260) out of the 235 procedure recommendations we received can be safely performed for the typical beneficiary in the ASC setting and meet the general standards and exclusion criteria for the ASC CPL as set forth in 42 CFR 416.166(b) and (c), respectively. These 11 codes correspond to procedures that are frequently performed in outpatient settings and increasingly show lower risks of serious complications and inpatient admissions. We agree with commenters who provided support and evidence stating that these procedures can be safely performed in an ASC setting. We will continue to monitor clinical data on these services in the ASC setting and address any new trends in future rulemaking These procedures, listed in Table 123 below, are:

- 21194 (Reconstruction of mandibular rami, horizontal, vertical, c, or l osteotomy; with bone graft (includes obtaining graft))
- 21195 (Reconstruction of mandibular rami and/or body, sagittal split; without internal rigid fixation)
- 23470 (Arthroplasty, glenohumeral joint; hemiarthroplasty)
- 23472 (Arthroplasty, glenohumeral joint; total shoulder (glenoid and proximal humeral replacement (eg, total shoulder))
- 27006 (Tenotomy, abductors and/or extensor(s) of hip, open (separate procedure))
- 27702 (Arthroplasty, ankle; with implant (total ankle))

[202] 88 FR 57462 (August 23, 2023); *https://www.federalregister.gov/documents/2023/08/23/2023-18154/agency-information-collection-activities-submission-for-omb-review-comment-request.*

[203] 88 FR 39255 (June 15, 2023); *https://www.federalregister.gov/documents/2023/06/15/2023-12773/agency-information-collection-activities-proposed-collection-comment-request.*

- 29868 (Arthroscopy, knee, surgical; meniscal transplantation (includes arthrotomy for meniscal insertion), medial or lateral)
- 33289 (Transcatheter implantation of wireless pulmonary artery pressure sensor for long-term hemodynamic monitoring, including deployment and calibration of the sensor, right heart catheterization, selective pulmonary catheterization, radiological supervision and interpretation, and pulmonary artery angiography, when performed)
- 37192 (Repositioning 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)
- 60260 (Thyroidectomy, removal of all remaining thyroid tissue following previous removal of a portion of thyroid)
- C9734 (Focused ultrasound ablation/therapeutic intervention, other than uterine leiomyomata, with magnetic resonance (mr) guidance)

Due to patient safety concerns, we believe the remaining recommended procedures should not be added to the ASC CPL. Below, we explain our rationale for not including the 224 remaining recommended procedures, organized by category.

- *10 cardiovascular codes,* including arterial revascularization, coronary atherectomies, cardioversion, and echocardiography. The coronary intervention codes have associated inpatient admissions, where the beneficiary requires active medical monitoring and care at midnight following the procedure. Additionally, these procedures would pose a significant safety risk to beneficiaries without post-operative inpatient care and because patients requiring these procedures are often higher risk at baseline. The cardioversion and echocardiography codes are non-surgical procedures, which means they would not qualify for addition to the ASC CPL, and most of these codes are not integral to a covered surgical procedure.
- *77 dental codes,* including resin composites, amalgam, porcelain crowns, prefabricated crows, pulpal therapy, endodontic therapy, gingivectomy, and lesion excision codes. Many of the codes recommended, including the gingivectomies, periodontal scaling, and impacted tooth removal, are already on the ASC CPL as separately payable surgical procedures. A subset of these procedures, including coronectomies and lesion excisions, are not currently separately paid in the OPPS and would not be eligible to be added to the ASC CPL. The remaining dental recommendations are ancillary codes that are currently on the covered ancillary services list, and we believe they are appropriately placed as integral to the G0330 code for CY 2024.
- *3 endocrine codes,* including thyroidectomy and parathyroidectomy procedures. While these procedures have increasing outpatient volume, there are inpatient admissions associated with these procedures, indicating the beneficiary would be expected to stay past midnight following the procedure. Additionally, the intraservice time for these procedures can vary greatly, often becoming a prolonged invasion of body cavities.
- 23 *gastrointestinal codes,* including appendectomy, proctectomy, hernia repairs, gastric motility studies, and laparoscopic gastric restrictive procedures. Several of the hernia repair and protectomy procedures are still on the inpatient only list and would not be eligible for the ASC CPL. For other surgical procedures, while some of these procedures show increasing outpatient volume, many still have inpatient admissions and potential procedure risks, indicating that the beneficiary would require active monitoring and care past midnight following the procedure. Additionally, these procedures can involve prolonged invasion of body cavities, and be life-threatening or emergent in nature. Additionally, several of these procedures are less commonly done in Medicare patients and more frequently performed in a younger population. The study and imaging codes are non-surgical and not eligible for addition to the CPL.
- *8 genitourinary codes,* including hysterectomy, cystectomy, and prostatectomy codes. Several of these codes are not commonly done in Medicare populations. Additionally, these procedures would require active medical monitoring and care at midnight following the procedure and pose a significant safety risk to beneficiaries when performed in an ASC, as some require major or prolonged invasion of body cavities.
- *19 medicine codes,* including esophageal recordings, intra-atrial and intra-ventricular recordings, comprehensive electrophysiologic evaluations. These codes are inherently non-surgical and would not qualify for the ASC CPL.
- *17 musculoskeletal codes,* including total ankle arthroplasty procedures, mandibular reconstruction, osteotomy, and midface reconstruction. Several of these procedures are inpatient only and would not qualify for the ASC CPL. Although a few of these procedures have some claims volume in the outpatient setting, many are mostly performed in the inpatient setting. These are complex procedures with inpatient admissions and multiple post-operative inpatient days, indicating that the beneficiary would require active monitoring and care past midnight following the procedure.
- *1 nervous system code,* which is a laminectomy procedure. This code has associated inpatient admissions and multiple post-operative days, indicating that the beneficiary would require active monitoring and care past midnight following the procedure. This procedure could also pose a significant safety risk to the beneficiary when close post-operative surveillance is not provided.
- *22 radiology codes,* including angiography, aortography, venography, and computed tomography. Most of these codes are currently on the covered ancillary services list. As they are non-surgical, they would not qualify as separately payable surgical procedures on the ASC CPL.
- *8 unlisted codes.* Unlisted codes are not eligible to be added to the ASC CPL.
- *35 vascular codes,* including catheter placements. Nearly all the catheter placement codes recommended are already on the ASC CPL as packaged procedures. We believe this placement is appropriate, given that these procedures are in support of a service. The remaining vascular codes related to atherectomies and revascularization directly involve major blood vessels and many of these procedures have associated inpatient admissions, where the beneficiary requires active medical monitoring and care at midnight following the procedure.

Given these considerations, we believe that these 224 codes do not meet the criteria to be included on the ASC CPL due to the following factors: likelihood of inpatient admissions, the need for multiple-day stays past midnight, safety risks posed to the typical beneficiary without active post-operative monitoring, involvement of major blood vessels, prolonged invasion of a body cavity, the risk of being life-threatening or emergent, less commonly performed in Medicare beneficiaries, or are non-surgical.

Therefore, in this CY 2023 OPPS/ASC final rule with comment period, we are finalizing 37 procedures, 26 proposed dental procedures and 11 additional

procedures evaluated during the public comment period, to be added to the ASC CPL. These procedures are listed below in Table 123 of this CY 2024 OPPS/ASC final rule with comment period.

Comment: Commenters also offered suggestions on different approaches for CMS to consider for the ASC CPL, including standardizing CPL additions by covering all surgical procedures paid separately under the OPPS, unless the procedure meets the exclusionary criteria, and allowing clinicians to decide whether their patients are eligible for care in an ASC.

Response: We thank the commenters for their suggestions. We believe that standardizing this process by adding all eligible procedures paid separately under the OPPS and excluding certain procedures for safety risks would not produce a different outcome than our current review process, since we are already adding procedures that meet these criteria to the CPL. As we previously discussed in the CY 2022 OPPS/ASC final rule (86 FR 63779), we believe that reviewing procedures against the general standards and exclusion criteria before adding them to the ASC CPL is the most appropriate way to ensure that procedures that cannot be safely performed on an ambulatory basis for Medicare beneficiaries are not added to the ASC CPL and payable under the ASC payment system. We will take these suggestions into consideration for future rulemaking.

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TABLE 123: SURGICAL PROCEDURES ADDED TO THE ASC CPL IN CY 2024

CY 2024 CPT/HCPCS/CDT Code	CY 2024 Long Descriptor	Final CY 2024 ASC Payment Indicator
D4210	Gingivectomy or gingivoplasty - four or more contiguous teeth or tooth bounded spaces per quadrant	D2
D4211	Gingivectomy or gingivoplasty - one to three contiguous teeth or tooth bounded spaces per quadrant	D2
D4212	Gingivectomy or gingivoplasty to allow access for restorative procedure, per tooth	D2
D4260	Osseous surgery (including elevation of a full thickness flap entry and closure) - four or more contiguous teeth or tooth bounded spaces per quadrant	D2
D4263	Bone replacement graft - retained natural tooth - first site in quadrant	D2
D4270	Pedicle soft tissue graft procedure	D2
D4273	Autogenous connective tissue graft procedure (including donor and recipient surgical sites) first tooth, implant, or edentulous tooth position in graft	D2
D7111	Extraction, coronal remnants - primary tooth	D2
D7140	Extraction – erupted tooth or exposed root (elevation and/or forcep removal)	D2
D7210	Surgical removal of an erupted tooth requiring removal of bone and/or sectioning of tooth and including elevation of mucoperiosteal flap if indicated	D2
D7220	Removal of impacted tooth – soft tissue	D2
D7230	Removal of impacted tooth – partially bony	D2
D7240	Removal of impacted tooth – completely bony	D2
D7241	Removal of impacted tooth – completely bony, with unusual surgical complications	D2
D7250	Surgical removal of residual tooth roots (cutting procedure)	D2
D7270	Tooth reimplantation and/or stabilization of accidentally evulsed or displaced tooth	D2
D7310	Alveoloplasty in conjunction with extractions - four or more teeth or tooth spaces, per quadrant	D2
D7311	Alveoloplasty in conjunction with extractions - one to three teeth or tooth spaces, per quadrant	D2

CY 2024 CPT/HCPCS/CDT Code	CY 2024 Long Descriptor	Final CY 2024 ASC Payment Indicator
D7472	Removal of torus palatinus	D2
D7473	Removal of torus mandibularis	D2
D7510	Incision and drainage of abscess-intraoral soft tissue	D2
D7511	Incision and drainage of abscess - intraoral soft tissue - complicated (includes drainage of multiple fascial spaces)	D2
D7520	Incision and drainage of abscess-extraoral soft tissue	D2
D7550	Partial ostectomy/sequestrectomy for removal of non-vital bone	D2
D7950	Osseous, osteoperiosteal, or cartilage graft of the mandible or maxilla - autogenous or nonautogenous, by report	D2
G0330	Facility services for dental rehabilitation procedure(s) performed on a patient who requires monitored anesthesia (e.g., general, intravenous sedation (monitored anesthesia care) and use of an operating room	D2
33289	Transcatheter implantation of wireless pulmonary artery pressure sensor for long-term hemodynamic monitoring, including deployment and calibration of the sensor, right heart catheterization, selective pulmonary catheterization, radiological supervision and interpretation, and pulmonary artery angiography, when performed	J8
60260	Thyroidectomy, removal of all remaining thyroid tissue following previous removal of a portion of thyroid	G2
C9734	Focused ultrasound ablation/therapeutic intervention, other than uterine leiomyomata, with magnetic resonance (mr) guidance	G2
21194	Reconstruction of mandibular rami, horizontal, vertical, c, or l osteotomy; with bone graft (includes obtaining graft)	G2
21195	Reconstruction of mandibular rami and/or body, sagittal split; without internal rigid fixation	J8
23472	Arthroplasty, glenohumeral joint; total shoulder (glenoid and proximal humeral replacement (eg, total shoulder))	J8
27006	Tenotomy, abductors and/or extensor(s) of hip, open (separate procedure)	G2

CY 2024 CPT/HCPCS/CDT Code	CY 2024 Long Descriptor	Final CY 2024 ASC Payment Indicator
29868	Arthroscopy, knee, surgical; meniscal transplantation (includes arthrotomy for meniscal insertion), medial or lateral	G2
23470	Arthroplasty, glenohumeral joint; hemiarthroplasty	J8
27702	Arthroplasty, ankle; with implant (total ankle)	J8
37192	Repositioning 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

TABLE 124: SURGICAL PROCEDURES RECOMMENDATIONS RECEIVED FROM COMMENTERS

CY 2024 CPT/HCPCS/CDT Code	CY 2024 Long Descriptor	Final CY 2024 ASC Payment Indicator
23473	Revision of total shoulder arthroplasty, including allograft when performed; humeral or glenoid component	X5
21141	Reconstruction midface, lefort i; single piece, segment movement in any direction (eg, for long face syndrome), without bone graft	X5
21142	Reconstruction midface, lefort i; 2 pieces, segment movement in any direction, without bone graft	X5
21143	Reconstruction midface, lefort i; 3 or more pieces, segment movement in any direction, without bone graft	X5
21193	Reconstruction of mandibular rami, horizontal, vertical, c, or l osteotomy; without bone graft	X5
21196	Reconstruction of mandibular rami and/or body, sagittal split; with internal rigid fixation	X5
21422	Open treatment of palatal or maxillary fracture (lefort i type);	X5
21470	Open treatment of complicated mandibular fracture by multiple surgical approaches including internal fixation, interdental fixation, and/or wiring of dentures or splints	X5
22558	Arthrodesis, anterior interbody technique, including minimal discectomy to prepare interspace (other than for decompression); lumbar	C5
22633	Arthrodesis, combined posterior or posterolateral technique with posterior interbody technique including laminectomy and/or discectomy sufficient to prepare interspace (other than for decompression), single interspace; lumbar	X5
23474	Revision of total shoulder arthroplasty, including allograft when performed; humeral and glenoid component	C5
23929	Unlisted procedure, shoulder	U5
24999	Unlisted procedure, humerus or elbow	U5
26989	Unlisted procedure, hands or fingers	U5
27235	Percutaneous skeletal fixation of femoral fracture, proximal end, neck	X5
27299	Unlisted procedure, pelvis or hip joint	U5
27450	Osteotomy, femur, shaft or supracondylar; with fixation	C5

27485	Arrest, hemiepiphyseal, distal femur or proximal tibia or fibula (eg, genu varus or valgus)	X5
27486	Revision of total knee arthroplasty, with or without allograft; 1 component	C5
27535	Open treatment of tibial fracture, proximal (plateau); unicondylar, includes internal fixation, when performed	C5
27599	Unlisted procedure, femur or knee	U5
28805	Amputation, foot; transmetatarsal	X5
28899	Unlisted procedure, foot or toes	U5
36005	Injection procedure for extremity venography (including introduction of needle or intracatheter)	N1
36010	Introduction of catheter, superior or inferior vena cava	N1
36011	Selective catheter placement, venous system; first order branch (eg, renal vein, jugular vein)	N1
36012	Selective catheter placement, venous system; second order, or more selective, branch (eg, left adrenal vein, petrosal sinus)	N1
36100	Introduction of needle or intracatheter, carotid or vertebral artery	N1
36120	Introduction of needle or intracatheter; retrograde brachial artery	N/A
36140	Introduction of needle or intracatheter, upper or lower extremity artery	N1
36200	Introduction of catheter, aorta	N1
36215	Selective catheter placement, arterial system; each first order thoracic or brachiocephalic branch, within a vascular family	N1
36216	Selective catheter placement, arterial system; initial second order thoracic or brachiocephalic branch, within a vascular family	N1
36217	Selective catheter placement, arterial system; initial third order or more selective thoracic or brachiocephalic branch, within a vascular family	N1
36218	Selective catheter placement, arterial system; additional second order, third order, and beyond, thoracic or brachiocephalic branch, within a vascular family (list in addition to code for initial second or third order vessel as appropriate)	N1
36221	Non-selective catheter placement, thoracic aorta, with angiography of the extracranial carotid, vertebral, and/or intracranial vessels, unilateral or bilateral, and all associated radiological supervision and interpretation, includes angiography of the cervicocerebral arch, when performed	N1

36222	Selective catheter placement, common carotid or innominate artery, unilateral, any approach, with angiography of the ipsilateral extracranial carotid circulation and all associated radiological supervision and interpretation, includes angiography of the cervicocerebral arch, when performed	N1
36223	Selective catheter placement, common carotid or innominate artery, unilateral, any approach, with angiography of the ipsilateral intracranial carotid circulation and all associated radiological supervision and interpretation, includes angiography of the extracranial carotid and cervicocerebral arch, when performed	N1
36224	Selective catheter placement, internal carotid artery, unilateral, with angiography of the ipsilateral intracranial carotid circulation and all associated radiological supervision and interpretation, includes angiography of the extracranial carotid and cervicocerebral arch, when performed	N1
36225	Selective catheter placement, subclavian or innominate artery, unilateral, with angiography of the ipsilateral vertebral circulation and all associated radiological supervision and interpretation, includes angiography of the cervicocerebral arch, when performed	N1
36226	Selective catheter placement, vertebral artery, unilateral, with angiography of the ipsilateral vertebral circulation and all associated radiological supervision and interpretation, includes angiography of the cervicocerebral arch, when performed	N1
36227	Selective catheter placement, external carotid artery, unilateral, with angiography of the ipsilateral external carotid circulation and all associated radiological supervision and interpretation (list separately in addition to code for primary procedure)	N1
36228	Selective catheter placement, each intracranial branch of the internal carotid or vertebral arteries, unilateral, with angiography of the selected vessel circulation and all associated radiological supervision and interpretation (eg, middle cerebral artery, posterior inferior cerebellar artery) (list separately in addition to code for primary procedure)	N1
36245	Selective catheter placement, arterial system; each first order abdominal, pelvic, or lower extremity artery branch, within a vascular family	N1
36246	Selective catheter placement, arterial system; initial second order abdominal, pelvic, or lower extremity artery branch, within a vascular family	N1

36247	Selective catheter placement, arterial system; initial third order or more selective abdominal, pelvic, or lower extremity artery branch, within a vascular family	N1
36248	Selective catheter placement, arterial system; additional second order, third order, and beyond, abdominal, pelvic, or lower extremity artery branch, within a vascular family (list in addition to code for initial second or third order vessel as appropriate)	N1
36251	Selective catheter placement (first-order), main renal artery and any accessory renal artery(s) for renal angiography, including arterial puncture and catheter placement(s), fluoroscopy, contrast injection(s), image postprocessing, permanent recording of images, and radiological supervision and interpretation, including pressure gradient measurements when performed, and flush aortogram when performed; unilateral	N1
36252	Selective catheter placement (first-order), main renal artery and any accessory renal artery(s) for renal angiography, including arterial puncture and catheter placement(s), fluoroscopy, contrast injection(s), image postprocessing, permanent recording of images, and radiological supervision and interpretation, including pressure gradient measurements when performed, and flush aortogram when performed; bilateral	N1
36253	Superselective catheter placement (one or more second order or higher renal artery branches) renal artery and any accessory renal artery(s) for renal angiography, including arterial puncture, catheterization, fluoroscopy, contrast injection(s), image postprocessing, permanent recording of images, and radiological supervision and interpretation, including pressure gradient measurements when performed, and flush aortogram when performed; unilateral	N1
36254	Superselective catheter placement (one or more second order or higher renal artery branches) renal artery and any accessory renal artery(s) for renal angiography, including arterial puncture, catheterization, fluoroscopy, contrast injection(s), image postprocessing, permanent recording of images, and radiological supervision and interpretation, including pressure gradient measurements when performed, and flush aortogram when performed; bilateral	N1
37183	Revision of transvenous intrahepatic portosystemic shunt(s) (tips) (includes venous access, hepatic and portal vein catheterization, portography with hemodynamic evaluation, intrahepatic tract	X5

	recannulization/dilatation, stent placement and all associated imaging guidance and documentation)	
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	X5
41899	Unlisted procedure, dentoalveolar structures	U5
44180	Laparoscopy, surgical, enterolysis (freeing of intestinal adhesion) (separate procedure)	X5
44970	Laparoscopy, surgical, appendectomy	X5
45120	Proctectomy, complete (for congenital megacolon), abdominal and perineal approach; with pull-through procedure and anastomosis (eg, swenson, duhamel, or soave type operation)	C5
46999	Unlisted procedure, anus	U5
49596	Repair of anterior abdominal hernia(s) (ie, epigastric, incisional, ventral, umbilical, spigelian), any approach (ie, open, laparoscopic, robotic), initial, including implantation of mesh or other prosthesis when performed, total length of defect(s); greater than 10 cm, incarcerated or strangulated	C5
49616	Repair of anterior abdominal hernia(s) (ie, epigastric, incisional, ventral, umbilical, spigelian), any approach (ie, open, laparoscopic, robotic), recurrent, including implantation of mesh or other prosthesis when performed, total length of defect(s); 3 cm to 10 cm, incarcerated or strangulated	C5
50543	Laparoscopy, surgical; partial nephrectomy	X5
50544	Laparoscopy, surgical; pyeloplasty	X5
51990	Laparoscopy, surgical; urethral suspension for stress incontinence	X5
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	X5
55866	Laparoscopy, surgical prostatectomy, retropubic radical, including nerve sparing, includes robotic assistance, when performed	X5
58270	Vaginal hysterectomy, for uterus 250 g or less; with repair of enterocele	X5
58740	Lysis of adhesions (salpingolysis, ovariolysis)	C5

58925	Ovarian cystectomy, unilateral or bilateral	X5
60252	Thyroidectomy, total or subtotal for malignancy; with limited neck dissection	X5
60254	Thyroidectomy, total or subtotal for malignancy; with radical neck dissection	C5
60502	Parathyroidectomy or exploration of parathyroid(s); re-exploration	X5
63267	Laminectomy for excision or evacuation of intraspinal lesion other than neoplasm, extradural; lumbar	X5
75571	Computed tomography, heart, without contrast material, with quantitative evaluation of coronary calcium	N1
75572	Computed tomography, heart, with contrast material, for evaluation of cardiac structure and morphology (including 3d image postprocessing, assessment of cardiac function, and evaluation of venous structures, if performed)	Z2
75573	Computed tomography, heart, with contrast material, for evaluation of cardiac structure and morphology in the setting of congenital heart disease (including 3d image postprocessing, assessment of left ventricular [lv] cardiac function, right ventricular [rv] structure and function and evaluation of vascular structures, if performed)	Z2
75574	Computed tomographic angiography, heart, coronary arteries and bypass grafts (when present), with contrast material, including 3d image postprocessing (including evaluation of cardiac structure and morphology, assessment of cardiac function, and evaluation of venous structures, if performed)	Z2
75600	Aortography, thoracic, without serialography, radiological supervision and interpretation	N1
75605	Aortography, thoracic, by serialography, radiological supervision and interpretation	N1
75625	Aortography, abdominal, by serialography, radiological supervision and interpretation	N1
75630	Aortography, abdominal plus bilateral iliofemoral lower extremity, catheter, by serialography, radiological supervision and interpretation	N1
75658	Angiography, brachial, retrograde, radiological supervision and interpretation	N1
75710	Angiography, extremity, unilateral, radiological supervision and interpretation	N1
75716	Angiography, extremity, bilateral, radiological supervision and interpretation	N1
75726	Angiography, visceral, selective or supraselective (with or without flush aortogram), radiological supervision and interpretation	N1

75736	Angiography, pelvic, selective or supraselective, radiological supervision and interpretation	N1
75756	Angiography, internal mammary, radiological supervision and interpretation	N1
75774	Angiography, selective, each additional vessel studied after basic examination, radiological supervision and interpretation (list separately in addition to code for primary procedure)	N1
75820	Venography, extremity, unilateral, radiological supervision and interpretation	N1
75822	Venography, extremity, bilateral, radiological supervision and interpretation	Z3
75825	Venography, caval, inferior, with serialography, radiological supervision and interpretation	N1
75827	Venography, caval, superior, with serialography, radiological supervision and interpretation	N1
75831	Venography, renal, unilateral, selective, radiological supervision and interpretation	N1
75833	Venography, renal, bilateral, selective, radiological supervision and interpretation	N1
75860	Venography, venous sinus (eg, petrosal and inferior sagittal) or jugular, catheter, radiological supervision and interpretation	N1
75970	Transcatheter biopsy, radiological supervision and interpretation	N1
91010	Esophageal motility (manometric study of the esophagus and/or gastroesophageal junction) study with interpretation and report;	S1
91013	Esophageal motility (manometric study of the esophagus and/or gastroesophageal junction) study with interpretation and report; with stimulation or perfusion (eg, stimulant, acid or alkali perfusion) (list separately in addition to code for primary procedure)	S1
91020	Gastric motility (manometric) studies	S1
91022	Duodenal motility (manometric) study	S1
91030	Esophagus, acid perfusion (bernstein) test for esophagitis	S1
91034	Esophagus, gastroesophageal reflux test; with nasal catheter ph electrode(s) placement, recording, analysis and interpretation	S1
91037	Esophageal function test, gastroesophageal reflux test with nasal catheter intraluminal impedance electrode(s) placement, recording, analysis and interpretation;	S1
91038	Esophageal function test, gastroesophageal reflux test with nasal catheter intraluminal impedance electrode(s) placement, recording, analysis and	S1

	interpretation; prolonged (greater than 1 hour, up to 24 hours)	
91040	Esophageal balloon distension study, diagnostic, with provocation when performed	S1
91110	Gastrointestinal tract imaging, intraluminal (eg, capsule endoscopy), esophagus through ileum, with interpretation and report	S1
91111	Gastrointestinal tract imaging, intraluminal (eg, capsule endoscopy), esophagus with interpretation and report	S1
91112	Gastrointestinal transit and pressure measurement, stomach through colon, wireless capsule, with interpretation and report	S1
91117	Colon motility (manometric) study, minimum 6 hours continuous recording (including provocation tests, eg, meal, intracolonic balloon distension, pharmacologic agents, if performed), with interpretation and report	S1
91120	Rectal sensation, tone, and compliance test (ie, response to graded balloon distention)	S1
91122	Anorectal manometry	S1
92924	Percutaneous transluminal coronary atherectomy, with coronary angioplasty when performed; single major coronary artery or branch	S1
92925	Percutaneous transluminal coronary atherectomy, with coronary angioplasty when performed; each additional branch of a major coronary artery (list separately in addition to code for primary procedure)	S1
92937	Percutaneous transluminal revascularization of or through coronary artery bypass graft (internal mammary, free arterial, venous), any combination of intracoronary stent, atherectomy and angioplasty, including distal protection when performed; single vessel	S1
92938	Percutaneous transluminal revascularization of or through coronary artery bypass graft (internal mammary, free arterial, venous), any combination of 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)	S1
92960	Cardioversion, elective, electrical conversion of arrhythmia; external	S1
92961	Cardioversion, elective, electrical conversion of arrhythmia; internal (separate procedure)	S1
93306	Echocardiography, transthoracic, real-time with image documentation (2d), includes m-mode recording, when performed, complete, with	S1

	spectral doppler echocardiography, and with color flow doppler echocardiography	
93312	Echocardiography, transesophageal, real-time with image documentation (2d) (with or without m-mode recording); including probe placement, image acquisition, interpretation and report	S1
93318	Echocardiography, transesophageal (tee) for monitoring purposes, including probe placement, real time 2-dimensional image acquisition and interpretation leading to ongoing (continuous) assessment of (dynamically changing) cardiac pumping function and to therapeutic measures on an immediate time basis	S1
93600	Bundle of his recording	S1
93602	Intra-atrial recording	S1
93603	Right ventricular recording	S1
93610	Intra-atrial pacing	S1
93612	Intraventricular pacing	S1
93615	Esophageal recording of atrial electrogram with or without ventricular electrogram(s);	S1
93616	Esophageal recording of atrial electrogram with or without ventricular electrogram(s); with pacing	S1
93618	Induction of arrhythmia by electrical pacing	S1
93619	Comprehensive electrophysiologic evaluation with right atrial pacing and recording, right ventricular pacing and recording, his bundle recording, including insertion and repositioning of multiple electrode catheters, without induction or attempted induction of arrhythmia	S1
93620	Comprehensive electrophysiologic evaluation including insertion and repositioning of multiple electrode catheters with induction or attempted induction of arrhythmia; with right atrial pacing and recording, right ventricular pacing and recording, his bundle recording	S1
93623	Programmed stimulation and pacing after intravenous drug infusion (list separately in addition to code for primary procedure)	N1
93624	Electrophysiologic follow-up study with pacing and recording to test effectiveness of therapy, including induction or attempted induction of arrhythmia	S1
93642	Electrophysiologic evaluation of single or dual chamber transvenous pacing cardioverter-defibrillator (includes defibrillation threshold	S1

	evaluation, induction of arrhythmia, evaluation of sensing and pacing for arrhythmia termination, and programming or reprogramming of sensing or therapeutic parameters)	
93650	Intracardiac catheter ablation of atrioventricular node function, atrioventricular conduction for creation of complete heart block, with or without temporary pacemaker placement	S1
93653	Comprehensive electrophysiologic evaluation with insertion and repositioning of multiple electrode catheters, induction or attempted induction of an arrhythmia with right atrial pacing and recording and catheter ablation of arrhythmogenic focus, including intracardiac electrophysiologic 3-dimensional mapping, right ventricular pacing and recording, left atrial pacing and recording from coronary sinus or left atrium, and his bundle recording, when performed; with treatment of supraventricular tachycardia by ablation of fast or slow atrioventricular pathway, accessory atrioventricular connection, cavo-tricuspid isthmus or other single atrial focus or source of atrial re-entry	S1
93654	Comprehensive electrophysiologic evaluation with insertion and repositioning of multiple electrode catheters, induction or attempted induction of an arrhythmia with right atrial pacing and recording and catheter ablation of arrhythmogenic focus, including intracardiac electrophysiologic 3-dimensional mapping, right ventricular pacing and recording, left atrial pacing and recording from coronary sinus or left atrium, and his bundle recording, when performed; with treatment of ventricular tachycardia or focus of ventricular ectopy including left ventricular pacing and recording, when performed	S1
93655	Intracardiac catheter ablation of a discrete mechanism of arrhythmia which is distinct from the primary ablated mechanism, including repeat diagnostic maneuvers, to treat a spontaneous or induced arrhythmia (list separately in addition to code for primary procedure)	S1
93656	Comprehensive electrophysiologic evaluation including transseptal catheterizations, insertion and repositioning of multiple electrode catheters with intracardiac catheter ablation of atrial fibrillation by pulmonary vein isolation, including intracardiac electrophysiologic 3-dimensional mapping, intracardiac echocardiography including imaging supervision and interpretation, induction or attempted induction of an arrhythmia including left or right atrial pacing/recording, right ventricular	S1

	pacing/recording, and his bundle recording, when performed	
93657	Additional linear or focal intracardiac catheter ablation of the left or right atrium for treatment of atrial fibrillation remaining after completion of pulmonary vein isolation (list separately in addition to code for primary procedure)	S1
93660	Evaluation of cardiovascular function with tilt table evaluation, with continuous ECG monitoring and intermittent blood pressure monitoring, with or without pharmacological intervention	S1
0780T	Instillation of fecal microbiota suspension via rectal enema into lower gastrointestinal tract	S1
C9602	Percutaneous transluminal coronary atherectomy, with drug eluting intracoronary stent, with coronary angioplasty when performed; single major coronary artery or branch	X5
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)	X5
C9604	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; single vessel	X5
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	X5
C9780	Insertion of central venous catheter through central venous occlusion via inferior and superior approaches (e.g., inside-out technique), including imaging guidance	X5
C9784	Gastric restrictive procedure, endoscopic sleeve gastroplasty, with esophagogastroduodenoscopy and intraluminal tube insertion, if performed, including all system and tissue anchoring components	X5
C9785	Endoscopic outlet reduction, gastric pouch application, with endoscopy and intraluminal tube insertion, if performed, including all system and tissue anchoring components	X5
D2140	Amalgam-one surface, primary or permanent	D1
D2150	Amalgam-two surfaces, primary or permanent	D1

D2160	Amalgam-three surfaces, primary or permanent	D1
D2161	Amalgam-four or more surfaces, primary or permanent	D1
D2330	Resin-one surface, anterior	D1
D2331	Resin-two surfaces, anterior	D1
D2332	Resin-three surfaces, anterior	D1
D2335	Resin-four or more surfaces or involving incisal angle (anterior)	D1
D2390	Resin-based composite crown, anterior	D1
D2391	Resin-based composite - one surface, posterior	D1
D2392	Resin-based composite - two surfaces, posterior	D1
D2393	Resin-based composite - three surfaces, posterior	D1
D2394	Resin-based composite - four or more surfaces, posterior	D1
D2740	Crown - porcelain/ceramic	D1
D2750	Crown-porcelain fused to high noble metal	D1
D2751	Crown-porcelain fused to predominantly base metal	D1
D2752	Crown-porcelain fused to noble metal	D1
D2791	Crown-full cast predominantly base metal	D1
D2799	Interim crown - further treatment or completion of diagnosis necessary prior to final impression	D1
D2920	Re-cement or re-bond crown	D1
D2929	Prefabricated porcelain/ceramic crown - primary tooth	D1
D2930	Prefabricated stainless steel crown-primary tooth	D1
D2931	Prefabricated stainless steel crown-permanent tooth	D1
D2932	Prefabricated resin crown	D1
D2933	Prefabricated stainless steel crown with resin window	D1
D2934	Prefabricated esthetic coated stainless steel crown - primary tooth	D1

D2940	Protective restoration	D1
D2941	Interim therapeutic restoration - primary dentition	D1
D2950	Core build-up, including any pins when required	D1
D2951	Pin retention-per tooth, in addition to restoration	D1
D2952	Post and core in addition to crown, indirectly fabricated	D1
D2954	Prefabricated post and core in addition to crown	D1
D3220	Therapeutic pulpotomy (excluding final restoration) removal of pulp coronal to the dentinocemental junction and application of medicament	D1
D3222	Partial pulpotomy for apexogenesis - permanent tooth with incomplete root development	D1
D3230	Pulpal therapy (resorbable filling)-anterior, primary tooth (excluding final restoration)	D1
D3240	Pulpal therapy (resorbable filling)-posterior, primary tooth (excluding final restoration)	D1
D3310	Endodontic therapy, anterior tooth (excluding final restoration)	D1
D3320	Endodontic therapy, premolar tooth (excluding final restoration)	D1
D3330	Endodontic therapy, molar tooth (excluding final restoration)	D1
D3460	Endodontic endosseous implant	D1
D3910	Surgical procedure for isolation of tooth with rubber dam	D1
D4210	Gingivectomy or gingivoplasty - four or more contiguous teeth or tooth bounded spaces per quadrant	D2
D4211	Gingivectomy or gingivoplasty - one to three contiguous teeth or tooth bounded spaces per quadrant	D2
D4212	Gingivectomy or gingivoplasty to allow access for restorative procedure, per tooth	D2
D4260	Osseous surgery (including elevation of a full thickness flap entry and closure) - four or more contiguous teeth or tooth bounded spaces per quadrant	D2
D4263	Bone replacement graft - retained natural tooth - first site in quadrant	D2
D4270	Pedicle soft tissue graft procedure	D2

D4273	Autogenous connective tissue graft procedure (including donor and recipient surgical sites) first tooth, implant, or edentulous tooth position in graft	D2
D4341	Periodontal scaling and root planing - four or more teeth per quadrant	D1
D4342	Periodontal scaling and root planing - one to three teeth, per quadrant	D1
D4346	Scaling in presence of generalized moderate or severe gingival inflammation - full mouth, after oral evaluation	D1
D4355	Full mouth debridement to enable a comprehensive periodontal evaluation and diagnosis on a subsequent visit	D1
D4910	Periodontal maintenance	D1
D7111	Extraction, coronal remnants - primary tooth	D2
D7140	Extraction – erupted tooth or exposed root (elevation and/or forcep removal)	D2
D7210	Surgical removal of an erupted tooth requiring removal of bone and/or sectioning of tooth and including elevation of mucoperiosteal flap if indicated	D2
D7220	Removal of impacted tooth – soft tissue	D2
D7230	Removal of impacted tooth – partially bony	D2
D7240	Removal of impacted tooth – completely bony	D2
D7251	Coronectomy - intentional partial tooth removal, impacted teeth only	M6
D7280	Exposure of an unerupted tooth	M6
D7283	Placement of device to facilitate eruption of impacted tooth	B5
D7320	Alveoloplasty not in conjunction with extractions - four or more teeth or tooth spaces, per quadrant	M6
D7321	Alveoloplasty not in conjunction with extractions - one to three teeth or tooth spaces, per quadrant	B5
D7410	Excision of benign lesion up to 1.25 cm	M6
D7411	Excision of benign lesion greater than 1.25 cm	M6
D7412	Excision of benign lesion, complicated	M6
D7413	Excision of malignant lesion up to 1.25 cm	M6
D7414	Excision of malignant lesion greater than 1.25 cm	M6

D7415	Excision of malignant lesion, complicated	M6
D7440	Excision of malignant tumor-lesion diameter up to 1.25 cm	M6
D7441	Excision of malignant tumor-lesion diameter greater than 1.25 cm	M6
D7450	Removal of benign odontogenic cyst or tumor-lesion diameter up to 1.25 cm	M6
D7451	Removal of benign odontogenic cyst or tumor-lesion diameter greater than 1.25 cm	M6
D7471	Removal of lateral exostosis (maxilla or mandible)	M6
D7530	Removal of foreign body from mucosa, skin, or subcutaneous alveolar tissue	M6
D7540	Removal of reaction-producing foreign bodies-musculoskeletal system	M6

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3. Covered Ancillary Services

Covered ancillary services are specified in § 416.164(b) and, as stated previously, are eligible for separate ASC payment. As provided at § 416.164(b), we make separate ASC payments for ancillary items and services when they are provided integral to ASC covered surgical procedures that include the following: (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; (5) certain radiology services for which separate payment is allowed under the OPPS; and (6) non-opioid pain management drugs that function as a supply when used in a surgical procedure. 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.

In the CY 2019 OPPS/ASC final rule with comment period (83 FR 59062 and 59063), consistent with the established ASC payment system policy (72 FR 42497), we finalized the policy to update the ASC list of covered ancillary services to reflect the payment status for the services under the OPPS and to continue this reconciliation of packaged status for subsequent calendar years. As discussed in prior rulemaking, maintaining consistency with the OPPS may result in changes to ASC payment indicators for some covered ancillary services. For example, if a covered ancillary service was separately paid under the ASC payment system in CY 2023, but will be packaged under the CY 2024 OPPS, we would also package the ancillary service under the ASC payment system for CY 2024 to maintain consistency with the OPPS. Comment indicator ''CH'' is used in Addendum BB (which is available via the internet on the CMS website) to indicate covered ancillary services for which we proposed a change in the ASC payment indicator to reflect a proposed change in the OPPS treatment of the service for CY 2024.

In the CY 2022 OPPS/ASC final rule with comment period, we finalized our proposal to revise 42 CFR 416.164(b)(6) to include, as ancillary items that are integral to a covered surgical procedure and for which separate payment is allowed, non-opioid pain management drugs and biologicals that function as a supply when used in a surgical procedure as determined by CMS (86 FR 63490).

New CPT and HCPCS codes for covered ancillary services for CY 2024 can be found in section XIII.B of this final rule. All ASC covered ancillary services and their final payment indicators for CY 2024 are also included in Addendum BB to this final rule (which is available via the internet on the CMS website).

Claims Processing Limitations for Covered Ancillary Procedures Performed with G0330

HCPCS code G0330 (*Facility services for dental rehabilitation procedure(s) performed on a patient who requires monitored anesthesia (e.g., general, intravenous sedation (monitored anesthesia care) and use of an operating room)*) is an addition to the ASC CPL for CY 2024, as discussed in section XIII.D.1 of this final rule. In ASC Addendum BB, there is a specific and definitive list of covered ancillary dental services with proposed payment indicator of ''D1.'' For CY 2024, we proposed that code G0330 could only be billed with a covered ancillary procedure that has the proposed payment indicator of ''D1,'' indicating an ancillary dental service or item with no separate payment made. This limitation would ensure that only covered ancillary services we have evaluated for safety in the ASC setting can be performed with code G0330. While HCPCS code G0330 must be billed with a covered ancillary procedure with a proposed payment indicator of ''D1,'' these covered ancillary procedures can be billed with procedures other than G0330. When billed with procedures other than code G0330, these procedures would be packaged in accordance with our policy for covered ancillary procedures. The fact that a drug, device, procedure, or service is assigned an HCPCS code and a payment rate under the ASC payment system indicates only how the product, procedure, or service may be paid if covered by the program. MACs will be involved in the final decision regarding whether a drug, device, procedure, or other service meets all program requirements and conditions for coverage and payment. Therefore, even if a code describing a dental service has an associated payment rate on the ASC CPL, Medicare will only make payment for the service if it meets applicable requirements. More detail on the final ASC dental indicators can be found in section XIII.B.6 of this final rule.

Comment: Several commenters requested guidance on hospital outpatient reporting of HCPCS code G0330. Since CMS proposed to require that code G0330 be reported in addition

to one or more of the ancillary dental codes with payment indicator ''D1'' when performed in an operating room under anesthesia in the ASC setting, hospitals expected the same explicit guidance.

Response: The claims processing limitations around code G0330, for example, the requirement that code G0330 must be billed with a covered dental ancillary procedure with payment indicator ''D1,'' are only applicable in the ASC setting, allowing us to ensure that only covered ancillary services we have evaluated for safety in the ASC setting can be performed with code G0330.

After consideration of the public comments we received, we are finalizing this policy as proposed.

E. ASC Payment Policy for Non-Opioid Post-Surgery Pain Management Drugs, Biologicals, and Devices

1. Background on OPPS/ASC Non-Opioid Pain Management Packaging Policies

On October 24, 2018, the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities (SUPPORT) Act (Pub. L. 115–271) was enacted. 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 outpatient department (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. Revisions under this paragraph are required to be treated as adjustments for purposes of paragraph (9)(B) of the Act, which requires any adjustments to be made in a budget neutral manner. Section 1833(i)(8) of the Act, as added by section 6082(b) of the SUPPORT Act, requires the Secretary to conduct a similar type of review as required for the OPPS and to make revisions to the ASC payment system in an appropriate manner, as determined by the Secretary.

For a detailed discussion of rulemaking on non-opioid alternatives prior to CY 2020, we refer readers to the CYs 2018 and 2019 OPPS/ASC final rules with comment period (82 FR 59345; 83 FR 58855 through 58860).

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, 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. For the CY 2020 OPPS/ASC proposed rule (84 FR 39423 through 39427), we proposed to continue our policy to pay separately at ASP plus 6 percent for 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.

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 plus 6 percent for non-opioid pain management drugs that function as surgical supplies when furnished in the ASC setting for CY 2020. Under this policy, for CY 2020, the only drug that qualified for separate payment in the ASC setting as a non-opioid pain management drug that functions as a surgical supply was Exparel.

In the CY 2021 OPPS/ASC final rule with comment period (85 FR 85896 through 85899), we continued the policy to pay separately at ASP plus 6 percent for non-opioid pain management drugs that function as surgical supplies in the performance of surgical procedures when they were 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. For CY 2021, only Exparel and Omidria met the criteria as non-opioid pain management drugs that function as surgical supplies in the ASC setting, and received separate payment under the ASC payment system.

In the CY 2022 OPPS/ASC final rule with comment period (86 FR 63483), we finalized a policy to unpackage and pay separately at ASP plus 6 percent for non-opioid pain management drugs that function as surgical supplies when they are furnished in the ASC setting, are FDA-approved, have an FDA-approved indication for pain management or as an analgesic, and have a per-day cost above the OPPS/ASC drug packaging threshold; and we finalized our proposed regulation text changes at 42 CFR 416.164(a)(4) and (b)(6), 416.171(b)(1), and 416.174 as proposed.

In the CY 2023 OPPS/ASC final rule with comment period (87 FR 72089), we determined that five products were eligible for separate payment in the ASC setting under our final policy for CY 2022. We noted that future products, or products not discussed in that rulemaking that may be eligible for separate payment under this policy, would be evaluated in future rulemaking (86 FR 63496). In the CY 2023 final rule with comment period, we finalized that five drugs would receive separate payment in the ASC setting for CY 2023 under the policy for non-opioid pain management drugs and biologicals that function as surgical supplies (86 FR 63496). These drugs are described by HCPCS code C9290 (*Injection, bupivacaine liposome, 1 mg*), J1096 (*Dexamethasone, lacrimal ophthalmic insert, 0. mg*), HCPCS code J1097 (*Phenylephrine 10.16 mg/ml and ketorolac 2.88 mg/ml ophthalmic irrigation solution, 1 ml*), HCPCS code C9089 (*Bupivacaine, collagen-matrix implant, 1 mg*), and HCPCS code C9144 *(Injection, bupivacaine (posimir), 1 mg*)) (86 FR 63496).

2. CY 2024 Qualification Evaluation for Separate Payment of Non-Opioid Pain Management Drugs and Biologicals That Function as a Surgical Supply

As noted above, in the CY 2022 OPPS/ASC final rule with comment period, we finalized a policy to

unpackage and pay separately at ASP plus 6 percent for non-opioid pain management drugs that function as surgical supplies when they are furnished in the ASC setting, are FDA-approved, have an FDA-approved indication for pain management or as an analgesic, and have a per-day cost above the OPPS drug packaging threshold beginning on or after January 1, 2022. For CY 2024, the OPPS drug packaging threshold was proposed to be $140. However, based on updated data, we are finalizing a threshold of $135 for CY 2024. For more information on the drug packaging threshold, see section V.B.1.a of this CY 2024 OPPS/ASC final rule with comment period.

In the CY 2023 OPPS/ASC final rule, we finalized a clarification of our policy by codifying the two additional criteria for separate payment for non-opioid pain management drugs and biologicals that function as surgical supplies in the regulatory text at § 416.174 as a technical change. First, we finalized at new § 416.174(a)(3) that non-opioid pain management drugs or biologicals that function as a supply in a surgical procedure are eligible for separate payment if the drug or biological does not have transitional pass-through payment status under § 419.64. In the case where a drug or biological otherwise meets the requirements under § 416.174 and has transitional pass-through payment status that will expire during the calendar year, the drug or biological would qualify for separate payment under § 416.174 during such calendar year on the first day of the next calendar year quarter after its pass-through status expires. Second, we finalized that new § 416.174(a)(4) would reflect that the drug or biological must not already be separately payable in the OPPS or ASC payment system under a policy other than the one specified in § 416.174.

The following sections include the non-opioid alternatives of which we are aware and our evaluations, including consideration of comments, of whether these non-opioid alternatives meet the criteria established at § 416.174 for CY 2024.

(a) Finalized Annual Eligibility Re-Evaluations of Non-Opioid Alternatives That Were Separately Paid in the ASC Setting During CY 2023

In the CY 2023 final rule with comment period, we finalized that five drugs would receive separate payment in the ASC setting for CY 2023 under the policy for non-opioid pain management drugs and biologicals that function as surgical supplies (86 FR 63496). These drugs are described by HCPCS code C9290 (*Injection, bupivacaine liposome, 1 mg*), J1096 (*Dexamethasone, lacrimal ophthalmic insert, 0. mg*), HCPCS code J1097 (*Phenylephrine 10.16 mg/ml and ketorolac 2.88 mg/ml ophthalmic irrigation solution, 1 ml*), HCPCS code C9089 (*Bupivacaine, collagen-matrix implant, 1 mg*), and HCPCS code C9144 (*Injection, bupivacaine (posimir), 1 mg*).

In the CY 2024 (88 FR 49763) proposed rule, we re-evaluated these products outlined in the previous paragraph against the criteria specified in § 416.174, including the technical clarifications we proposed to that section, to determine whether they continue to qualify for separate payment in CY 2024. Based on our evaluation, we proposed that the drugs described by HCPCS codes C9290, J1096, J1097, and C9089 continue to meet the required criteria and should receive separate payment in the ASC setting. We proposed that the drug described by HCPCS code C9144 would not receive separate payment in the ASC setting under this policy, as this drug will be separately payable during CY 2024 under OPPS transitional pass-through status. Please see section V.A of this CY 2024 OPPS/ASC final rule for additional details on the pass-through status of HCPCS code C9144. We welcomed comment on our evaluations in the proposed rule, and below is our finalized policy for CY 2024.

Comment: There was overall general support for our proposal to pay separately in the ASC setting for the four drugs proposed in the proposed rule.

Response: We thank the commenters for their support.

(b) Finalized Eligibility Evaluation for the Separate Payment of Exparel

Based on our internal review as described in the proposed rule, we believe that Exparel, described by HCPCS code C9290 (*Injection, bupivacaine liposome, 1 mg*), meets the criteria described at § 416.174; and we proposed to continue paying separately for it under the ASC payment system for CY 2024. Exparel was approved by the FDA with a New Drug Application (NDA #022496) under section 505(c) of the Federal Food, Drug, and Cosmetic Act on October 28, 2011.[204] Exparel's FDA-approved indication is ''in patients 6 years of age and older for single-dose infiltration to produce postsurgical local analgesia'' and ''in adults as an interscalene brachial plexus nerve block to produce postsurgical regional analgesia.'' [205] No component of Exparel is opioid-based. Accordingly, we proposed that Exparel meets the criterion described at § 416.174(a)(1). Under the methodology described at V.B.1.a. of the proposed rule (88 FR 49676), the per-day cost of Exparel exceeded the proposed $140 per-day cost threshold. Therefore, we proposed that Exparel meets the criterion described at § 416.174(a)(2). Additionally, Exparel will not have transitional pass-through payment status under § 419.64 in CY 2024, nor will it be otherwise separately payable in the OPPS or ASC payment system in CY 2024 under a policy other than the one specified in § 416.174. Therefore, we proposed that Exparel meets the criteria in the regulation text at § 416.174(a)(3) and (4).

Based on the above discussion, we believed that Exparel meets the criteria described at § 416.174; and we proposed to continue making separate payment for it as a non-opioid pain management drug that functions as a supply in a surgical procedure under the ASC payment system for CY 2024.

Comment: We received general support on our proposal to continue making separate payment for Exparel as a non-opioid pain management drug that functions as a supply in a surgical procedure under the ASC payment system for CY 2024.

Response: We thank commenters for their support on our proposal to pay separately for Exparel in the ASC setting as a non-opioid pain management drug that functions as a surgical supply. After consideration of the public comments we received, we believe that Exparel, described by HCPCS code C9290 (Injection, bupivacaine liposome, 1 mg), continues to meet the criteria described at § 416.174. We note that our proposed rule evaluation continues to be accurate. We note that the per-day cost of Exparel exceeded the proposed $140 per-day cost threshold and continues to exceed the finalized $135 per-day cost threshold, so Exparel continues to meet the criterion described at § 416.174(a)(2). We are finalizing that we will continue to pay separately for Exparel as a non-opioid pain management drug that functions as a supply in a surgical procedure under the ASC payment system for CY 2024.

[204] Exparel. FDA Letter. 28 October 2011. *https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2011/022496s000ltr.pdf.*

[205] Exparel. FDA Package Insert. 22 March 2021. *https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/022496s035lbl.pdf.*

(c) Finalized Eligibility Evaluation for the Separate Payment of Omidria

Based on our internal review as described in the proposed rule, we believe that Omidria, described by HCPCS code J1097 (*Phenylephrine 10.16 mg/ml and ketorolac 2.88 mg/ml ophthalmic irrigation solution, 1 ml*), meets the criteria described at § 416.174(a), and we proposed to continue paying separately for it under the ASC payment system for CY 2024. Omidria was approved by the FDA with a New Drug Application (NDA #205388) under section 505(c) of the Federal Food, Drug, and Cosmetic Act on May 30, 2014.[206] Omidria's FDA-approved indication is as ''an alpha 1-adrenergic receptor agonist and nonselective cyclooxygenase inhibitor indicated for: Maintaining pupil size by preventing intraoperative miosis; Reducing postoperative pain.'' [207] No component of Omidria is opioid-based. Accordingly, we propose that Omidria meets the criterion described at § 416.174(a)(1). Under the methodology described at section V.B.1.a. of the proposed rule (88 FR 49676), the per-day cost of Omidria exceeds the proposed $140 per-day cost threshold. Therefore, we proposed that Omidria meets the criterion described at § 416.174(a)(2). Additionally, we believed that Omidria will not have transitional pass-through payment status under § 419.64 in CY 2024, nor will it be otherwise separately payable in the OPPS or ASC payment system in CY 2024 under a policy other than the one specified in § 416.174. Therefore, we proposed that Omidria meets the criteria in the regulation text at § 416.174(a)(3) and (4).

Based on the above discussion, we proposed that Omidria meets the criteria described at § 416.174 and should receive separate payment as a non-opioid pain management drug that functions as a supply in a surgical procedure under the ASC payment system for CY 2024.

Comment: We received general support on our proposal to continue making separate payment for Omidria as a non-opioid pain management drug that functions as a supply in a surgical procedure under the ASC payment system for CY 2024. A commenter also provided updated clinical information regarding the use of Omidria and demonstrated how separate payment of Omidria in the ASC setting has supported utilization of the drug.

Response: We thank commenters for their support and for their helpful comments and data analysis regarding the use of Omidria across different settings of care. We will continue to consider this information for future policy development.

After consideration of the public comments we received, we believe that Omidria, described by HCPCS code J1097 (*Phenylephrine 10.16 mg/ml and ketorolac 2.88 mg/ml ophthalmic irrigation solution, 1 ml*), continues to meet the criteria described at § 416.174. We note that our proposed rule evaluation continues to be accurate. We note that the per-day cost of Omidria exceeded the proposed $140 per-day cost threshold and continues to exceed the finalized $135 per-day cost threshold, so Omidria continues to meet the criterion described at § 416.174(a)(2). We are finalizing that we will continue to pay separately for Omidria as a non-opioid pain management drug that functions as a supply in a surgical procedure under the ASC payment system for CY 2024.

(d) Finalized Eligibility Evaluation for the Separate Payment of Xaracoll

Based on our internal review as described in the proposed rule, we believe Xaracoll, described by C9089 (*Bupivacaine, collagen-matrix implant, 1 mg*), meets the criteria described at § 416.174(a), and we proposed to continue paying separately for it under the ASC payment system for CY 2023. Xaracoll was approved by the FDA with a New Drug Application (NDA # 209511) under section 505(c) of the Federal Food, Drug, and Cosmetic Act on August 28, 2020.[208] Xaracoll is ''indicated in adults for placement into the surgical site to produce postsurgical analgesia for up to 24 hours following open inguinal hernia repair.'' [209] No component of Xaracoll is opioid-based. Accordingly, we proposed that Xaracoll meets the criterion described at § 416.174(a)(1). Under the methodology described at section V.B.1.a. of the proposed rule (88 FR 49676), the per-day cost of Xaracoll exceeds the proposed $140 per-day cost threshold. Therefore, we proposed that Xaracoll meets the criterion described at § 416.174(a)(2). Additionally, at this time we do not believe that Xaracoll will have transitional pass-through payment status under § 419.64 in CY 2024, nor do we believe it will otherwise be separately payable in the OPPS or ASC payment system under a policy other than the one specified in § 416.174. Therefore, we proposed that Xaracoll meets the criteria in the regulation text at § 416.174(a)(3) and (4).

Based on the above discussion, we proposed that Xaracoll meets the criteria described at § 416.174 and should receive separate payment as a non-opioid pain management drug that functions as a supply in a surgical procedure under the ASC payment system for CY 2024.

Comment: We received general support on our proposal to continue making separate payment for Xaracoll as a non-opioid pain management drug that functions as a supply in a surgical procedure under the ASC payment system for CY 2024.

Response: We thank commenters for their support on our proposal to pay separately for Xaracoll in the ASC setting as a non-opioid pain management drug that functions as a surgical supply.

After consideration of the public comments we received, we believe that Xaracoll, described by C9089 (*Bupivacaine, collagen-matrix implant, 1 mg*), continues to meet the criteria described at § 416.174. We note that our proposed rule evaluation continues to be accurate. We note that the per-day cost of Xaracoll exceeded the proposed $140 per-day cost threshold and continues to exceed the finalized $135 per-day cost threshold, so Xaracoll continues to meet the criterion described at § 416.174(a)(2). We are finalizing that we will continue to pay separately for Xaracoll as a non-opioid pain management drug that functions as a supply in a surgical procedure under the ASC payment system for CY 2024.

(e) Finalized Eligibility Evaluation for the Separate Payment of Dextenza

Based on our internal review as described in the proposed rule, we believe Dextenza, described by HCPCS code J1096 (*Dexamethasone, lacrimal ophthalmic insert, 0.1 mg*), meets the criteria described at § 416.174; and we proposed to provide separate payment for it under the ASC payment system for CY 2024. Dextenza was approved by the FDA with a New Drug Application (NDA # 208742) under section 505(c) of the Federal Food, Drug, and Cosmetic Act on November 30, 2018.[210] Dextenza's FDA-approved indication is

[206] Omidria. FDA Letter. 30 May 2014. *https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2014/205388Orig1s000ltr.pdf.*

[207] Omidria. FDA Package Insert. December 2017. *https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/205388s006lbl.pdf.*

[208] Xaracoll. FDA Letter. August 2020. *https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2020/209511Orig1s000ltr.pdf.*

[209] Xaracoll. FDA Labeling. August 2020. *https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/209511s000lbl.pdf.*

[210] Dextenza. FDA Letter. November 2018. *https://www.accessdata.fda.gov/drugsatfda_docs/nda/2018/208742Orig1s000Approv.pdf.*

as ''a corticosteroid indicated for the treatment of ocular pain following ophthalmic surgery'' and ''the treatment of ocular itching associated with allergic conjunctivitis.'' [211] No component of Dextenza is opioid-based. Accordingly, we proposed that Dextenza meets the criterion described at § 416.174(a)(1). Under the methodology described at section V.B.1.a. of the proposed rule, the per-day cost of Dextenza exceeds the proposed $140 per-day cost threshold (88 FR 49676). Therefore, we proposed that Dextenza meets the criterion described at § 416.174(a)(2). Additionally, we believed that Dextenza will not have transitional pass-through payment status under § 419.64 in CY 2024, nor do we believe it will otherwise be separately payable in the OPPS or ASC payment system under a policy other than the one specified in § 416.174. Therefore, we proposed that Dextenza meets the criteria in the regulation text at § 416.174(a)(3) and (4).

Based on the above discussion, we proposed that Dextenza meets the criteria described at § 416.174 and should receive separate payment as a non-opioid pain management drug that functions as a supply in a surgical procedure under the ASC payment system for CY 2024.

Comment: We received general support on our proposal to continue making separate payment for Dextenza as a non-opioid pain management drug that functions as a supply in a surgical procedure under the ASC payment system for CY 2024. We received many comments indicating the clinical benefit of Dextenza, and many of these comments requested separate payment for Dextenza.

Response: We thank commenters for their support on our proposal to pay separately for Dextenza in the ASC setting as a non-opioid pain management drug that functions as a surgical supply.

Comment: One commenter made a general statement regarding the use of Dextenza within their practice and stated that, in their view, the drug does not have the value that is currently assigned to it. Meaning, in their view, there are other options that give the same clinical results at a fraction of the cost.

Response: We thank this commenter for their input; however, it is not directly relevant to our analysis of whether Dextenza meets the criteria outlined in § 416.174. We may, however, take this input into consideration for future policy consideration.

After consideration of the public comments we received, we believe that Dextenza, described by HCPCS code J1096 (*Dexamethasone, lacrimal ophthalmic insert, 0.1 mg*), continues to meet the criteria described at § 416.174. We note that our proposed rule evaluation continues to be accurate. We note that the per-day cost of Dextenza exceeded the proposed $140 per-day cost threshold and continues to exceed the finalized $135 per-day cost threshold, so Dextenza continues to meet the criterion described at § 416.174(a)(2). We are finalizing that we will continue to pay separately for Dextenza as a non-opioid pain management drug that functions as a supply in a surgical procedure under the ASC payment system for CY 2024. Also, please see section III.E.2 of this final rule with comment period for details on the status of HCPCS code J1096 in the HOPD, as well as CPT code 68841.

(f) Finalized Eligibility Evaluation for the Separate Payment of Posimir

Based on our internal review as described in the proposed rule, we do not believe that Posimir, described by HCPCS code C9144 (*Injection, bupivacaine (Posimir), 1 mg*), meets the criteria described at § 416.174(a); and we did not propose to continue paying separately for it under the ASC payment system for CY 2024. Posimir was approved by the FDA with a New Drug Application (NDA #204803) under section 505(c) of the Federal Food, Drug, and Cosmetic Act on February 1, 2021.[212] Posimir contains an amide local anesthetic and is indicated in adults for administration into the subacromial space under direct arthroscopic visualization to produce post-surgical analgesia for up to 72 hours following arthroscopic subacromial decompression.'' [213]

No component of Posimir is opioid-based. Accordingly, we proposed that Posimir meets the criterion described at § 416.174(a)(1). Under the methodology described at V.B.1.a. of the proposed rule (88 FR 49676), the per-day cost of Posimir exceeds the proposed $140 per-day cost threshold. Therefore, we proposed that Posimir meets the criterion described at § 416.174(a)(2). However, Posimir will have transitional pass-through payment status under § 419.64 in CY 2024, and it will be otherwise separately payable in the OPPS or ASC payment system in CY 2024 under a policy other than the one specified in § 416.174. Therefore, we proposed that Posimir does not meet the criteria at the regulation text at § 416.174(a)(3) and (4).

Based on the above discussion, we proposed that Posimir does not meet the criteria in the regulation text at § 416.174(a)(3) and (4) and should not receive separate payment as a non-opioid pain management drug that functions as a supply in a surgical procedure under the ASC payment system for CY 2024. However, we stated that HCPCS code C9144 will continue to receive separate payment under its pass-through status as outlined in section V of the proposed rule (88 FR 49674).

We did not receive any public comments on our proposal and are finalizing our proposal that Posimir does not meet the criteria in the regulation text at § 416.174(a)(3) and (4) and should not receive separate payment as a non-opioid pain management drug that functions as a supply in a surgical procedure under the ASC payment system for CY 2024. However, HCPCS code C9144 will continue to receive separate payment under its pass-through status as outlined in section V of this final rule.

Comment Solicitation on New Products That Meet the Criteria Specified in § 416.174

We solicited comment on additional non-opioid pain management drugs and biologicals that function as surgical supplies that may meet the criteria specified in § 416.174 and qualify for separate payment under the ASC payment system. We encouraged commenters to include an explanation of how the drug or biological meets the eligibility criteria in § 416.174. We stated if we found that any additional drugs or biologicals described by commenters do satisfy the criteria established at § 416.174, we would finalize their separate payment status for CY 2024 in the ASC setting in the CY 2024 OPPS/ASC final rule with comment period.

We did not receive any public comments detailing additional new products that may meet the criteria specified at § 416.174 and therefore, we are not finalizing any additional new drugs or biologicals as meeting the criteria at § 416.174 to receive separate payment in the ASC setting.

Comment: Some commenters supported CMS continuing the objective criteria outlined at § 416.174 as they believe this policy has proven effective

[211] Dextenza. FDA Labeling. October 2021. *https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/208742s007lbl.pdf.*

[212] Posimir. FDA Approval Letter. *https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2021/204803Orig1s000ltr.pdf.*

[213] Posimir. FDA Package Insert. *https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/204803Orig1s001lbl.pdf.*

in expanding patient access to alternatives of opioids.

Response: We thank commenters for their support.

Comment: One commenter suggested that certain drugs should be grandfathered into this policy for a period of two to three years in order to allow them adequate time to receive an FDA indication for pain management or analgesia. These commenters believed that a temporary grandfathering policy would provide manufacturers the time and opportunity to complete new clinical trials in order to allow their products to apply for the necessary FDA approved indications. These commenters thought this was appropriate as they believed drugs, such as Dexycu, were already being used as pain management alternatives to opioids, despite not yet having FDA indications for pain management or analgesia.

Response: We thank the commenter for this feedback. We remind interested parties that we did not propose any modifications to our policy at § 416.174 but may consider this feedback in future rulemaking.

Comment: Many commenters encouraged CMS to consider a policy that unpackages non-opioid pain management drugs in the HOPD setting for CY 2024 in order to align with the current ASC payment policy for non-opioid pain management drugs that function as a surgical supply and to pay for the four separately payable drugs in the ASC setting in the HOPD setting as well. These commenters stated that the same reasons underlying separate payment for drugs in the ASC setting support separate payment for drugs in the HOPD setting. Many stated that utilization in the HOPD has decreased as a result of packaged payment and could be higher with separate payment and that they believed opioid alternatives serve a valuable clinical purpose and their use should be encouraged in all settings of care. Several commenters provided data regarding how packaging negatively impacted the utilization of their products in the HOPD setting. We note that many commenters were non-specific as to whether their request was for CMS to expand the policy outlined at § 416.174 to include payment in the HOPD setting or whether their request was for CMS to enact section 4135 of the Consolidated Appropriations Act a year earlier, which is discussed in the next section of this rule.

Similarly, one commenter stated that CMS has failed to conduct any review of payments in OPPS for these non-opioid drugs or provide justification for continuing to package payment for non-opioid pain management drugs in the HOPD. The commenter urged CMS to take a more comprehensive look at whether its OPPS drug packaging policies are negatively impacting quality of care for Medicare beneficiaries.

Response: We thank commenters for their input, and we appreciate the comments urging expansion of this policy to the HOPD setting. We will take these comments into consideration for future rulemaking. We remind interested parties that we did not propose to modify, and we are not modifying our policy at § 416.174 or creating new policies in response to these comments at this time.

Comment: We received comments from interested parties who advocated for payment changes. Many commenters were non-specific as to whether their request was for CMS to expand the policy outlined at § 416.174 or whether their comment was in response to CMS' comment solicitation on enacting section 4135 of the Consolidated Appropriations Act, 2023. Specifically, however, some commenters expressed their support for CMS for unpackaging and paying separately for non-opioid alternative devices and claimed that assessing utilization of a product is not appropriate in determining whether there is an access issue. These commenters requested that CMS revise the current eligibility criteria to permit medical devices to be eligible for separate payment under § 416.174. Some commenters recommended CMS implement a peer review literature requirement for such devices. Other commenters recommended a longer-term solution, such as a finalization of policy for several years to provide stability. Similarly, commenters requested CMS educate providers on the availability of the various opioid alternative modalities available to them.

Response: We thank commenters for these policy suggestions. We may take these comments into consideration for future rulemaking. We remind interested parties that we did not propose to modify, and we are not modifying our policy at § 416.174 at this time.

We note that the current policy outlined at § 416.174 is different from the policy contained within section 4135 of the Consolidated Appropriations Act, 2023 and we intend to make a proposal for the implementation of section 4135 in the CY 2025 OPPS/ASC proposed rule. We also intend to discuss the interaction of such proposal and our current policy outlined at § 416.174 in the CY 2025 OPPS/ASC proposed rule.

In summary, after consideration of the public comments received, we are finalizing without modification, that the drugs described by HCPCS code C9290 (*Injection, bupivacaine liposome, 1 mg*), J1096 (*Dexamethasone, lacrimal ophthalmic insert, 0. mg*), HCPCS code J1097 (*Phenylephrine 10.16 mg/ml and ketorolac 2.88 mg/ml ophthalmic irrigation solution, 1 ml*), HCPCS code C9089 (*Bupivacaine, collagen-matrix implant, 1 mg*), continue to function as non-opioid pain management drugs and biologicals that function as surgical supplies and meet the criteria at § 416.174. Similarly, we are finalizing our proposal that HCPCS code C9144 (*Injection, bupivacaine (posimir), 1 mg*), no longer meets all of the criteria at § 416.174 and will not receive separate payment in the ASC setting under that policy.

Table 125 below lists the four drugs that we proposed and are finalizing as eligible to receive separate payment as a non-opioid pain management drug that functions as a supply in a surgical procedure under the ASC payment system and meets the criteria at § 416.174(a) for CY 2024.

TABLE 125: SUMMARY OF PRODUCTS PROPOSED AND FINALIZED TO MEET CMS'S CRITERIA FOR SEPARATE PAYMENT IN THE ASC SETTING UNDER THE NON-OPIOID PAIN MANAGEMENT DRUGS THAT FUNCTION AS A SURGICAL SUPPLY PACKAGING POLICY FOR CY 2024

HCPCS Code	Brand Name	Long Descriptor	CY 2024 OPPS Status Indicator (SI)*	CY 2024 ASC Payment Indicator (PI)*
C9290	Exparel	Injection, bupivacaine liposome, 1 mg	N	K2
J1097	Omidria	Phenylephrine 10.16 mg/ml and ketorolac 2.88 mg/ml ophthalmic irrigation solution, 1 ml	N	K2
J1096	Dextenza	Dexamethasone, lacrimal ophthalmic insert, 0.1 mg	N	K2
C9089	Xaracoll	Bupivacaine, collagen-matrix implant, 1 mg	N	K2

*Please see ASC Addendum BB for applicable payment rates, OPPS Addendum D1 for SI definitions, and

F. Comment Solicitation on Access to Non-Opioid Treatments for Pain Relief Under the OPPS and ASC Payment System

1. Background on Access to Non-Opioid Treatments for Pain Relief

The Consolidated Appropriations Act (CAA), 2023 (Pub. L. 117–328), was signed into law on December 29, 2022. Section 4135(a) and (b) of the CAA, 2023, titled ''Access to Non-Opioid Treatments for Pain Relief,'' amended section 1833(t)(16) and section 1833(i) of the Social Security Act, respectively, to provide for temporary additional payments for non-opioid treatments for pain relief (as that term is defined in section 1833(t)(16)(G)(i) of the Act). In particular, section 1833(t)(16)(G) provides that with respect to a non-opioid treatment for pain relief furnished on or after January 1, 2025, and before January 1, 2028, the Secretary shall not package payment for the non-opioid treatment for pain relief into payment for a covered OPD service (or group of services) and shall make an additional payment for the non-opioid treatment for pain relief as specified in clause (ii) of that section. Clauses (ii) and (iii) of section 1833(t)(16)(G) of the Act provide for the amount of additional payment and set a limitation on that amount.

Paragraph (10) of section 1833(i) of the Act cross-references the OPPS provisions about the additional payment amount and payment limitation for non-opioid treatments for pain relief and applies them to payment under the ASC payment system. In particular, subparagraph (A) of paragraph (10) of section 1833(i) of the Act, as added by section 4135(b) of the CAA, 2023, provides that in the case of surgical services furnished on or after January 1, 2025, and before January 1, 2028, additional payments shall be made under the ASC payment system for non-opioid treatments for pain relief in the same amount provided in clause (ii) and subject to the limitation in clause (iii) of section 1833(t)(16)(G) of the Act for the OPPS. Subparagraph (B) of section 1833(i)(10) of the Act provides that a drug or biological that meets the requirements of 42 CFR 416.174 and is a non-opioid treatment for pain relief shall also receive additional payment in the amount provided in clause (ii) and subject to the limitation in clause (iii) of section 1833(t)(16)(G) of the Act.

Because the additional payments are required to begin on January 1, 2025, we stated in the proposed rule (88 FR 49767) that we plan to include our proposals to implement the section 4135 amendments in the CY 2025 OPPS/ASC proposed rule. We specifically sought comment on the issues discussed in the following sections, as well as comments on the implementation of all facets of this provision.

2. Comment Solicitation for CY 2025 Implementation

a. Potential Qualifying Drugs, Biologicals, and Devices

In preparation for implementing section 4135 of the CAA, 2023, for CY 2025, we sought comment on any drug, biological, or medical device that a commenter believes would meet the definition of a non-opioid treatment for pain relief under section 1833(t)(16)(G)(iv) of the Act. We encouraged commenters to submit appropriate FDA documentation, published peer-reviewed literature, or other evidence-based support, if applicable, to illustrate why the commenters believe the drug, biological, or medical device meets the definition of a non-opioid treatment for pain relief. For these products, we also solicited comment on appropriate codes and descriptors if no HCPCS codes currently exist for the product. We noted that we will evaluate these products, including the information submitted by commenters, and proposed additional payments, subject to the payment limitation, for those that meet the definition of a non-opioid treatment for pain relief in the CY 2025 OPPS/ASC rulemaking cycle, rather than during the CY 2024 OPPS/ASC final rule with comment period.

b. Evidence Requirement for Medical Devices

Section 1833(t)(16)(G)(iv)(II)(bb) of the Act specifies an additional requirement for medical devices to meet the definition of non-opioid treatment for pain relief. This section requires that a medical device demonstrate the ability to replace, reduce, or avoid intraoperative or postoperative opioid use or the quantity of opioids prescribed in a clinical trial or through data published in a peer-reviewed journal.

As the statute requires information from a clinical trial or data published in a peer-reviewed journal, we seek comment on the best way to obtain and evaluate that information. We also sought comment on how we should assess information from a clinical trial or data published in a peer-reviewed journal, including how to assess for conflicts of interest or integrity concerns, whether to focus on outcomes rather than surrogate endpoints, and whether to require that all decreases in opioid use be statistically and clinically significant compared to the usual standard of care (rather than placebo).

c. Amount of Payment

Section 1833(t)(16)(G)(ii)(I) of the Act states that, subject to the limitation in clause (iii), the amount of payment for a non-opioid treatment for pain relief that is a drug or biological product is the amount of payment for such drug or biological determined under section 1847A of the Act that exceeds the portion of the otherwise applicable Medicare OPD fee schedule that the Secretary determines is associated with the drug or biological. As this language is very similar to the transitional pass-through language at section 1833(t)(6)(D)(i) of the Act, we anticipate implementing a similar payment methodology for drugs and biologicals under this future policy.

Section 1833(t)(16)(G)(ii)(II) of the Act states that the amount of payment for a non-opioid treatment for pain relief that is a medical device is the amount of the hospital's charges for the device, adjusted to cost, that exceeds the portion of the otherwise applicable Medicare OPD fee schedule that the Secretary determines is associated with the device. As this language is very similar to the transitional pass-through language at section 1833(t)(6)(D)(ii) of the Act, we anticipate implementing a similar payment methodology for medical devices under this future policy.

Section 1833(i)(10) of the Act provides that the same payment rate shall apply in the ASC setting as the rates described in section 1833(t)(16)(G)(ii) of the Act for hospital outpatient departments, subject to the limitation in section 1833(t)(16)(G)(iii) of the Act.

d. Payment Limitation

Section 1833(t)(16)(G)(iii) of the Act states that the additional payment amount specified in clause (ii), and as described in the previous section, shall not exceed the estimated average of 18 percent of the OPD fee schedule amount for the OPD service (or group of services) with which the non-opioid treatment for pain relief is furnished, as determined by the Secretary. We sought comment on how we should determine the OPD service or groups of services with which non-opioid treatments for pain relief are furnished for purposes of calculating the payment limitation for each treatment. Specifically, we sought comment on the scenarios outlined below. Additionally, we welcomed other recommendations from interested parties consistent with the statutory requirements.

Scenario 1: Payment Limitation Based on the Top Five Services by Volume with Known Claims Data

As demonstrated in this example (Table 126), one possible approach is to use the top five services associated with a hypothetical drug, biological, or medical device, to determine the volume-weighted payment rate and the payment limit, based on the most recent claims data available. For the non-opioids that are currently separately paid, we predict that the majority of utilization is focused in the top five mostly frequently performed services, thus using the top five services would provide a representative estimate for the payment limit. However, we solicit comment on this prediction and welcome input from commenters if they believe another number of procedures, or another metric, would be appropriate to determine the list of procedures in which the payment limitation would be calculated.

For this example, we would begin by identifying the top five services by volume that package this drug, biological, or device into their payment rate. Second, we would calculate the volume-weighted payment rate per claim, which would be $700 in the example below. Third, we would apply the 18 percent payment limit per clinical dose, rather than per HCPCS dosage unit, which is $126 in the case below. We note that we have rounded these numbers for ease of illustration for this example. We would apply this payment limit to the clinical dose received by the beneficiary as the payment limit applies to the total amount of payment, rather than the HCPCS dosage unit payment, which may only represent a small fraction of the total amount of payment. This means that even if the non-opioid treatment for pain relief had an amount of additional payment under section 1833(t)(16)(G)(ii) of the Act that was greater than $126 per dose, it would be limited to $126 by 1833(t)(16)(G)(iii) of the Act. In this example, this non-opioid treatment for pain relief would not be subject to the threshold packaging policy in section V.B.1.a. of the proposed rule (88 FR 49676) even though its payment falls below the proposed CY 2024 drug packaging threshold of $140, per section 1833(t)(16)(G)(i) of the Act, and would also be separately paid when used during a comprehensive APC (C–APC) procedure in the HOPD setting. We note, for CY 2024, the OPPS drug packaging threshold was proposed to be $140. However, based on updated data, we are finalizing a threshold of $135 for CY 2024. For more information on the drug packaging threshold, see section V.B.1.a of this CY 2024 OPPS/ASC final rule with comment period.

TABLE 126: Example of Payment Limitation Based on the Top Five Services by Volume

Service	Volume (claims)	Payment	Total Payment (volume * claims)	Volume Weighted Payment per claim (total payment / total volume)	Payment Limit
1	100	1000	100,000	$\frac{(100{,}000 + 4{,}000 + 1{,}000 + 1{,}000 + 1{,}000)}{100 + 20 + 10 + 10 + 10}$ = $700	$700 * 0.18 = $126
2	20	200	4,000		
3	10	100	1,000		
4	10	100	1,000		
5	10	100	1,000		

We welcomed comments on this approach. We sought comment on whether utilizing the top five services by volume is an appropriate method by which to establish this payment limit. We also sought comment on additional methodologies, such as determining the payment limit based on the top 10 services by volume, by total payment rather than volume, or any number of services with more than a certain percentage of overall utilization, such as 10 percent.

Scenario 2: Payment Limit Without Claims Data

Additionally, we sought comment on the best approach for determining a payment limit, pursuant to section 1833(t)(16)(G)(iii) of the Act for drugs, biologicals, and devices when there are no known claims data, such as for newly FDA-approved and marketed products. CMS could propose the services with which a product would be expected to be furnished and would typically be packaged absent this policy during calendar year rulemaking, based on expected clinical use patterns. Determining the service, or group of services, to use to calculate the payment limit could be accomplished through engagement with interested parties and a review by CMS Medical Officers and clinical staff. Absent engagement from interested parties, CMS could make its determination of the service, or group of services, to use to calculate the payment limit based on expected clinical use patterns. CMS could then adjust the services that are used to calculate the payment limit as claims data becomes available in subsequent years. We sought comment on this approach as well as other approaches of interest to commenters.

We welcomed comment from interested parties on the implementation of all facets of section 4135.

Comment: We received a significant number of comments in response to our comment solicitation and we are including a high-level overview of the comments we received. Many of the comments we received focused on opioids broadly, some comments addressed future policy implementing section 4135 of the Consolidated Appropriations Act of 2023, and others addressed the policy authorized under the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act (SUPPORT) Act (Pub. L. 115–271) as described in the previous section.

Response: We thank the numerous commenters for their significant interest on the topic of non-opioid pain management and CMS's role in addressing the opioid epidemic. We will not be responding directly to all of these comments because, as we stated in the proposed rule (88 FR 49767), we plan to include our proposals to implement the section 4135 amendments in the CY 2025 OPPS/ASC proposed rule. These comments will be taken into account when crafting that proposed policy and discussed in the CY 2025 OPPS/ASC proposed rule.

Comment: We received a number of comments urging CMS to expedite the implementation timeline for the section 4135 amendments from CY 2025 to CY 2024. One commenter suggested that CMS use all measures at its disposal, including certain waivers available under the ongoing opioid public health emergency, in order to accomplish this request. Commenters generally spoke of the severity of the opioid epidemic and its harmful effects. A couple commenters specifically requested an additional comment period for CMS to gather thorough input from all interested stakeholders. One commenter expressed concern that the proposed rule did not more aggressively seize the opportunity to prevent opioid addiction by increasing access to non-opioid pain management approaches across outpatient surgical settings. Another commenter stated that the existing separate payment policies for non-opioid pain management approaches did not adequately incentivize facilities to use these alternative methods for pain management.

Response: We thank the commenters for expressing their concerns on this important issue. Section 4135 of the CAA, 2023 requires separate payments to begin on January 1, 2025, and we will undertake notice and comment rulemaking to implement it. As such, we will include our implementation proposal in the CY 2025 OPPS/ASC proposed rule. We note that we agree with commenters on the importance of this issue.

It is a top priority of CMS to address the opioid misuse epidemic and its impact on communities. CMS is committed to a comprehensive and multi-pronged strategy to combat this public health emergency. Please see our Roadmap Strategy to Fight the Opioid Crisis.[214]

Although not a component of the OPPS/ASC payment policies, we note that through the CMS Behavioral Health Strategy,[215] CMS seeks to remove barriers to care and services, and to adopt a data-informed approach to evaluate our behavioral health programs and policies. CMS is working to improve access to substance use disorder (SUD) prevention, treatment and recovery services. As of January 1, 2020, CMS makes bundled payments for opioid use disorder treatment services provided by Opioid Treatment Programs under with Medicare Part B.[216] Additionally, CMS covers a monthly bundle service for the treatment of OUD and other SUDs in office-based settings,[217] as well as screenings for OUD.

We thank commenters again for their insightful comments that will assist us in crafting well informed future policy.

Comment: We received several comments supporting the existing efforts CMS has taken to reduce the financial incentives that may exist as a result of OPPS packaging policies to use opioids over non-opioid alternatives for pain relief in surgical settings. Several commenters expressed appreciation that CMS is engaging stakeholders in advance of the implementation of this statutory provision. One commenter stated that unbundling and stand-alone payment for these alternative medications and treatment plans will ensure a change in pain management practices, prescription patterns, and ultimately improve patient care.

Response: We thank commenters for their support.

Comment: We received very broad support for extending our current policy under § 416.174(a) to encompass payment in the HOPD setting, and to include payment for expanded drugs, biologicals, devices, and procedures. Specifically, we received a significant number of comments that suggested drugs, biologicals, medical devices, and other modalities that could be utilized as non-opioid alternatives for pain management as well as the criteria CMS should employ to evaluate these requests, including evidence requirements for medical devices. The non-opioid alternatives that were suggested in the comment solicitation include, but are not limited to the following: enhanced recovery after surgery protocols; ultrasound equipment when it is used to guide the injection of non-opioid treatments for pain relief; certain PNS systems such as Sprint; oral drugs; IV acetaminophen; IV NSAIDS such as Caldolor; massage therapy; acupuncture; chiropractic services; osteopathic manipulation; cognitive behavioral therapy; physical therapy; neurological devices such as pain pumps; spinal cord stimulators; cold therapy devices; cryoablation; local anesthetics via pump; ON–Q pump; interspinous spacers; Polar ice devices; NerveCap; THC oil; acupuncture; and more drugs, biologicals, items, services, and devices.

We received a couple of comments that supported continuing to make separate payments for Exparel, Omidria, Xaracoll, and Dextenza as non-opioid management drugs. These are the 4 drugs that will be paid separately in the ASC setting in CY 2024 under the policy described at § 416.174(a).

We also received a comment requesting that CMS designate the Addinex System as a non-opioid pain management drug technology. We also received a comment asking for the ioversa system, a medical device with 510(k) pre-market clearance, to receive separate payment. One commenter requested separate payment be made for Zynrelef under the non-opioid pain management payment policy for CY 2025, effective once its pass-through status expires in CY 2025.

For many of the suggested items listed above, commenters provided current HCPCS codes, suggested possible new HCPCS coding, or suggested that CMS create appropriate new coding for the new items paid under this policy.

Another commenter suggested that CMS examine and alleviate barriers to appropriate treatment options that can reduce the duration or impact of acute pain experienced with some diseases such as sickle cell anemia. Similarly, one commenter recommended that we provide education and outreach to ensure providers and patients are aware of and can access non-opioid therapies to manage acute and chronic pain in these settings. Another commenter suggested that CMS create separate billing codes for non-opioid anesthesia services and treatments for pain.

Finally, we received several comments regarding the criteria used to determine if a drug, device, or treatment modality qualifies as a non-opioid pain management alternative. One comment supported maintaining the existing criteria that CMS has outlined for determining FDA-approved non-opioid pain management drugs for separate payment in the ASC setting and further recommended extending these determinations on a longer-term basis.

Response: We appreciate all of the comments received suggesting additional therapeutic modalities for which CMS should consider paying under this policy for CY 2025. We will take these suggestions into consideration as we develop our proposal for CY 2025.

Comment: A few commenters discussed their views on evidence requirements for medical devices that CMS should impose. Many commenters believed that CMS should follow the clinical evidence requirement set out in the statute when evaluating eligibility for medical devices as non-opioid treatments. They believed that CMS should implement this requirement of the statute to include only those devices that replace or reduce the use of opioids, as demonstrated through a clinical trial or data published in a peer review journal. Many of these commenters did not believe CMS should set additional specific trial design or outcomes criteria not found in the Act. Another commenter suggested that CMS create a transparent process for evaluating the clinical evidence that indicate certain technologies reduce opioid use. The commenter specifically stated that CMS should utilize a p-value of 0.10 for statistical significance when device safety has been established and provide payment for these devices using CMS existing pass-through policies.

Alternatively, some commenters recommend a more stringent evaluation process. One commenter stated that CMS should focus on outcomes, not surrogate endpoints. The commenter stated specifically that CMS should assess whether the medical device (1) reduced the percentage of patients using opioids or (2) reduced morphine milligram equivalents (MMEs). The reduction in opioid use should be of a duration that is clinically appropriate for the patient's condition.

Response: We appreciate all of the comments received on evidence requirements for medical devices that CMS should impose. We will take these into consideration as we develop our proposal for CY 2025.

Comment: Regarding payment, commenters generally felt that the CMS

[214] *https://www.cms.gov/about-cms/agency-information/emergency/downloads/opioid-epidemic-roadmap.pdf.*

[215] *https://www.cms.gov/cms-behavioral-health-strategy.*

[216] *https://www.cms.gov/medicare/payment/opioid-treatment-program.*

[217] *https://www.cms.gov/medicare/payment/fee-schedules/physician/opioid-use-disorder-screening-treatment.*

methodology outlined in the comment solicitation was appropriate for determining the payment limitation, particularly the payment limitation based on the top five services by volume with known claims data and payment limit without claims data. Other commenters suggested alternative methodologies such as developing a non-claims data-based approach for payment of non-opioid alternatives, which relied on available clinical data. Some commenters felt the ASP approach for setting the payment amount is appropriate, given how CMS reimburses for other separately paid drugs and biologicals. Many commenters requested that CMS be consistent with the transitional pass-through status payment methodology for drugs and devices. One commenter was concerned that reducing the payment amount by some portion of the associated procedure APC may lead to improper and inconsistent payment for non-opioid treatments. One commenter urged CMS to provide additional clarification and work to ensure that there is transparency on the potential methodology to be used to calculate the specific payments for qualifying non-opioid treatments, particularly in the case of treatments with multiple applicable procedures and, thus, potentially varying payments as well as how CMS intends to define clinical dose as discussed in the proposed rule.

Response: We appreciate all of the comments received on the topic of payment. We will take these into consideration as we develop our proposal for CY 2025.

Comment: One commenter requested CMS amend its non-opioid pain management drug policies to permit temporary ''grandfathering'' of certain drugs approved before CY 2022 that have relevant and documentable clinical support for their pain management attributes but do not have current FDA label indication for pain management or analgesia.

Response: We thank the commenter for their comment. We are currently unaware of any authority that would allow us to implement this recommendation, but we will consider that point for future rulemaking.

Comment: Other commenters continued to express more general concerns with opioid use and access to non-opioid alternatives. For example, one commenter stated that beneficiaries in rural regions lack access to adequate healthcare, reliable transportation to health programs, and insurance coverage.

Response: While we recognize some of the concerns presented by commenters fall outside of the scope of our OPPS and ASC Medicare payment policies, we appreciate these comments and learning more about how we can structure policies to address this multifaceted issue.

We sincerely thank commenters for their responses on this important issue. We encourage further engagement from interested parties on this issue. As previously mentioned, we will take all of these comments into consideration in order to create an informed policy proposal to implement the section 4135 of the CAA, 2023, in the CY 2025 OPPS/ASC proposed rule.

G. 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 requested in the guidance document titled ''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: *https://www.cms.gov/medicare/payment/prospective-payment-systems/ambulatory-surgical-center-asc/new-technology-intraocular-lenses-ntiols.*
- 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 with comment period 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 2024

We did not receive any requests for review to establish a new NTIOL class for CY 2024 by March 1, 2023, the due date published in the CY 2023 OPPS/ASC final rule with comment period (87 FR 72091).

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 do not propose to revise the payment adjustment amount for CY 2024.

The comments and our responses to the comments are set forth below:

Comment: Some commenters requested we re-evaluate our payment adjustment for a new NTIOL class. Commenters noted that our $50 payment adjustment has not been adjusted since CY 1999, the payment has lagged behind the overall economic inflation rate, and that the stagnant payment adjustment has been a barrier to intraocular lens innovation. Commenters recommended that we set the $50 payment adjustment at $91.04 and update this payment annually.

Response: At the inception of the ASC benefit on September 7, 1982, Medicare paid 90 percent of the reasonable charge for intraocular lenses (IOLs) inserted concurrent with or following cataract surgery performed in an ASC. The Omnibus Budget Reconciliation Act of 1987 (Pub. L. 100–203) mandated that we include payment for an IOL furnished by an ASC for insertion during or following cataract surgery as part of the facility fee. Section 141(b)(1) of the Social Security Amendments of 1994 required us to develop and implement a process under which interested parties may request a review

of the appropriateness of the payment amount for an IOL to ensure that the facility fee for the procedure is reasonable and related to the cost of acquiring a lens that belongs to a class of NTIOLs. In response, in June 1999, CMS established the payment adjustment for NTIOLs at $50 per lens (with the beneficiary responsible for a 20 percent coinsurance). In light of the commenters' recommendation but in the absence of cost and volume data for potential forthcoming NTIOLs, we performed an analysis to determine if the cost of IOLs has significantly changed and if the $50 payment adjustment is no longer reasonable and appropriate as the commenters suggest.

For our analysis, we looked at the change in the median cost, mean cost, and geometric mean cost of the most commonly-billed intraocular lens HCPCS code—HCPCS code V2632 (Posterior chamber intraocular lens) from CY 2010 (the furthest year back we could readily retrieve hospital outpatient claims data) to CY 2022 (the most recently available full year of claims data). In CY 2010, over 162,000 units of HCPCS code V2632 were reported on hospital outpatient claims at a median cost of $204.34, mean cost of $259.32, and geometric mean cost of $199.84. For CY 2022, over 220,000 units of HCPCS code V2632 were reported on hospital outpatient claims at a median cost $189.26, mean cost of $230.18, and a geometric mean cost of $184.10. Interestingly, we did not observe a strong increase, or any increase at all, in the cost of IOLs since CY 2010 but a noticeable decline (between 8 and 12 percent depending on the cost metric) in the cost of an IOL. Therefore, given the decline in the cost of IOLs we observed from CY 2010 to CY 2022, we do not accept the commenters' suggestion that the $50 payment adjustment has been a barrier to intraocular lens innovation, and we continue to believe the $50 per lens payment adjustment is a reasonable and appropriate payment adjustment for NTIOLs.

4. Announcement of CY 2024 Deadline for Submitting Requests for CMS Review of Applications for a New Class of NTIOLs

In accordance with 42 CFR 416.185(a) of our regulations, CMS announces that in order to be considered for payment effective beginning in CY 2025, requests for review of applications for a new class of new technology IOLs must be received by 5:00 p.m. EST, on March 1, 2024. Send requests via email to *outpatientpps@cms.hhs.gov* or by mail to ASC/NTIOL, Division of Outpatient Care, Mailstop C4–05–17, Centers for Medicare and Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21244–1850. To be considered, requests for NTIOL reviews must include the information requested on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ASCPayment/*NTIOLs.

H. Calculation of the ASC Payment Rates and the ASC Conversion Factor

1. Background

In the August 2, 2007, ASC 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 and 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, ASC 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 XIII.D.2 of the CY 2023 OPPS/ASC proposed rule (87 FR 44715 and 44716)), 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 ASC final rule (72 FR 42517 and 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 result 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/wp-content/uploads/legacy_drupal_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.bls.gov/bls/omb-bulletin-15-01-revised-delineations-of-metropolitan-statistical-areas.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/wp-content/uploads/legacy_drupal_files/omb/bulletins/2017/b-17-01.pdf.*)

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 18–04, which superseded the April 10, 2018 OMB Bulletin No. 18–03. A copy of OMB Bulletin No. 18–03 may be obtained at *https://www.whitehouse.gov/wp-content/uploads/2018/04/OMB-BULLETIN-NO.-18-03-Final.pdf.* A copy of OMB Bulletin No. 18–04 may be obtained at *https://www.whitehouse.gov/wp-content/uploads/2018/09/Bulletin-18-04.pdf.*

On March 6, 2020, OMB issued Bulletin No. 20–01, which provided updates to and superseded OMB Bulletin No. 18–04 that was issued on September 14, 2018. (For a copy of this bulletin, we refer readers to the following website: *https://www.whitehouse.gov/wp-content/uploads/2020/03/Bulletin-20-01.pdf.*)

The final CY 2024 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. 13–01, 15–01, 17–01, 18–03, 18–04, and 20–01). 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 2024, we are applying a proxy wage index based on this methodology to ASCs located in CBSA 25980 (Hinesville-Fort Stewart, GA).

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 and 72059). In other situations, where there are no IPPS hospitals located in a relevant labor market area, we apply 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 2024 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 are 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.

As discussed in section II.A.1.a of this final rule, we are using the CY 2022 claims data to be consistent with the OPPS claims data for this rule. Consistent with our established policy, we proposed to scale the CY 2024 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 2022, we proposed to compare the estimated total payment using the CY 2023 ASC

relative payment weights with the estimated total payment using the CY 2024 ASC relative payment weights to take into account the changes in the OPPS relative payment weights between CY 2023 and CY 2024.

Additionally, in light of our policy to provide a higher ASC payment rate through the use of ASC complexity adjustment codes for certain primary procedures when performed with add-on packaged services, we incorporate estimated total spending and estimated utilization for these codes in our budget neutrality calculation. We estimated in the CY 2023 OPPS/ASC final rule with comment period (87 FR 72094) that the impact on CY 2023 estimated total payments from our proposed CY 2023 ASC complexity adjustment codes would be $5 million in spending and we propose to incorporate this $5 million in estimated CY 2023 total payments for the budget neutrality calculation of this final rule. For estimated CY 2024 total payments, we proposed to incorporate the estimated total spending and estimated utilization related to our proposed CY 2024 ASC complexity adjustment codes. In this final rule with comment period, we estimate the additional CY 2024 spending related to our proposed ASC complexity adjustment codes will be approximately $5 million.

We proposed to use the ratio of estimated CY 2023 to estimated CY 2024 total payments (the weight scalar) to scale the ASC relative payment weights for CY 2024. The proposed CY 2024 ASC weight scalar was 0.8649. Consistent with historical practice, we proposed to scale, using this method, 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.

We proposed that we would not scale 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. We proposed to use the CY 2022 claims data to model our budget neutrality adjustment for CY 2024.

Comment: Many commenters reiterated their past recommendation that we discontinue applying the ASC weight scalar to achieve budget neutrality and greater parity between the OPPS and ASC. Commenters were concerned that the ASC weight scalar has decreased overall since the implementation of the revised ASC payment system for CY 2008 and stated that relative weights have already been scaled for budget neutrality and do not require secondary rescaling to achieve budget neutrality under the ASC payment system. Commenters proposed that CMS combine the OPPS and ASC utilization and mixes of services to establish a single weight scalar, applying a single budget neutrality calculation to the OPPS and ASC payment systems, which commenters felt would align the payment systems and more accurately scale for outpatient volume across both sites of service.

Response: We disagree with commenters' assessment and are not accepting the recommendation to discontinue applying the ASC weight scalar. As we have stated in past rulemaking (82 FR 59421), applying the ASC weight scalar, which is 0.8881 for this final rule with comment period and an increase from the CY 2023 ASC weight scalar of 0.8594, ensures that the ASC payment system remains budget neutral. This annual budget neutrality adjustment is performed similarly to updates for the IPPS, OPPS, PFS, and other Medicare payment systems. We apply the ASC weight scalar to scaled OPPS relative weights to ensure that current Medicare payments under the ASC payment system do not increase as a result of newer data used to determine the cost relativity between surgical procedures. The scaled prospective OPPS relative weights that are used to determine scaled prospective ASC relative weights have not, as commenters suggest, been adjusted to achieve budget neutrality within the ASC payment system prior to the application of the ASC weight scalar. We also note that no stakeholder presented empirical evidence that the budget neutrality adjustment under the ASC payment system has impacted beneficiary access to surgical procedures in the ASC setting.

After consideration of the public comments we received, we are finalizing our proposal to use the ratio of CY 2023 to CY 2024 total payments (the weight scalar) to scale the ASC relative payment weights for CY 2024. The final CY 2024 ASC weight scalar is 0.8881. Consistent with historical practice, we are finalizing our proposal to 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. Additionally, CY 2024 total payments will include additional spending and utilization related to these ASC complexity adjustment C codes, which we estimate to be approximately $5 million for CY 2024.

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 2024, we calculated the proposed adjustment for the ASC payment system by using the most recent CY 2022 claims data available and estimating the difference in total payment that would be created by introducing the proposed CY 2024 ASC wage indexes. Specifically, holding CY 2022 ASC utilization, service-mix, and the proposed CY 2024 national payment rates after application of the weight scalar constant, we calculated the total adjusted payment using the CY 2023 ASC wage indexes and the total adjusted payment using the proposed CY 2024 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 2023 ASC wage indexes to the total adjusted payment calculated with

the proposed CY 2024 ASC wage indexes and applied the resulting ratio of 1.0017 (the proposed CY 2024 ASC wage index budget neutrality adjustment) to the CY 2023 ASC conversion factor to calculate the proposed CY 2024 ASC conversion factor.

Section 1833(i)(2)(D)(v) of the Act requires that the ASC conversion factor be reduced by a productivity adjustment in each calendar year. Section 1886(b)(3)(B)(xi)(II) of the 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). We finalized the methodology for calculating the productivity 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 productivity adjustment for CY 2024 was projected to be 0.2 percentage point, as published in the FY 2024 IPPS/LTCH PPS proposed rule (88 FR 27005) based on IGI's 2022 fourth quarter forecast.

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 a policy to apply the productivity-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 would 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 productivity-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. The most recent available full year of claims data to assess the expected migration applying the productivity-adjusted hospital market basket update during the interim period would fall within the period from CY 2019 through CY 2022. However, the impact of the COVID–19 PHE on health care utilization, in particular in CY 2020, was tremendously profound, particularly for elective surgeries, because many beneficiaries avoided healthcare settings when possible, to avoid possible infection from the SARS–CoV–2 virus. As a result, it is nearly impossible to disentangle the effects from the COVID–19 PHE in our analysis of whether the higher update factor for the ASC payment system caused increased migration to the ASC setting. To analyze whether procedures migrated from the hospital setting to the ASC setting, we need to use claims data from a period during which the COVID–19 PHE had less of an impact on health care utilization. Therefore, for the CY 2024 OPPS/ASC proposed rule, we proposed to extend the 5-year interim period an additional 2 years, that is, through CY 2024 and CY 2025. We believe hospital outpatient and ASC utilization data from CYs 2023 and 2024 will enable us to more accurately analyze whether the application of the productivity-adjusted hospital market basket update to the ASC payment system had an effect on the migration of services from the hospital setting to the ASC setting. We proposed to revise our regulations at 42 CFR 416.171(a)(2)(iii) and (iv), which establish the annual update to the ASC conversion factor, to reflect this 2-year extension. We also proposed to revise our regulations at § 416.171(a)(2)(vi) and (vii), which establish the 2.0 percentage point reduction for ASCs that fail to meet the standards for reporting ASC quality measures, and § 416.171(a)(2)(viii)(B) and (C), which establish the productivity adjustment, to reflect this 2-year extension.

For CY 2024, in accordance with our proposed revisions to § 416.171(a)(2)(iii) and (vi) and (a)(2)(viii)(B), we proposed to utilize the hospital market basket update of 3.0 percent reduced by the productivity adjustment of 0.2 percentage point, resulting in a proposed productivity-adjusted hospital market basket update factor of 2.8 percent for ASCs meeting the quality reporting requirements. Therefore, we proposed to apply a 2.8 percent productivity-adjusted hospital market basket update factor to the CY 2023 ASC conversion factor for ASCs meeting the quality reporting requirements to determine the CY 2024 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 productivity-adjusted hospital market basket 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 and 59139) and section XIV.E of this final rule for a detailed discussion of our policies regarding payment reduction for ASCs that fail to meet ASCQR Program requirements. We proposed to utilize the inpatient hospital market basket percentage increase of 3.0 percent reduced by 2.0 percentage points for ASCs that do not meet the quality reporting requirements and then reduced by the 0.2 percentage point productivity adjustment. Therefore, we proposed to apply a 0.8 percent productivity-adjusted hospital market basket update factor to the CY 2023 ASC conversion factor for ASCs not meeting the quality reporting requirements. We also proposed that if more recent data are subsequently available (for example, a more recent estimate of the inpatient hospital market basket percentage increase or productivity adjustment), we would use such data, if appropriate, to determine the CY 2024 ASC update for the CY 2024 OPPS/ASC final rule with comment period.

For CY 2024, we proposed to adjust the CY 2023 ASC conversion factor ($51.854) by the proposed wage index budget neutrality factor of 1.0017 in addition to the productivity-adjusted hospital market basket update of 2.8 percent discussed above, which results in a proposed CY 2024 ASC conversion factor of $53.397 for ASCs meeting the quality reporting requirements. For ASCs not meeting the quality reporting requirements, we proposed to adjust the CY 2023 ASC conversion factor ($51.854) by the proposed wage index budget neutrality factor of 1.0017 in addition to the quality reporting/productivity-adjusted hospital market basket update of 0.8 percent discussed above, which results in a proposed CY 2024 ASC conversion factor of $52.358.

Comment: Most commenters supported our proposed increase to the CY 2024 ASC payment rates. These commenters supported the continued use of the hospital market basket update for the ASC payment system, due to better alignment with the OPPS, and were supportive of extending the five-

year interim period for an additional two years. Several of these commenters suggested the use of the hospital market basket update should become a permanent update for ASCs.

However, a subset of commenters, including MedPAC, were against the extension proposal. MedPAC was opposed to extending the interim period, citing evidence that the hospital market basket index does not accurately reflect ASC costs and that surgical procedure migration was occurring before this update factor was used in ASCs. MedPAC did not support CMS collecting additional data on the effects of using the hospital market basket update on ASC volume. (As discussed in section XII.C., MedPAC has suggested that neither the hospital market basket update nor CPI–U likely reflect an ASC's cost structure and recommended collecting cost data to establish an appropriate price index for ASCs.) Several other commenters also recommended that CMS allow the proposal to expire after CY 2023, as hospitals and ASC have different costs and patient populations. They suggested CMS work with ASCs to develop and implement a minimally burdensome way to collect ASC costs that could be used to finalize an appropriate update mechanism in the future, if necessary.

Response: We appreciate the feedback from commenters. As we stated above, the profound impact of the COVID–19 PHE on health care utilization, particularly for elective surgeries, makes it difficult to clarify whether the higher update factor for the ASC payment system caused increased migration to the ASC setting. We believe using the additional two years of data, CY2024 and CY 2025, will enable us to more accurately analyze the impact of the hospital market basket update on the ASC payment system; and we do not believe we should make any determination regarding the most appropriate update mechanism until we perform such analysis.

After consideration of the public comments we received, for CY 2024, we are finalizing temporarily extending a CY 2019 ASC payment system policy that implemented a five-year interim period using the productivity-adjusted hospital market basket, instead of the CPI–U to update ASC payment rates.

For CY 2024, we are also finalizing the hospital market basket update of 3.3 percent reduced by the productivity adjustment of 0.2 percentage point, resulting in a productivity-adjusted hospital market basket update factor of 3.1 percent for ASCs meeting the quality reporting requirements. Therefore, we apply a 3.1 percent productivity-adjusted hospital market basket update to the CY 2023 ASC conversion factor for ASCs meeting the quality reporting requirements to determine the CY 2024 ASC payments. We are finalizing the hospital market basket update of 3.3 percent reduced by 2.0 percentage points for ASCs that do not meet the quality reporting requirements and an additional reduction of 0.2 percentage point for the productivity adjustment. Therefore, we apply a 1.1 percent productivity-adjusted hospital market basket update to the CY 2023 ASC conversion factor for ASCs not meeting the quality reporting requirements.

For CY 2024, we are adjusting the CY 2023 ASC conversion factor ($51.854) by a wage index budget neutrality factor of 1.0010 in addition to the productivity-adjusted hospital market basket update of 3.1 percent, discussed above, which results in a final CY 2024 ASC conversion factor of $53.514 for ASCs meeting the quality reporting requirements. For ASCs not meeting the quality reporting requirements, we are adjusting the CY 2023 ASC conversion factor ($51.854) by the wage index budget neutrality factor of 1.0010 in addition to the reduced productivity-adjusted hospital market 1.1 percent, discussed above, which results in a final CY 2024 ASC conversion factor of $52.476 for ASCs not meeting the quality reporting requirements.

3. Display of the Final CY 2024 ASC Payment Rates

Addenda AA and BB to this final rule (which are available on the CMS website) display the proposed ASC payment rates for CY 2024 for covered surgical procedures and covered ancillary services, respectively. The final payment rates included in Addenda AA and BB to this final 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 2024 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 and 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.

For CY 2021, we finalized adding a new column to ASC Addendum BB titled ''Drug Pass-Through Expiration during Calendar Year'' where we 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 ''Final CY 2024 Payment Weight'' are the proposed relative payment weights for each of the listed services for CY 2024. 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 final CY 2024 payment rate displayed in the ''Final CY 2024 Payment Rate'' column, each ASC payment weight in the ''Final CY 2024 Payment Weight'' column was multiplied by the final CY 2024 conversion factor. 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 final CY 2024 ASC conversion factor uses the CY 2024 productivity-adjusted hospital market basket update factor of 3.1 percent (which is equal to the inpatient hospital market basket percentage increase of 3.3 percent reduced by the productivity adjustment of 0.2 percentage point).

In Addendum BB, there are no relative payment weights displayed in the ''Final CY 2024 Payment Weight'' column for items and services with predetermined national payment amounts, such as separately payable drugs and biologicals. The ''Final CY 2024 Payment'' column displays the final CY 2024 national unadjusted ASC payment rates for all items and services. The final CY 2024 ASC payment rates listed in Addendum BB for separately payable drugs and biologicals are based on the most recently available data used for payment in physicians' offices.

Addendum EE to this final rule provides the HCPCS codes and short descriptors for surgical procedures that are finalized to be excluded from payment in ASCs for CY 2024.

Addendum FF to this final rule displays the OPPS payment rate (based on the standard ratesetting methodology), the device offset percentage for determining device-intensive status (based on the standard ratesetting methodology), and the device portion of the ASC payment rate for CY 2024 for covered surgical procedures.

XIV. Requirements for the Hospital Outpatient Quality Reporting (OQR) Program

A. Background

We seek to promote higher quality, more efficient, and equitable healthcare for patients. Consistent with these goals, we have implemented quality reporting programs for multiple care settings, including the Hospital Outpatient Quality Reporting (OQR) Program for hospital outpatient care.

We refer readers to the CY 2011 Outpatient Prospective Payment System (OPPS) and Ambulatory Surgical Center (ASC) payment system final rule (75 FR 72064 and 72065) for a detailed discussion of the statutory history of the Hospital OQR Program. We refer readers to the CYs 2008 through 2023 OPPS/ASC final rules for detailed discussions of the regulatory history of the Hospital OQR Program (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; 84 FR 61410 through 61420; 85 FR 86179 through 86187; 86 FR 63822 through 63875; and 87 FR 72096 through 72117).

We have codified certain requirements under the Hospital OQR Program at 42 CFR 419.46. We refer readers to section XIV.F of this final rule with comment period for a detailed discussion of the payment reduction for hospitals that fail to meet Hospital OQR Program requirements.

B. Hospital OQR Program Quality Measures

1. Retention, Removal, Replacement, or Suspension of Quality Measures from the Hospital OQR Program Measure Set

We refer readers to § 419.46(i) for our policies regarding: (1) measure retention; (2) immediate measure removal; and (3) measure removal, suspension, or replacement through the rulemaking process.

In the CY 2024 OPPS/ASC proposed rule (88 FR 49774), we proposed to amend our immediate measure removal policy codified at § 419.46(i)(2) to replace references to ''QualityNet'' with ''CMS-designated information system'' or ''CMS website,'' and to make other conforming technical edits, to accommodate recent and future systems requirements and mitigate confusion for program participants.

We invited public comment on the proposal.

We received no comments on the proposal. We are finalizing our proposal as proposed.

a. Removal of the Left Without Being Seen Measure Beginning with the CY 2024 Hospital OQR Reporting Period

We refer readers to the CY 2011 OPPS/ASC final rule (75 FR 72088 and 72089) where we adopted the Left Without Being Seen (LWBS) measure beginning with the CY 2013 payment determination. The LWBS measure was initially endorsed by a consensus-based entity (CBE) in 2008. This process measure assesses the percent of patients who leave the emergency department (ED) without being evaluated by a physician, advanced practice nurse, or physician assistant. Our rationale for adopting the LWBS measure was that patients leaving without being seen was an indicator of ED overcrowding (75 FR 72089).

Endorsement of the measure was removed in 2012 because the measure steward did not choose to resubmit the measure to maintain endorsement. We continued to retain the LWBS measure because our data showed variation/gap in performance and improvement. However, as we described in the CY 2024 OPPS/ASC proposed rule (88 FR 49774), over the last few years, our routine measure monitoring and evaluation indicated: (1) limited evidence linking the measure to improved patient outcomes; (2) that increased LWBS rates may reflect poor access to timely clinic-based care rather than intrinsic systemic issues within the ED; [218] and (3) unintended effects on LWBS rates caused by other policies, programs, and initiatives may lead to skewed measure performance.[219] [220] [221]

We recognized that LWBS performance issues could be due to inefficient patient flow in the ED for a variety of reasons or due to insufficient community resources, which result in higher ED patient volumes that lead to long wait times and patients deciding to leave without being seen. These patients' reasoning for visiting the ED is often not severe enough that they would want to wait if the ED is crowded. Additionally, we stated that we did not believe the LWBS measure provides enough specificity to give value because it does not provide granularity for actionable meaningful data toward quality improvement. Based on these findings during the development of the CY 2024 OPPS/ASC proposed rule, we identified measure removal factor 2 as applicable (that is, performance or improvement on a measure does not result in better patient outcomes), as codified under § 419.46(i)(3)(i)(B).

ED performance and care continues to be an important topic area of the Hospital OQR Program. In the CY 2024 OPPS/ASC proposed rule, we discussed the Median Time from ED Arrival to ED Departure for Discharged ED Patients measure (Median Time for Discharged ED Patients measure) as a better measure for measuring ED performance and care. In our discussion, we stated that the Median Time for Discharged ED Patients measure, adopted for reporting in the Hospital OQR Program, provides more meaningful data compared to the LWBS measure because the measure presents more granular data on length of time of ED throughput. Additionally, we stated that the Median Time for Discharged ED Patients measure provides useful information to facilities for improvement efforts because the measure is stratified, showing the median time from ED departure for discharged ED patients in four different strata in the Hospital Outpatient Department (HOPD) setting. These improvement efforts by facilities could ultimately reduce the number of patients who leave without being seen.

Based on the above assessment and rationale, in the CY 2024 OPPS/ASC proposed rule (88 FR 49774), we stated our belief that the LWBS measure does

[218] Li DR, Brennan JJ, Kreshak AA, et al. (2019). Patients who leave the emergency department without being seen and their follow-up behavior: a retrospective descriptive analysis. *J Emerg Med,* 57(1), 106–13. *https://doi.org/10.1016/j.jemermed.2019.03.051.*

[219] Allen L, Cong TG, & Kosali S. (2022). The Impact of Medicaid Expansion on Emergency Department Wait Times. *Health Services Research,* 57(2), 294–99. *https://doi.org/10.1111/1475-6773.13892.*

[220] Roby N, Smith H, Hurdelbrink J, et al. (2022). Characteristics and Retention of Emergency Department Patients Who Left without Being Seen (LWBS). *Internal and Emergency Medicine,* 17(2): 551–58. *https://doi.org/10.1007/S11739-021-02775-Z.*

[221] Yoo MJ, Schauer SG, & Trueblood WE. (2022). 'Swab and Go' Impact on Emergency Department Left without Being Seen Rates.'' *The American Journal of Emergency Medicine,* 57(July): 164–65. *https://doi.org/10.1016/J.AJEM.2021.11.043.*

not provide enough evidence to promote quality of care and improved patient outcomes to justify retaining the measure in the Hospital OQR Program. Therefore, we proposed to remove the LWBS measure from the program beginning with the CY 2024 reporting period/CY 2026 payment determination.

We invited public comment on our proposal.

Comment: Many commenters supported CMS's proposal to remove the LWBS measure beginning with the CY 2024 reporting period/CY 2026 payment determination. Several of these commenters noted that high LWBS rates may reflect factors beyond the control of HOPDs rather than intrinsic systemic issues within the ED. A few of these commenters further stated that there are more meaningful measures, such as Median Time for Discharged ED Patients, in the Hospital OQR Program that are better for measuring ED performance and care. A few of these commenters concurred with the rationale in the CY 2024 OPPS/ASC proposed rule to remove the LWBS measure based on measure removal factor 2. These commenters specifically stated that they supported CMS's proposal to remove the LWBS measure because the LWBS measure does not provide actionable data toward quality improvement and lacks sufficient evidence that the measure promotes quality of care and improved patient outcomes.

Response: We thank commenters for their feedback. After consideration of public comments and assessment of the latest monitoring and evaluation data, we are not finalizing our proposal to remove the LWBS measure at this time. While our routine monitoring and evaluation of this measure initially indicated lack of variation among hospital performance as well as limited evidence linking the measure to improved patient outcomes, since publication of the CY 2024 OPPS/ASC proposed rule we have received new data indicating an increase (worsening) in LWBS rates that we believe warrants further investigation before potentially removing the LWBS measure under measure removal factor 2—performance or improvement on a measure does not result in better patient outcomes.

Comment: Some commenters disagreed that the measure had met the criteria to qualify for measure removal factor 2. One of these commenters cited evidence from Gravel, Smalley, and Mataloni indicating that people who leave without being seen are at higher risk of poor outcomes, higher readmission rates, and increased mortality, and recommended retaining the LWBS measure.[222] [223] [224] According to this commenter, leaving the ED without receiving a medical opinion from the visit is sub-optimal care that should be accounted for. Another commenter provided evidence [225] to support its belief that patients might leave the ED because they are too sick to stay, not because they were not sick enough, and that CMS cannot presume that the only reason patients left without being seen was because they did not need to be in the ED to begin with.

Response: We appreciate the commenters' feedback regarding the LWBS measure and note that we are not finalizing our proposal to remove the LWBS measure. More recent data in the evaluation of this measure have indicated an increase in LWBS rates that we believe warrants further investigation before potentially removing the LWBS measure under measure removal factor 2—performance or improvement on a measure does not result in better patient outcomes.

Comment: Some commenters opposed the removal of the measure as they believe it helps capture ''ED boarding,'' which one commenter defined as a concept where patients are held in the ED awaiting admission to an inpatient bed or transfer elsewhere.[226] These commenters believe that ED wait times and boarding reflect the overall issue of ED overcrowding, and that CMS should retain this measure to keep tracking and reporting these important data. One commenter stated that information from this measure could help incentivize investments in more targeted solutions to the issue of ED overcrowding. Another commenter stated that removing this measure would signal that CMS does not recognize or acknowledge the seriousness of the negative effects of ED wait times, overcrowding, and boarding.

Response: We acknowledge the commenters' concerns regarding the lack of ED measures in the Hospital OQR Program and emphasize that ED performance and care, including overcrowding and boarding, continue to be important topic areas of the Hospital OQR Program. After consideration of public comments and assessment of recent LWBS rates, which indicate a worsening in LWBS rates, we believe that the LWBS measure may provide meaningful information about patient patterns in EDs and that, prior to potentially removing this measure from the Hospital OQR Program, additional examination of the measure's utility is warranted. We are also committed to conducting a broader re-examination of how to improve measurement of quality of care in the ED setting that could help address gaps not directly measured by the Median Time for Discharged ED Patients and LWBS measures.

Comment: A few commenters suggested that CMS explore an alternative measure for access to care to ensure patients have access to timely emergency care. One commenter additionally suggested that CMS adopt the Median Admit Decision Time to ED Departure Time for Admitted Patients eCQM and noted that, while the Hospital Inpatient Quality Reporting (IQR) Program is removing this eCQM in 2024, several state quality reporting programs wish to continue to report the measure. This commenter further stated that adoption of the Median Admit Decision Time to ED Departure Time for Admitted Patients eCQM in the Hospital OQR Program would allow hospitals already familiar with the measure to continue to report this measure and reduce reporting burden while also monitoring ED wait times until admission.

Response: We thank the commenters for their recommendations. We agree that we should continue to prioritize ED measures in the Hospital OQR Program and will continue to assess and develop relevant measures for future rulemaking. We note that proposal and adoption of the Median Admit Decision Time to ED Departure Time for Admitted Patients eCQM would address the National Quality Strategy goal of ''Interoperability'' under the priority area ''Interoperability and Scientific Advancement.'' We will take this recommendation into consideration.

[222] Gravel J, Gouin S, Carrière B, et al. (2013). Unfavourable outcome for children leaving the emergency department without being seen by a physician. CJEM 15(5), 289–299. *https://doi.org/10.2310/8000.2013.130939*.

[223] Smalley CM, Meldon SW, Simon EL, et al. (2021). Emergency Department patients who leave before treatment is complete. *WestJEM* 22(2), 148–155. *https://doi.org/10.5811/westjem.2020.11.48427*.

[224] Mataloni F, Colais P, Galassi C, et al. (2018). Patients who leave Emergency Department without being seen or during treatment in the Lasio Regio (Central Italy): Determinants and short term outcomes. PloS ONE 13(12), 0208914. *https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6291150/*.

[225] Baker DW, Stevens CD, Brook RH. Patients who leave a public hospital emergency department without being seen by a physician. Causes and consequences. JAMA. 1991;266:1085–90. *https://jamanetwork.com/journals/jama/article-abstract/391369*.

[226] American College of Emergency Physicians. (n.d.). Emergency Department Boarding and Crowding. Available at: *https://www.acep.org/boarding*.

We believe that it is important to evaluate a measure's effectiveness based on its capacity to deliver better patient outcomes and remove measures that show limited evidence in improving patient outcomes. As stated above, our routine monitoring and evaluation of this measure has indicated a recent increase in LWBS rates that we believe warrants further investigation before potentially removing the LWBS measure under measure removal factor 2—performance or improvement on a measure does not result in better patient outcomes. Several commenters emphasized the importance of quality measurement for the ED care setting, particularly to address persistent problems of ED overcrowding and boarding. We agree with commenters who noted the benefits of retaining the LWBS measure in order to identify and inform quality improvement efforts or beneficiary care decision-making and using that information to identify a more granular measure that could potentially replace the LWBS measure. Therefore, after considering the concerns raised by commenters, we are not finalizing our proposal to remove the LWBS measure beginning with the CY 2024 reporting period/CY 2026 payment determination.

2. Modifications to Previously Adopted Measures

In the CY 2024 OPPS/ASC proposed rule (88 FR 49774), we proposed to modify three previously adopted measures beginning with the CY 2024 reporting period/CY 2026 payment determination: (1) COVID–19 Vaccination Coverage Among Healthcare Personnel (HCP) measure; (2) Cataracts: Improvement in Patient's Visual Function Within 90 Days Following Cataract Surgery measure; and (3) Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients measure. We discuss each of these measures, along with the public comments that we received on them, in subsequent sections.

a. Modification of the COVID–19 Vaccination Coverage Among Health Care Personnel (HCP) Measure Beginning with the CY 2024 Reporting Period/CY 2026 Payment Determination

(1) Background

On January 31, 2020, the Secretary of the Department of Health and Human Services (HHS) declared a public health emergency (PHE) for the United States in response to the global outbreak of SARS–CoV–2, a then novel coronavirus that causes a disease named ''coronavirus disease 2019'' (COVID–19).[227] Subsequently, the COVID–19 Vaccination Coverage Among Health Care Personnel (HCP) measure was adopted across multiple quality reporting programs, including the Hospital OQR Program (86 FR 63824 through 63833).[228] The Secretary renewed the PHE on April 21, 2020, and then every 3 months thereafter, with the final renewal on February 9, 2023.[229] The PHE expired on May 11, 2023; however, the public health response to COVID–19, which includes vaccination efforts, remains a public health priority.[230] As we noted in the CY 2024 OPPS/ASC proposed rule (88 FR 49776), there had been more than 102.7 million COVID–19 cases and 1.1 million COVID–19 deaths in the United States as of February 13, 2023; in reviewing these numbers for this final rule, as of September 15, 2023 there have been more than 103.4 million COVID–19 cases and 1.1 million COVID–19 deaths in the United States.[231] [232]

We stated in the CY 2022 OPPS/ASC final rule (86 FR 63825), and in our ''Revised Guidance for Staff Vaccination Requirements,'' that vaccination is a critical part of the Nation's strategy to effectively counter the spread of COVID–19.[233] [234] [235] We continue to believe it is important to incentivize and track HCP vaccination through quality measurement across care settings, including the HOPD setting, to protect health care workers, patients, and caregivers, and to help sustain the ability of HCP in each of these care settings to continue serving their communities. Studies indicate higher levels of population-level vaccine effectiveness in preventing COVID–19 infection among HCP and other frontline workers in multiple industries, with vaccines having a 90 percent effectiveness in preventing symptomatic and asymptomatic infection from December 2020 through August 2021.[236] Since the Food and Drug Administration (FDA) issued emergency use authorizations (EUAs) for selected initial and primary vaccines for adults, vaccines have been highly effective in real-world conditions at preventing COVID–19 in HCP with up to 96 percent efficacy for fully vaccinated HCP, including those at risk for severe infection and those in racial and ethnic groups disproportionately affected by COVID–19.[237] [238] [239] [240] Overall, data

[227] U.S. Dept. of Health and Human Services, Office of the Assistant Secretary for Preparedness and Response (2020). Determination that a Public Health Emergency Exists. Available at: *https://www.phe.gov/emergency/news/healthactions/phe/Pages/2019-nCoV.aspx*.

[228] The Ambulatory Surgical Center Quality Reporting (ASCQR) Program (86 FR 63875 through 63883), the Hospital Inpatient Quality Reporting (IQR) Program (86 FR 45374 through 45382), the Inpatient Psychiatric Facility Quality Reporting Program (86 FR 42633 through 42640), the PPS-Exempt Cancer Hospital Quality Reporting Program (86 FR 45428 through 45434), the Long-Term Care Hospital Quality Reporting Program (86 FR 45438 through 45446), the Skilled Nursing Facility Quality Reporting Program (86 FR 42480 through 42489), the End-Stage Renal Disease Quality Incentive Program (87 FR 67244 through 67248), and the Inpatient Rehabilitation Facility Quality Reporting Program (86 FR 42385 through 42396).

[229] U.S. Dept. of Health and Human Services. Office of the Assistant Secretary for Preparedness and Response. (2023). Renewal of Determination that a Public Health Emergency Exists. Available at: *https://aspr.hhs.gov/legal/PHE/Pages/COVID19-9Feb2023.aspx*.

[230] U.S. Dept. of Health and Human Services. Fact Sheet: COVID–19 Public Health Emergency Transition Roadmap. February 9, 2023. Available at: *https://www.hhs.gov/about/news/2023/02/09/fact-sheet-covid-19-public-health-emergency-transition-roadmap.html*.

[231] World Health Organization. United States of America. Accessed September 15, 2023. Available at: *https://covid19.who.int/region/amro/country/us*.

[232] Centers for Disease Control and Prevention. COVID Data Tracker. Accessed February 13, 2023. Available at: *https://covid.cdc.gov/covid-data-tracker/#datatracker-home*.

[233] Centers for Medicare & Medicaid Services (October 26, 2022). Revised Guidance for Staff Vaccination Requirements. Available at: *https://www.cms.gov/files/document/qs0-23-02-all.pdf*.

[234] Centers for Disease Control and Prevention. (September 24, 2021). Morbidity and Mortality Weekly Report (MMWR). Comparative Effectiveness of Moderna, Pfizer-BioNTech, and Janssen (Johnson & Johnson) Vaccines in Preventing COVID–19 Hospitalizations Among Adults Without Immunocompromising Conditions—United States, March–August 2021. Available at: *https://cdc.gov/mmwr/volumes/70/wr/mm7038e1.htm?s_cid=mm7038e1_w*.

[235] Centers for Medicare & Medicaid Services. (October 26, 2022). Revised Guidance for Staff Vaccination Requirements. Available at: *https://www.cms.gov/files/document/qs0-23-02-all.pdf*.

[236] Centers for Disease Control and Prevention (August 27, 2021). Morbidity and Mortality Weekly Report (MMWR). Effectiveness of COVID–19 Vaccines in Preventing SARS–COV–2 Infection Among Frontline Workers Before and During B.1.617.2 (Delta) Variant Predominance—Eight U.S. Locations, December 2020–August 2021. Available at: *https://www.cdc.gov/mmwr/volumes/70/wr/mm7034e4.htm*.

[237] Pilishivi T, Gierke R, Fleming-Dutra KE, et al. (2022). Effectiveness of mRNA Covid–19 Vaccine among U.S. Health Care Personnel. *New England Journal of Medicine,* 385(25), e90. *https://doi.org/10.1056/NEJMoa2106599*.

[238] Centers for Disease Control and Prevention. (2021). Morbidity and Mortality Weekly Report (MMWR). Monitoring Incidence of COVID–19 Cases, Hospitalizations, and Deaths, by Vaccination Status—13 U.S. Jurisdictions, April 4–July 17, 2021. Available at: *https://www.cdc.gov/mmwr/volumes/70/wr/mm7037e1.htm*.

[239] Centers for Medicare & Medicaid Services (October 26, 2022). Revised Guidance for Staff Vaccination Requirements. Available at: *https://www.cms.gov/files/document/qs0-23-02-all.pdf*.

[240] Food and Drug Administration (2020). FDA Takes Key Action in Fight Against COVID–19 By Issuing Emergency Use Authorization for First COVID–19 Vaccine. Available at: *https://www.fda.gov/news-events/press-announcements/fda-takes-key-action-fight-against-covid-19-issuing-emergency-use-authorization-first-covid-19*.

demonstrate that COVID–19 vaccines are effective and prevent severe disease, hospitalization, and death from COVID–19 infection.[241]

When we adopted the COVID–19 Vaccination Coverage Among HCP measure in the CY 2022 OPPS/ASC final rule (86 FR 63824 through 63833), we acknowledged that the measure did not address booster shots for COVID–19 vaccination (86 FR 63829) although the FDA authorized, and the Centers for Disease Control and Prevention (CDC) recommended additional doses and booster doses of the COVID–19 vaccine for certain individuals, particularly those who are immunocompromised due to age or condition or who are living or working in high-risk settings, such as HCP (86 FR 63829). However, we also stated that we believed the numerator of the measure was sufficiently broad to include potential future boosters as part of a ''complete vaccination course'' (86 FR 63829).

Since then, new variants of SARS–CoV–2 have emerged around the world and within the United States. Specifically, the Omicron variant (and its related subvariants) is listed as a ''variant of concern'' by the CDC because it spreads more easily than earlier variants.[242] Vaccine manufacturers have responded to the Omicron variant by developing bivalent COVID–19 vaccines, which include a component of the original virus strain to provide broad protection against COVID–19 and a component of the Omicron variant to provide better protection against COVID–19 caused by the Omicron variant.[243] Booster doses of the bivalent COVID–19 vaccine have proven effective at increasing immune response to SARS–CoV–2 variants, including Omicron, particularly in individuals who are more than six months removed from receipt of their primary series.[244] Updated COVID–19 vaccine booster doses are associated with a greater reduction in infections among HCP and their patients relative to those who only received primary series vaccination, with a rate of breakthrough infections among HCP who received only the two-dose regimen of 21.4 percent compared to a rate of 0.7 percent among boosted HCP.[245] [246] [247] In the CY 2024 OPPS/ASC proposed rule (88 FR 49774 through 49776), we stated that data from the existing COVID–19 Vaccination Coverage Among HCP measure demonstrate clinically significant variation in booster dose vaccination rates across HOPDs, but are clarifying here that literature has indicated disparities in COVID–19 booster vaccine uptakes across healthcare personnel irrespective of specific care setting.[248]

We believe that vaccination remains the most effective means to prevent the worst consequences of COVID–19, including severe illness, hospitalization, and death. Given the availability of vaccine efficacy data, EUAs, and Biologics License Application approvals issued by the FDA for updated 2023–2024 formulations of the vaccine bivalent boosters, continued presence of SARS–CoV–2 in the United States, and variance among rates of updated vaccinations, we believe it is important to modify the COVID–19 Vaccination Coverage Among HCP measure for HCP to receive primary series and updated vaccine doses in a timely manner per CDC's recommendation that bivalent COVID–19 vaccine booster doses might improve protection against SARS–CoV–2 Omicron sublineages, including the most recent September 2023 Omicron variant that came to light after the publication of the CY 2024 OPPS/ASC proposed rule.[249] [250]

In the CY 2024 OPPS/ASC proposed rule (88 FR 49774 through 49776), we proposed to modify the COVID–19 Vaccination Coverage Among HCP measure to utilize the term ''up to date'' in the HCP vaccination definition. We also proposed to update the numerator to specify the timeframes within which an HCP is considered up to date with CDC recommended COVID–19 vaccines, including updated vaccine doses, beginning with CY 2024 reporting period/CY 2026 payment determination for the Hospital OQR Program.

(2) Overview of Measure

The COVID–19 Vaccination Coverage Among HCP measure is a process measure developed by the CDC to track COVID–19 vaccination coverage among HCP in various settings and is reported via the CDC's National Healthcare Safety Network (NHSN). We refer readers to the CY 2022 OPPS/ASC final rule with comment period (86 FR 63827 and 63828) for more information on the initial review of the measure by the Measure Applications Partnership (MAP).[251]

We included an updated version of the measure on the Measures Under Consideration (MUC) list for the 2022–2023 pre-rulemaking cycle for consideration by the MAP. We note that when reviewed by the MAP, reporting for contract personnel providing care or services not specifically included in the measure denominator was fully optional, whereas this reporting is now required to complete NHSN data entry but is not included in the measure calculation. In December 2022, during the MAP's Hospital Workgroup discussion, the workgroup stated that the revision of the current measure captures up to date vaccination information in accordance with the CDC's updated recommendations for additional and booster doses since the measure's initial development. Additionally, the Hospital Workgroup

[241] McGarry BE, Barnett ML, Grabowski DC, et al. (2022). Nursing Home Staff Vaccination and Covid–19 Outcomes. *New England Journal of Medicine,* 386(4), 397–398. *https://doi.org/10.1056/NEJMc2115674*.

[242] Centers for Disease Control and Prevention (2021). Variants of the Virus. Available at: *https://www.cdc.gov/coronavirus/2019-ncov/variants/index.html*.

[243] Food and Drug Administration (November 2022). COVID–19 Bivalent Vaccine Boosters. Available at *https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-authorizes-moderna-pfizer-biontech-bivalent-covid-19-vaccines-use*. (In the CY 2024 OPPS/ASC proposed rule, we cited this information to: *https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/covid-19-bivalent-vaccines*. However, after review, the information appears to have moved. Thus, we have updated the citation.)

[244] Chalkias S, Harper C, Vrbicky K, et al. (2022). A Bivalent Omicron-Containing Booster Vaccine against Covid–19. *New England Journal of Medicine,* 387(14), 1279–1291. *https://doi.org/10.1056/NEJMoa2208343*.

[245] Prasad N, Derado G, Nanduri SA, et al. (May 2022). Effectiveness of a COVID–19 Additional Primary or Booster Vaccine Dose in Preventing SARS–CoV–2 Infection Among Nursing Home Residents During Widespread Circulation of the Omicron Variant—United States, February 14–March 27, 2022. Morbidity and Mortality Weekly Report (MMWR). 71(18), 633–637. Available online at: *https://www.cdc.gov/mmwr/volumes/71/wr/mm7118a4.htm*.

[246] Oster Y, Benenson S, Nir-Paz R, et al. (2022). The effect of a third BNT162b2 vaccine on breakthrough infections in health care workers: a cohort analysis. *Clinical Microbiology and Infection,* 28(5), 735.e1–735.e3. *https://doi.org/10.1016/j.cmi.2022.01.019*.

[247] Ibid.

[248] Wigdan F. et al. (April 2023). Who is getting boosted? Disparities in COVID–19 vaccine booster uptake among health care workers. Available at: *https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9918311/pdf/main.pdf*.

[249] Link-Gelles et al. (February 2023). Early Estimates of Bivalent mRNA Booster Dose Vaccine Effectiveness in Preventing Symptomatic SARs–CoV–2 Infection Attributable to Omicron BA.5- and XBB/XBB.1.5-Relating Sublineages Among Immunocompetent Adults—Increasing Community Access to Testing Program, United States, December 2022–January 2023. Morbidity and Mortality Weekly Report (MMWR). February 3;72(5);119–124. Available online at: *https://www.cdc.gov/mmwr/volumes/72/wr/mm7205e1.htm#suggestedcitation*.

[250] Food and Drug Administration (June 2023). FDA Briefing Document: Vaccines and Related Biological Products Advisory Committee Meeting. Food and Drug Administration. Available Online: *https://www.fda.gov/media/169378/download*.

[251] Interested parties convened by the consensus-based entity will provide input and recommendations on the Measures Under Consideration (MUC) list as part of the pre-rulemaking process required by section 1890A of the Act. We refer readers to *https://p4qm.org/PRMR-MSR* for more information.

appreciated that the re-specified measure's target population is broader and simplified from seven categories of HCP to four.[252] During the MAP's Health Equity Advisory Group review, the group highlighted the importance of COVID–19 vaccination measures and questioned whether the proposed revised measure excludes individuals with contraindications to FDA authorized or approved COVID–19 vaccines, and if the measure would be stratified by demographic factors. The measure developer confirmed that HCP with contraindications to the vaccines are excluded from the measure denominator but stated that the measure would not be stratified since the data are submitted at an aggregate rather than an individual level. The MAP Rural Health Advisory Group expressed concerns about data collection burden, citing that collection is performed manually.[253] We note that when reviewed by the MAP, reporting for contract personnel providing care or services not specifically included in the measure denominator was fully optional, whereas this reporting is now required to complete NHSN data entry but is not included in the measure calculation.

The developer noted that the model used for this measure is based on the Influenza Vaccination Coverage Among HCP measure (CBE #0431).[254] We refer readers to sections XXIV.B and XXVI of this final rule with comment period for additional detail on the burden and impact of this measure modification.

The proposed revised measure received conditional support for rulemaking from the MAP pending (1) testing indicating the measure is reliable and valid, and (2) endorsement by the CBE. The MAP noted that the previous version of the measure received endorsement from the CBE (CBE #3636)[255] and that the measure steward (CDC) intends to submit the updated measure for endorsement.[256]

(a) Measure Specifications

This measure is calculated quarterly by averaging the hospital's most recently submitted and self-selected one week of data. The measure includes at least one week of data collection a month for each of the three months in a quarter. The denominator is calculated as the aggregated number of HCP eligible to work in the hospital for at least one day during the week of data collection, excluding denominator-eligible individuals with contraindications as defined by the CDC for all three months in a quarter.[257] Facilities report the following four categories of HCP to the NHSN:

- *Employees:* This includes all persons who receive a direct paycheck from the reporting facility (that is, on the facility's payroll), regardless of clinical responsibility or patient contact.)
- *Licensed independent practitioners (LIPs):* This includes only physicians (MD, DO), advanced practice nurses, and physician assistants who are affiliated with the reporting facility but are not directly employed by it (that is, they do not receive a paycheck from the reporting facility), regardless of clinical responsibility or patient contact. Post-residency-fellows are also included in this category if they are not on the facility's payroll.
- *Adult students/trainees and volunteers:* This includes medical, nursing, or other health professional students, interns, medical residents, or volunteers aged 18 or older who are affiliated with the facility but are not directly employed by it (that is, they do not receive a paycheck from the facility), regardless of clinical responsibility or patient contact.
- *Other contract personnel:* Contract personnel are defined as persons providing care, treatment, or services at the facility through a contract who do not fall into any of the previously discussed denominator categories. This also includes vendors providing care, treatment, or services at the facility who may or may not be paid through a contract. Facilities are required to enter data on other contract personnel for submission in the NHSN application, but data for this category are not included in the HCP COVID–19 Vaccine measure.[258]

As stated in the CY 2024 OPPS/ASC proposed rule (88 FR 49777), we did not propose to modify the denominator exclusions. The numerator is calculated as the cumulative number of HCP in the denominator population who are considered up to date with CDC recommended COVID–19 vaccine. Guidance issued by the CDC defines the term ''up to date'' as meeting the CDC's criteria on the first day of the applicable reporting quarter. The current definition of ''up to date'' can be found at: *https://www.cdc.gov/nhsn/pdfs/hps/covidvax/UpToDateGuidance-508.pdf*.

As proposed in the CY 2024 OPPS/ASC proposed rule (88 FR 49777), public reporting of the modified version of the COVID–19 Vaccination Coverage Among HCP measure for the Hospital OQR Program would begin with the Fall 2024 Care Compare refresh, or as soon as technically feasible.

(b) CBE Endorsement

The current version of the measure in the Hospital OQR Program received CBE endorsement (CBE #3636) on July 26, 2022.[259] The measure steward (CDC) is pursuing endorsement for the modified version of this measure.

(3) Data Submission and Reporting

We refer readers to the CY 2022 OPPS/ASC final rule (86 FR 63828 through 63833) for information on data submission and reporting of this measure. We did not propose any changes to the data submission or reporting process in the CY 2024 OPPS/ASC proposed rule (88 FR 49777). However, we did propose that reporting of the updated, modified version of this measure would begin with the CY 2024 reporting period for the Hospital OQR Program. Under the data submission and reporting process, which would remain unchanged under these proposals, hospitals collect the numerator and denominator for the COVID–19 Vaccination Coverage Among HCP measure for at least one self-selected week during each month of the reporting quarter and submit the data to the NHSN Healthcare Personnel Safety (HPS) Component before the quarterly deadline to meet Hospital

[252] Centers for Medicare & Medicaid Services. Pre-rulemaking MUC lists and map reports. The Measures Management System. Available at: *https://mmshub.cms.gov/measure-lifecycle/measure-implementation/pre-rulemaking/lists-and-reports*.

[253] Ibid.

[254] In previous years, we referred to the consensus-based entity (CBE) by corporate name. We have updated this language to refer to the CBE more generally.

[255] Centers for Medicare & Medicaid Services. Measures Inventory Tool. Available at: *https://cmit.cms.gov/cmit/#/MeasureView?variantId=11670&sectionNumber=1*.

[256] The measure steward owns and maintains a measure while a measure developer develops, implements, and maintains a measure. In this case, the CDC serves as both the measure steward and measure developer. For more information on measure development, we refer readers to: Centers for Medicare & Medicaid Services (2023). Roles in Measure Development. Available at: *https://mmshub.cms.gov/about-quality/new-to-measures/roles*.

[257] Centers for Disease Control and Prevention (2022). Contraindications and precautions. Available at: *https://www.cdc.gov/vaccines/covid-19/clinical-considerations/interim-considerations-us.html#contraindications*.

[258] For more details on the reporting of other contract personnel, we refer readers to the NHSN COVID–19 Vaccination Protocol, Weekly COVID–19 Vaccination Module for Healthcare Personnel available at: *https://www.cdc.gov/nhsn/pdfs/hps/covidvax/protocol-hcp-508.pdf*.

[259] Centers for Medicare & Medicaid Services. Measure Specifications for Hospital Workgroup for the 2022 MUC List. Available at: *https://mmshub.cms.gov/sites/default/files/map-hospital-measure-specifications-manual-2022.pdf*.

OQR Program requirements. If a hospital submits more than one week of data in a month, the most recent week's data are used to calculate the measure. For example, if both the first- and third-week of data for a facility are submitted, the third week data will be used for measure calculation and public reporting. Each quarter, the CDC calculates a single quarterly COVID–19 HCP vaccination coverage rate for each hospital, which is then calculated by taking the average of the data from the three weekly rates submitted by the hospital for that quarter. CMS publicly reports each quarterly COVID–19 HCP vaccination coverage rate as calculated by the CDC (86 FR 63878).

We refer readers to section XV.B.4.a of this final rule with comment period for the same proposal for the Ambulatory Surgical Center Quality Reporting (ASCQR) Program.

We invited public comment on the proposal.

Comment: Some commenters supported the proposed modification to the COVID–19 Vaccination Coverage Among HCP measure and noted the importance of maintaining alignment across programs and with current CDC guidelines. A few commenters highlighted the significance of vaccination in preventing greater spread of COVID–19 and the potential for continued vaccination to prevent future large-scale outbreaks. One commenter expressed the importance of ''up to date'' guidelines to ensure patients have accurate information to support their choice of provider.

Response: We thank commenters for their support. We agree that maintaining alignment across programs and current CDC guidelines is important, as is the new definition of ''up to date'' due to the changing nature of the virus's transmission and community spread. We agree that vaccination plays a critical part of the HHS's strategy to effectively counter the spread of COVID–19 and will continue to support it as the most effective means to prevent the worst consequences of COVID–19, including severe illness, hospitalization, and death. Additionally, we continue to believe it is important to incentivize and track HCP vaccination through quality measurement across care settings, including the outpatient and ASC settings. We believe that HCP vaccinations will protect healthcare workers, patients, and caregivers and help sustain the ability of HCP in each of these care settings to continue serving their communities.

Comment: Many commenters did not support modifying the COVID–19 Vaccination Coverage Among HCP measure due to concerns that the frequent changes to the CDC's definition of ''up to date'' combined with uncertainty around future vaccination schedules creates unnecessary burden for facilities. Many commenters expressed concern that changing definitions and guidance exacerbates staffing and resource challenges and requires updates to facility or system-level vaccination policies, adding burden and confusion. One commenter recommended that CMS educate stakeholders on the evolving COVID–19 vaccination requirements.

Response: We acknowledge commenters' concerns around data collection, burden, and staffing and resource challenges for reporting the COVID–19 Vaccination Coverage Among HCP measure. As evidenced by the increased cases and hospitalizations in September 2023 due to new variants, we believe that COVID–19 remains a relevant and evolving situation requiring monitoring of vaccination rates to ensure the safety of patients, caregivers, and providers, and that the burden of reporting is outweighed by the benefits of collecting and regularly publishing this data to inform care decision-making. Additionally, the data submission and reporting requirements provide flexibility for hospitals with staffing and resource challenges as this measure only requires hospitals to collect data for one self-selected week during each month of the reporting quarter at minimum.

When we finalized the adoption of the COVID–19 Vaccination Coverage Among HCP measure in the CY 2022 OPPS/ASC final rule with comment period (86 FR 63875), we received several comments encouraging us to update the measure as new evidence on COVID–19 is identified. While we acknowledge that the definition of ''up to date'' may change in the future, our intention is to continue to work with partners, including the FDA and CDC, to consider and align any updates to the measure specifications in future rulemaking as appropriate to ensure the safety of patients, providers, and caregivers in facilities of care.

Comment: Many commenters recommended that CMS reduce the required reporting frequency from quarterly to annually to reduce reporting burden for facilities. Many of these commenters observed that annual reporting would mirror the reporting schedule for the Influenza Vaccination Coverage Among HCP measure, which has been adopted into some quality reporting programs. Several commenters recommended that the COVID–19 Vaccination Coverage Among HCP measure be voluntary and not publicly reported. Other commenters recommended clear communication in what the publicly reported data for the measure reflects. A few commenters recommended changes to the data collection methods for the measure; one commenter recommended that the chosen week for data reporting be determined by individuals unaffiliated with the HOPD to avoid bias, while another commenter recommended using fewer specific criteria for the numerator and denominator to provide flexibility for hospitals.

Response: We thank commenters for their recommendations on data collection, reporting frequency, and measure criteria for the COVID–19 Vaccination Coverage Among HCP measure. As stated in the CY 2024 OPPS/ASC proposed rule (88 FR 49806), the measure developer based this measure on the Influenza Vaccination Coverage Among HCP measure (CBE #0431), which is reported annually. The measure developer (the CDC) intends to adopt a similar approach to the modified COVID–19 Vaccination Coverage Among HCP measure if vaccination strategy becomes seasonal. While monitoring and surveillance are ongoing, we do not currently have data demonstrating seasonal trends in the circulation of SARS–CoV–2. Additionally, these are different public health initiatives and vaccines, and therefore, the measure specifications are not in complete alignment (86 FR 45379). In addition, we do not believe that hospital-selection of the week for reporting on this measure introduces significant bias as the sampling is taken from within the same facility over time.

With regard to public reporting, the intent of the measure is to capture the vaccination rate within hospitals so that patients have information available on HCP vaccination to inform their health care decisions. We continue to believe that it is appropriate and important to collect and report these data and to make the data publicly available.

Comment: Several commenters did not support the measure due to concern of a time lag between data collection and public reporting. Commenters observed that publicly reporting these data may not be meaningful to consumers due to the changing definitions of vaccine guidance.

Response: We thank the commenters for their concern. Since the adoption of the current version of the measure, the public health response to COVID–19 has adapted to respond to the changing nature of the virus's transmission and community spread. When we finalized the adoption of the COVID–19

Vaccination Coverage Among HCP measure in the CY 2022 OPPS/ASC final rule with comment period (86 FR 63824), we received several comments encouraging us to update the measure as we learn more about COVID–19. Our intention is to continue to work with partners, including the FDA and CDC, to consider and align any updates to the measure specifications in future rulemaking as appropriate to ensure the safety of patients, providers, and caregivers in facilities of care.

While we understand that there is a delay between data collection and public reporting for this measure, we note that such a delay exists for all measures in the Hospital OQR Program. As with other measures, we believe that the data will provide meaningful information to consumers in making healthcare decisions because the data will be able to reflect differences between facilities in COVID–19 vaccination coverage among HCP within a relatively short timeframe.

Comment: A few commenters did not support updating the specifications for the COVID–19 Vaccination Coverage Among HCP measure because the PHE has expired and the Conditions of Participation (CoPs) for hospitals have been revised to no longer require reporting of this data. One commenter recommended removal of the measure for this reason. One commenter recommended that in addition to CoP alignment, the measure should capture individuals who decline vaccination. One commenter recommended removing non-clinical staff from the measure.

Response: We note that CoPs are a set of health and safety standards that health care organizations must meet to begin or continue participation in Medicare and Medicaid programs. As we acknowledged in the CY 2024 OPPS/ASC proposed rule (88 FR 49775), the PHE expired on May 11, 2023. While some state and Federal reporting requirements have since changed, the expiration of the PHE for COVID–19 has no bearing on the use of this measure for quality reporting because vaccination continues to be an essential tool in preventing COVID–19 transmission and that monitoring and surveillance of vaccination rates through measure performance is important as it provides patients, beneficiaries, and their caregivers with information to support informed decision-making.

While CMS requirements for Medicare and Medicaid-certified providers and suppliers to ensure that their staff were fully vaccinated for COVID–19 have ended with the expiration of the PHE, hospitals will continue to report on a reduced number of COVID–19 data elements through April 30, 2024 (FY 2023 IPPS/LTCH PPS final rule; 87 FR 48787).

We believe this measure continues to align with our goals to promote wellness and disease prevention, especially in light of new variants and an increase in COVID–19 infection and hospitalizations as of September 2023. Under CMS' Meaningful Measures Framework 2.0, the COVID–19 Vaccination Coverage Among HCP measure addresses the quality priorities of ''Immunizations'' and ''Public Health'' through the Meaningful Measures Area of ''Wellness and Prevention.'' Under the National Quality Strategy, the measure addresses the goal of Safety under the priority area Safety and Resiliency. As part of the Administration's continued response to COVID–19, and in light of the presence of new variants that have resulted in higher rates of infection and hospitalizations as of September 2023, we will continue to work to protect individuals and communities from the virus and its worst impacts.[260]

Comment: A few commenters expressed concern that the COVID–19 Vaccination Coverage Among HCP measure has not been endorsed by the CBE and recommended endorsement. One commenter recommended the continual monitoring of the measure for unintended consequences since it has not undergone full validity and reliability testing.

Response: The current version of the measure received CBE endorsement (CBE #3636, ''Quarterly Reporting of COVID–19 Vaccination Coverage among Healthcare Personnel'') on July 26, 2022. As stated when we first adopted CBE #3636 in the CY 2022 OPPS/ASC final rule (86 FR 63828), we prefer to adopt measures that have been endorsed by the entity with a contract under section 1890(a) of the Act; however, the requirement that measures reflect consensus among affected parties can be achieved in other ways, including through the measure development process, through broad acceptance, use of the measure(s), and through public comment. Although the COVID–19 Vaccination Coverage Among HCP measure was not CBE-endorsed, the measure steward, CDC, submitted the measure for consideration in the Fall 2021 measure cycle. Additionally, we considered whether there are other available measures that assessed COVID–19 vaccination rates among HCP and found no other feasible and practical measures on the topic of COVID–19 vaccination among HCP. The CDC intends to submit the modified measure for endorsement as the current version of the measure has already received endorsement.

Comment: A few commenters recommended that HOPDs stratify the measure data to identify sub-populations of HCP that have lower vaccine uptake.

Response: We thank the commenters for their recommendation; however, as we stated in the CY 2024 OPPS/ASC proposed rule, the measure cannot be stratified since the data are submitted at an aggregate rather than an individual level (88 FR 49776).

Comment: One commenter did not support inclusion of the measure in the Hospital OQR Program measure set due to conflict between state and local mandates and Federal quality reporting requirements. Another commenter recommended that the measure specifications have proper exclusion criteria in alignment with Federal and state vaccination exemption policies. Another commenter requested clarification on how the elimination of the vaccine mandate will impact the adoption or use of the measure.

Response: We reiterate that the Hospital OQR Program is a CMS quality reporting program separate from state, local, and Federal policies, including policies surrounding vaccination exemption. We note that neither the proposed modified measure nor the current version of the measure mandates vaccines, and the elimination of the Federal vaccine mandate is immaterial to the adoption and use of the measure.

Comment: One commenter expressed concern on how the measure may result in unintended consequences of exacerbating workforce shortages.

Response: We note that neither the proposed modified measure nor the current version of the measure mandates vaccines, nor do they reward or penalize HOPDs for the rate of HCP who have received a COVID–19 vaccine. Therefore, we believe it is unlikely that the measure will have any bearing on existing or future workforce shortages. For successful program participation, the COVID–19 Vaccination Coverage Among HCP measure only requires HOPDs to collect and report COVID–19 vaccination data that would support public health surveillance and provide beneficiaries and their caregivers information to support informed decision-making.

Comment: One commenter did not support the measure because it did not

[260] Centers for Disease Control and Prevention (August 23, 2023). Risk Assessment Summary for SARS CoV–2 Sublineage BA.2.86 Available at: *https://www.cdc.gov/respiratory-viruses/whats-new/covid-19-variant.html.*

consider those who opted out of receiving the vaccine due to religious or medical reasons. A few commenters recommended that CMS include an exclusion for sincerely held religious beliefs to adhere to HHS Office for Civil Rights Guidance. Some of these commenters also requested the measure be updated to track the number of HCP who decline vaccination. A few commenters observed that there are many factors beyond a facility's control that may affect performance on this measure.

Response: We recognize that there are many reasons, including religious objections and health concerns which may lead individual HCP to decline vaccination. The CDC's NHSN tool allows facilities to report on the number of HCP who were offered a vaccination but declined for religious or philosophical objections. We emphasize that neither the proposed modified measure nor the current version of the measure mandate vaccines, and that the COVID–19 Vaccination Coverage Among HCP measure only requires reporting of vaccination rates for successful program participation. We understand the commenters' concern that there are many factors outside of a facility's control that could affect vaccination coverage; however, we believe that all facilities face such concerns, and that public reporting of these data can help patients and their caregivers identify which HOPDs have better vaccination coverage among their HCP.

Comment: A commenter requested clarification on whether NHSN data submission for the measure meets all requirements for the measure under the Hospital OQR Program.

Response: The data for this measure can only be reported through NHSN, and no separate reporting to CMS is required. We refer readers to the Successful Reporting in the Hospital OQR Program guide for more information on how to register and submit data using NHSN, available at: *https://www.qualityreportingcenter.com/globalassets/2023/02/oqr/py-2024-hospital-oqr-successful-reporting-guide-final508.pdf.*

After consideration of the public comments we received, we are finalizing our proposed modification to the COVID–19 Vaccination Coverage Among HCP Measure in the Hospital OQR Program as proposed.

b. Modification of Survey Instrument Use for the Cataracts: Improvement in Patient's Visual Function Within 90 Days Following Cataract Surgery Measure Beginning With the Voluntary CY 2024 Reporting Period

(1) Background

In the CY 2014 OPPS/ASC final rule with comment period (78 FR 75102 through 75103), we finalized the adoption of the Cataracts: Improvement in Patient's Visual Function Within 90 Days Following Cataract Surgery (the Cataracts Visual Function) measure, beginning with the CY 2014 reporting period/CY 2016 payment determination. This measure assesses the percentage of patients aged 18 years and older who had cataract surgery and had improvement in visual function within 90 days following the cataract surgery via the administration of pre-operative and post-operative survey instruments (78 FR 75102). A ''survey instrument'' is an assessment tool that has been appropriately validated for the population for which it is being used.[261] For purposes of this modification to the Cataracts Visual Function measure, the survey instruments we considered and proposed assess the visual function of a patient pre- and post-operatively to determine whether the patient's visual function changed within 90 days of cataract surgery. Examples of survey instruments assessing visual function include, but are not limited to, the National Eye Institute Visual Function Questionnaire (NEI–VFQ), the Visual Function (VF–14), the modified (VF–8), the Activities of Daily Vision Scale (ADVS), the Catquest, and the modified Catquest-9. While the measure has been available for voluntary reporting in the Hospital OQR Program since the CY 2015 reporting period, a number of facilities have reported data consistently using the survey instrument-collection method of their choice (87 FR 72098). We refer readers to the Hospital OQR Program Specifications Manual for additional detail, which is available at: *https://qualitynet.cms.gov/outpatient/specifications-manuals.*

In the CY 2015 OPPS/ASC final rule with comment period (79 FR 66947), we expressed concerns that clinicians' use of varying survey instruments would lead to inconsistent measure results. However, a comparison study conducted of the 16 survey instruments that are currently accepted for use in collecting data for this measure by HOPDs found them to be scientifically valid, able to detect clinically important changes, and provide comparable results.[262] While all 16 survey instruments demonstrate usefulness for detecting clinically important changes in cataract patients, some survey instruments' detection sensitivity scored higher than others.[263]

Several commenters responding to the CY 2022 OPPS/ASC proposed rule (86 FR 63846) requested additional guidance from CMS regarding measure specifications and survey instruments. We agree that the use of survey instruments for the assessment of visual function pre- and post-cataract surgery should be clarified. The use of survey instruments should be standardized across HOPDs to minimize collection and reporting burden, as well as to improve measure reliability. Thus, in the CY 2024 OPPS/ASC proposed rule (88 FR 49777 through 49779), we proposed to clarify which specific survey instruments may be used for the assessment of visual function pre- and post-cataract surgery for the Cataracts Visual Function measure in both the Hospital OQR Program and the ASCQR Program, to ensure alignment of this measure's specifications across our quality reporting programs. We proposed to limit the allowable survey instruments that an HOPD may use to assess changes in patient's visual function for the purposes of the Cataracts Visual Function measure to those listed below:

- The National Eye Institute Visual Function Questionnaire–25 (NEI VFQ–25)
- The Visual Functioning Patient Questionnaire (VF–14)
- The Visual Functioning Index Patient Questionnaire (VF–8R)

(2) Considerations for the Standardization of Survey Instruments Assessing Improvement in Patient's Visual Function Within 90 Days Following Cataract Surgery

We considered several factors when identifying which specific survey instruments would be acceptable for HOPDs to use when collecting data for the Cataracts Visual Function measure, such as comprehensiveness, validity, reliability, length, and burden. We stated our belief that the three survey instruments listed above would allow HOPDs to select the length of the survey to be administered while ensuring

[261] Centers for Medicare & Medicaid Services (2023). Hospital OQR Specification Manual Version 16.0. Available at: *https://qualitynet.cms.gov/outpatient/specifications-manuals#tab1.*

[262] McAlinden C, Gothwal VK, Khadka J, et al. (2011). A head-to-head comparison of 16 cataract surgery outcome questionnaires. *Ophthalmology,* 118(12), 2374–81. *https://doi.org/10.1016/j.ophtha.2011.06.008.*

[263] *Ibid.*

adequate validity and reliability.[264] [265] [266] All three of the survey instruments are based upon the 51-item National Eye Institute Visual Function Questionnaire (NEI VFQ–51) survey instrument, which was the first survey instrument originally developed for assessing a patient's visual function before and after cataract surgery. Each of the three survey instruments have progressively fewer numbers of questions than the NEI VFQ–51: 25 questions for the NEI VFQ–25, 14 questions for the VF–14, and eight questions for the VF–8R. Even with fewer numbers of questions, all three of the survey instruments have been validated as providing results comparable to the NEI VFQ–51. In addition, all three of the survey instruments are readily available for hospitals to access and use.

In the CY 2024 OPPS/ASC proposed rule (88 FR 49778) we proposed to allow HOPDs to use the NEI VFQ–25 for administering and calculating the Cataracts Visual Function measure due to its comprehensiveness, its adequate validity and reliability, as well as its potential to reduce language barriers for patients. The NEI VFQ–25 is a shorter version of the NEI VFQ–51, being comprised of 25 items across 12 vision-specific domains (general health, general vision, ocular pain, near activities, distance activities, social functioning, mental health, role difficulties, dependency, driving, color vision, and peripheral vision).[267]

The NEI VFQ–25, similar to the VF–14 and VF–8R, displays adequate reliability and validity.[268] The NEI VFQ–25 composite, near activities, and distance activities subscales demonstrated good internal consistency reliability, test-retest reliability, convergent validity, and known-groups validity.[269] Furthermore, the NEI VFQ–25's high internal consistency, indicates that items of the NEI VFQ–25 are highly related to each other and to the scale as a whole.[270]

In addition, the survey instrument is publicly available on the RAND website at no cost and has been translated to many languages, which is a valuable benefit for patients with limited English proficiency. The NEI VFQ–25 was chosen over other survey instruments to reduce potential language barriers, as, for example, the currently available Activities of Daily Vision Scale (ADVS) is dependent on English language skills.[271] More information on the NEI VFQ–25 can be found at: *https://www.rand.org/health-care/surveys_tools/vfq.html.*

While the NEI VFQ–25 was shortened significantly from the original NEI VFQ–51, it has been criticized for its still lengthy test-time. However, the inclusion of this survey instrument in this measure's specifications would allow for a more detailed assessment of cataract surgery outcomes, as it was designed to include questions which are most important for persons who have chronic eye diseases.[272] Further, if a hospital finds the NEI VFQ–25 particularly burdensome to administer, the hospital may choose from the other two survey instruments proposed for inclusion in this measure's specifications, as both of these have even fewer survey questions to administer.

We also proposed to allow HOPDs to use the 14-item VF–14 and the 8-item VF–8R for administering and calculating the Cataracts Visual Function measure, which each can be administered in a shorter timeframe than the NEI VFQ–25 with high precision.[273] [274] Thus, the succinct formats of the VF–14 and VF–8R may ease HOPD's burden in administering the survey instruments and potentially increase the rate of patient responses for this measure, as compared with other survey instrument options we considered. We believe these survey instruments achieve comparable results with the longer NEI VFQ–25 and NEI VFQ–51 survey instruments with substantially fewer questions to administer.

Furthermore, we proposed inclusion of the VF–14 because currently it is the most commonly used survey instrument and we believe it would be beneficial to allow the majority of physicians who have already been using VF–14 to continue to have the option to do so.[275] The VF–14 is comprised of 14 items relating to daily living activities and function, such as reading, writing, seeing steps, stairs or curbs, and operating a motor vehicle.[276] Studies using this survey instrument generally report significant and clinically important improvement following cataract surgery.[277] The VF–14 additionally has achieved adequate reliability and validity, proving it to be a dependable survey instrument for cataract outcomes.[278] [279]

In the CY 2024 OPPS/ASC proposed rule (88 FR 49809), we also proposed the VF–8R as it is the most concise of the three survey instruments while still achieving adequate validity and reliability.[280] The VF–8R consists of questions related to reading, fine handwork, writing, playing board games, and watching television.[281] Given its conciseness compared to the majority of currently available survey instruments and its adequate psychometric properties, we stated our belief that the VF–8R would be beneficial for measuring cataract surgery outcomes without prompting further patient survey fatigue.[282]

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[264] Sivaprasad S, Tschosik E, Kapre A, et al. (2018). Reliability and construct validity of the NEI VFQ–25 in a subset of patients with geographic atrophy from the Phase 2 mahalo study. *American Journal of Ophthalmology,* 190, 1–8. *https://doi.org/10.1016/j.ajo.2018.03.006.*

[265] Hecht I, Kanclerz P, & Tuuminen R. (2022). Secondary outcomes of Lens and cataract surgery: More than just ''best-corrected visual acuity''. *Progress in Retinal and Eye Research,* 101150. *https://doi.org/10.1016/j.preteyeres.2022.101150.*

[266] Orizonartstudios (2023). 2023 MIPS measure #303: Cataracts: Improvement in patient's visual function within 90 days following cataract surgery. Mdinteractive. Available at: *https://mdinteractive.com/mips_quality_measure/2023-mips-quality-measure-303.*

[267] U.S. Department of Health and Human Services. *Visual function questionnaire 25.* National Eye Institute. Available at: *https://www.nei.nih.gov/learn-about-eye-health/outreach-campaigns-and-resources/outreach-materials/visual-function-questionnaire-25.*

[268] Sivaprasad S, Tschosik E, Kapre A, et al. (2018). Reliability and construct validity of the NEI VFQ–25 in a subset of patients with geographic atrophy from the Phase 2 mahalo study. *American Journal of Ophthalmology,* 190, 1–8. *https://doi.org/10.1016/j.ajo.2018.03.006.*

[269] Ibid.

[270] Ibid.

[271] Mangione CM, Phillips RS, Seddon JM, et al. (1992). Development of the 'Activities of Daily Vision Scale'. A measure of visual functional status. *Med Care,* 30(12), 1111–1126. *https://doi.org/10.1097/00005650-199212000-00004.*

[272] Hecht I, Kanclerz P, & Tuuminen R. (2022). Secondary outcomes of Lens and cataract surgery: More than just ''best-corrected visual acuity.'' Progress in Retinal and Eye Research, 101150. *https://doi.org/10.1016/j.preteyeres.2022.101150.*

[273] Ibid.

[274] Orizonartstudios (2023). 2023 MIPS measure #303: Cataracts: Improvement in patient's visual function within 90 days following cataract surgery. MDinteractive. Available at: *https://mdinteractive.com/mips_quality_measure/2023-mips-quality-measure-303.*

[275] Hecht, I., Kanclerz, P., &; Tuuminen, R. (2022). Secondary outcomes of Lens and cataract surgery: More than just ''best-corrected visual acuity.'' Progress in Retinal and Eye Research, 101150. *https://doi.org/10.1016/j.preteyeres.2022.101150.*

[276] Ibid.

[277] Ibid.

[278] Ibid.

[279] Orizonartstudios (2023). 2023 MIPS measure #303: Cataracts: Improvement in patient's visual function within 90 days following cataract surgery. MDinteractive. Retrieved March 13, 2023, from *https://mdinteractive.com/mips_quality_measure/2023-mips-quality-measure-303.*

[280] Ibid.

[281] Pre-Cataract Surgery—Visual Functioning Index (VF–8R) Available at: *https://www.aao.org/practice-management/coding/updates-resources.* (In the CY 2024 OPPS/ASC proposed rule, we cited this information to: *https://eyecaresite.com/wp-content/uploads/2020/02/Visual-Functioning-Index-Pre-Cat-SX.pdf.* However, after review, the information appears to have moved. Thus, we have updated the citation in this final rule.)

[282] Ibid.

For these reasons, we believe that the NEI VFQ–25, VF–14, and VF–8R are the most appropriate survey instruments for HOPDs to use to assess a patient's visual function pre- and post-cataract surgery for purposes of calculating and submitting data for the Cataracts Visual Function measure in the Hospital OQR Program.

In response to commenters' concerns as summarized in the CY 2023 OPPS/ASC final rule (87 FR 72097 through 72099) regarding the lack of specificity around survey instrument administration for the Cataracts Visual Function measure, we proposed to limit the survey instruments that can be used to administer this measure, beginning with the voluntary CY 2024 reporting period, to these three survey instruments: (1) NEI VFQ–25; (2) VF–14; and (3) VF–8R. We believe the use of these three survey instruments to report data on the Cataracts Visual Function measure will allow for a more standardized approach to data collection. Having a limited number of allowable survey instruments would also address commenters' requests for additional guidance on survey instruments as well as improve measure reliability.

(3) Considerations for Data Collection Modes for the Cataracts: Improvement in Patient's Visual Function Within 90 Days Following Cataract Surgery Measure Beginning With the Voluntary CY 2024 Reporting Period

As summarized in the CY 2023 OPPS/ASC final rule (87 FR 72104 and 72105), many commenters expressed concern about the high administrative burden of reporting the Cataracts Visual Function measure, as the measure uniquely requires coordination among clinicians of different specialties (that is, opticians and ophthalmologists). In an effort to decrease administrative burden surrounding in-office time constraints, we reiterate that, while we recommend the patient's physician or optometrist administer, collect, and report the survey instrument results to the HOPD, the survey instruments required for this measure can be administered by the HOPD itself via phone, by the patient via regular or electronic mail, or during clinician follow-up.

Scientific literature supports the conclusion that self-administered survey instruments produce statistically reliable results.[283] [284] Furthermore, scientific literature indicates that regular mail and electronic mail surveys respectively, are preferred by varying subgroups of patients. The inclusion of both options ensures that patients will be able to respond to surveys in their preferred format.[285] [286] These findings support the inclusion of varying survey instrument-collection methods for patient and provider convenience.

We invited public comment on the proposal.

Comment: Many commenters supported our proposal to modify the survey instruments allowable for the Cataracts Visual Function measure beginning with the voluntary CY 2024 reporting period. Several commenters concurred with CMS that this modification would standardize data collection and ensure comparability of the measure across HOPDs. Several commenters also expressed support for the modification because the three survey instruments demonstrate adequate reliability and validity.

Response: We thank commenters for their support. We agree that limiting the allowable survey instruments used to report on the Cataracts Visual Function measure to three survey instruments of different lengths will allow for a more standardized approach to data collection and improve measure reliability. We emphasize that all three surveys demonstrate adequate reliability and validity, which demonstrates that they are dependable survey instruments for measuring cataract outcomes. Further, by adopting this modification for this measure, we will be promoting alignment with the ASCQR Program.

Comment: Several commenters did not support modification of the survey instruments allowable for the Cataracts Visual Function measure and recommended that the measure be removed altogether from the Hospital OQR Program measure set, stating that the modification does little to address reporting burden, which they believe outweighs the measure's utility in improving care for patients undergoing cataract procedures.

Response: We acknowledge the commenters' concerns regarding burden but respectfully disagree that this measure should be removed from the Hospital OQR Program as we believe the benefits of the measure outweigh the reporting burden. Cataract surgery is one of the most commonly performed procedures in HOPDs, and there are currently no other measures assessing the quality of care provided for this procedure for the Hospital OQR Program. As a patient reported outcome measure, this measure aligns with the CMS National Quality Strategy (NQS) ''Foster Engagement'' goal, which seeks to increase engagement between individuals and their care teams to improve quality, establish trusting relationships, and bring the voices of people and caregivers to the forefront. The Meaningful Measures 2.0 goals also prioritize patient-reported measures and promoting better collection and integration of patient voices across CMS' quality programs.

We believe that the value of the information the measure provides to consumers about quality of care justifies the potential administrative burden for facilities reporting on it. As some HOPDs have been voluntarily reporting this measure successfully, we believe this indicates the measure is not overly burdensome, and that standardizing the allowable survey instruments will further improve its usability and reliability in this setting. We wish to reiterate that when selecting allowable surveys, we considered a variety of factors, including accessibility and prevalence, and that we proposed to limit the allowable surveys to the NEI–VFQ–25, VF–14, and VF–8R as they are commonly adopted survey instruments that are readily available online for entities to access and use. We also note that, in accordance with CMS standards,[287] hospitals failing to reach established thresholds will not be publicly reported but can still receive data through their Preview Reports which can drive quality improvement efforts.

Comment: A few commenters did not support this measure because it was unclear to them if the revisions have been tested to ensure performance scores are reliable and valid. One commenter recommended further reliability and validity testing, as well as CBE endorsement, before adoption into the Hospital OQR Program.

Response: We stated in the CY 2024 OPPS/ASC proposed rule (88 FR 49778)

[283] Bhandari NR, Kathe N, Hayes C, & Payakachat N. (2018). Reliability and validity of SF–12V2 among adults with self-reported cancer. *Research in Social and Administrative Pharmacy, 14*(11), 1080–1084. *https://doi.org/10.1016/j.sapharm.2018.01.007.*

[284] Stolwijk C, van Tubergen A, Ramiro S, et al. (2014). Aspects of validity of the self-administered comorbidity questionnaire in patients with ankylosing spondylitis. *Rheumatology, 53*(6), 1054–1064. *https://doi.org/10.1093/rheumatology/ket354.*

[285] Kelfve S, Kivi M, Johansson B, & Lindwall M. (2020). Going web or staying paper? the use of web-surveys among older people. BMC Medical Research Methodology, 20(1), 252. *https://doi.org/10.1186/s12874-020-01138-0.*

[286] Meyer VM, Benjamens S, Moumni ME, et al. (2020). Global overview of response rates in patient and health care professional surveys in surgery. *Annals of Surgery, 275*(1). *https://doi.org/10.1097/sla.0000000000004078.*

[287] CMS does not report measures publicly unless measures are the result of an analysis of more than 10 cases. See CMS Policy for Privacy Act Implementation & Breach Notification, July 23, 2007, Document Number: CMS–CIO–POL–PRIV01–01, p 4.

our belief that the three proposed survey instruments (NEI VFQ–25, VF–14, and VF–8R) will allow HOPDs to select the length of the survey to be administered while ensuring adequate validity and reliability, and cited literature to support this belief.[288] [289] [290] We also emphasize that all three surveys demonstrate adequate reliability and validity, which demonstrates that they are dependable survey instruments for measuring cataract outcomes. Additionally, we wish to reiterate that scientific literature demonstrates that self-administered surveys can produce statistically reliable results.[291] [292] Regarding CBE endorsement, the current version of the measure in the Hospital OQR Program received CBE endorsement (CBE #3636) on July 26, 2022. The measure steward (CDC) is pursuing endorsement for the modified version of this measure.

Comment: Many commenters provided recommendations regarding reporting requirements of the Cataracts Visual Function measure. Some of these commenters believed that the measure should remain voluntary in the Hospital OQR Program. One commenter recommended that the measure remain voluntary until a digital version is developed, in order to support the transition away from chart-abstracted measures. A couple of commenters conversely requested to make this measure mandatory to boost reporting, citing concerns that only a handful of facilities are voluntarily collecting these data and publicly reporting their performance.

Response: We appreciate commenters' input regarding maintaining this measure as voluntary. We are committed to having a cataract surgery, patient-reported outcome measure for the Hospital OQR Program, and our intent is to maintain this measure as voluntary while we consider mandatory reporting in future rulemaking. We will continue to evaluate the status of this measure moving forward. We also acknowledge that this measure requires cross-setting coordination among clinicians of different specialties (surgeons and ophthalmologists), increasing burden. If we determine that the value of mandatory reporting justifies increased burden on HOPDs, we will propose to transition the measure to mandatory reporting through rulemaking. Regarding the commenter's request to maintain the measure as voluntary until a digital version is available, we agree that moving from chart-abstracted measures to digital measures is an important step in working toward interoperability as well as reducing reporting burden, goals we outlined in the FY 2022 IPPS/LTCH PPS final rule (86 FR 45342 and 45343) and the FY 2023 IPPS/LTCH PPS final rule (87 FR 49181), and intend to take into consideration when making measure decisions in the future.

Comment: One commenter recommended removing the Cataracts Visual Function measure and adopting the Toxic Anterior Segment Syndrome (TASS) measure instead. Another commenter recommended the addition of Catquest 9 Short Form (Catquest-9SF) as an acceptable alternative to the proposed NEI VFQ–25, the VF–14, and VF–8R. One commenter recommended that CMS publicly report trends on HOPDs' choices of survey instruments. One commenter recommended CMS provide additional best practices as more facilities adopt the use of these three surveys during the voluntary measurement period.

Response: Although we are not currently considering the adoption of the TASS measure, we will continue to monitor the effects of the Cataracts Visual Function measure and will consider the adoption of new measures in future rulemaking. We note that the TASS measure is used to assess the number of ophthalmic anterior segment surgery patients diagnosed with TASS within 2 days of surgery. The Cataracts Visual Function measure assesses the percentage of patients aged 18 years and older who had cataract surgery and had improvement in visual function achieved within 90 days following the cataract surgery. Therefore, the TASS measure could not seamlessly replace the Cataracts Visual Function measure, as they measure two different outcomes. Similarly, we will monitor the impact of the three survey options (NEI VFQ–25, the VF–14, and VF–8R) and consider adjusting the chosen standardized surveys as needed in future rulemaking. We will also consider the value of reporting HOPD's choices of survey instruments in future rulemaking, as well as developing best practices based on facility use of these surveys during the voluntary measurement period.

Comment: One commenter, while supportive of limiting the survey instruments and allowing flexible administration to simplify data collection, expressed concerns about the complexity and burden of cross-setting coordination among clinicians of different specialties.

Response: We believe hospitals, facilities, ophthalmologists, and other clinicians should actively and routinely engage in exchanging information to better communicate and coordinate patient care to ensure and improve quality of care. We note that while it is recommended that the HOPD obtain the survey results from the appropriate physician or optometrist, in an effort to reduce administrative burden, the surveys can be administered by the HOPD via phone, mail, email, or during clinician follow-up. Patients can also self-administer the surveys and submit them directly to the HOPD via mail or email. Due to commenter concerns on complexity and burden of cross-setting coordination among clinicians of different specialties, we maintain this measure as voluntary.

Comment: A few commenters recommended exploring whether this measure is best captured under the Quality Payment Program, because patients likely receive ongoing care following the procedure from an ophthalmologist and not the hospital outpatient department or ambulatory surgical center. Commenters further recommended exploring adoption of this measure as part of its development of specialist-focused Merit-based Incentive Payment System (MIPS) Value Pathways (MVPs) around ophthalmology care. One commenter noted that this measure was not originally developed for use at the HOPD level.

Response: This measure is already included in the Quality Payment Program's Merit-based Incentive Payment System (MIPS) (Measure #303) for MIPS eligible clinicians (as defined in 42 CFR 414.1305) to report. Even though individual clinicians may report this measure in MIPS, we continue to view this measure as appropriate for assessing hospital-level of care as the procedures are provided in a hospital.

We appreciate the commenter's suggestion to include this measure in a

[288] Sivaprasad S., Tschosik E., Kapre A., et al. (2018). Reliability and construct validity of the NEI VFQ–25 in a subset of patients with geographic atrophy from the Phase 2 mahalo study. American Journal of Ophthalmology, 190, 1–8. *https://doi.org/10.1016/j.ajo.2018.03.006*.

[289] Hecht I., Kanclerz P., & Tuuminen R. (2022). Secondary outcomes of Lens and cataract surgery: More than just ''best-corrected visual acuity''. Progress in Retinal and Eye Research, 101150. *https://doi.org/10.1016/j.preteyeres.2022.101150.*

[290] Orizonartstudios. (2023). 2023 MIPS measure #303: Cataracts: Improvement in patient's visual function within 90 days following cataract surgery. Mdinteractive. Available at: *https://mdinteractive.com/mips_quality_measure/2023-mips-quality-measure-303*.

[291] Bhandari N.R., Kathe N., Hayes C., & Payakachat N. (2018). Reliability and validity of SF–12V2 among adults with self-reported cancer. Research in Social and Administrative Pharmacy, 14(11), 1080–1084. *https://doi.org/10.1016/j.sapharm.2018.01.007*.

[292] Stolwijk C., van Tubergen A., Ramiro S., et al. (2014). Aspects of validity of the self-administered comorbidity questionnaire in patients with ankylosing spondylitis. Rheumatology, 53(6), 1054–1064. *https://doi.org/10.1093/rheumatology/ket354.*

potential future ophthalmology care MVP. We will consider this suggestion in future rulemaking.

Furthermore, we continue to view this measure as appropriate for assessing hospital-level of care as the procedures are provided in HOPDs. We emphasize the importance of measuring cataract outcomes in all procedural settings.

After consideration of the public comments we received, we are finalizing our proposal to modify the Cataracts Visual Function measure as proposed. We also refer readers to the discussion of a similar proposal for the same measure as used in the ASCQR Program in section XV.B.4.b of this final rule with comment period.

c. Modification of the Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients Measure Denominator Change to Align With Current Clinical Guidelines Beginning With the CY 2024 Reporting Period/CY 2026 Payment Determination

(1) Background

In 2019, colorectal cancer (CRC) accounted for the 4th highest rate of new cancer cases and the 4th highest rate of cancer deaths in the United States.[293] The American Cancer Society (ACS) estimates that in 2023, 153,020 individuals will be newly diagnosed with CRC and 52,550 individuals will die from CRC in the United States.[294] The CDC advises, ''[c]olorectal cancer almost always develops from precancerous polyps (abnormal growths) in the colon or rectum. Screening tests can find precancerous polyps, so that they can be removed before they turn into cancer. Screening tests can also find colorectal cancer early, when treatment works best. Regular screening, beginning at age 45, is the key to preventing colorectal cancer and finding it early.'' [295]

In May 2021, the United States Preventive Services Task Force (USPSTF) issued a revised Final Recommendation Statement on CRC Screening.[296] This replaced the prior USPSTF 2016 Final Recommendation Statement and included a number of updated policy recommendations based on new evidence and understandings of CRC and CRC screening. The USPSTF recommended that adults who do not have signs or symptoms of CRC and who are at average risk for CRC begin screening at age 45 instead of the previous recommendation of age 50.[297] In addition, multiple professional organizations, including the ACS, American Society of Colon and Rectal Surgeons, and the U.S. Multi-Society Task Force on Colorectal Cancer (which represents the American College of Gastroenterology, the American Gastroenterological Association, and the American Society for Gastrointestinal Endoscopy), recommend that people of average risk of CRC start regular screening at age 45.[298] [299] [300] Based on the recent changes in clinical guidelines to begin CRC screening at age 45 instead of age 50, in the CY 2024 OPPS/ASC proposed rule (88 FR 49779 and 49780), we proposed to modify the Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients (the Colonoscopy Follow-Up Interval) measure to follow these clinical guideline changes.

(2) Overview of Measure

We refer readers to the CMS Measures Inventory Tool (CMIT) and the Hospital OQR Program specification manual for more information on the Colonoscopy Follow-Up Interval measure, including background on the measure and a complete summary of measure specifications.[301] [302] Currently, the Colonoscopy Follow-Up Interval measure assesses the ''percentage of patients aged 50 years to 75 years receiving a screening colonoscopy without biopsy or polypectomy who had a recommended follow-up interval of at least 10 years for repeat colonoscopy documented in their colonoscopy report.'' [303] In the CY 2024 OPPS/ASC proposed rule (88 FR 49780), we proposed to amend the measure's denominator language by replacing the phrase ''aged 50 years'' with the phrase ''aged 45 years.'' Under the proposal, the measure denominator would be modified to ''all patients aged *45 years to 75 years* receiving screening colonoscopy without biopsy or polypectomy'' from ''all patients aged *50 years to 75 years* receiving screening colonoscopy without biopsy or polypectomy.'' [304] We did not propose any changes to the measure numerator, other measure specifications, exclusions, or data collection for the Colonoscopy Follow-Up Interval measure.

In the CY 2023 Physician Fee Schedule final rule (87 FR 69760 through 69767), we adopted the modified Colonoscopy Follow-Up Interval measure (which we proposed here for the Hospital OQR Program) for the Merit-based Incentive Payment System (MIPS). We have considered the importance of aligning the minimum age requirement for CRC screening across quality reporting programs and clinical guidelines. As a result, in the CY 2024 OPPS/ASC proposed rule (88 FR 49779 and 49780), we proposed to modify the Colonoscopy Follow-Up Interval measure denominator to ''all patients aged 45 to 75 years'' for the Hospital OQR Program. We proposed the modification of the Colonoscopy Follow-Up Interval measure beginning with the CY 2024 reporting period/CY 2026 payment determination.

We invited public comment on the proposal.

Comment: Many commenters supported the modification of the Colonoscopy Follow-Up Interval measure beginning with the CY 2024 reporting period/CY 2026 payment determination. Many commenters stated that the modification to the denominator aligns with clinical guidelines. Some of these commenters noted the modification to the denominator provides alignment across quality programs. Other commenters supported the proposal because commenters believe that the measure will ensure appropriate patient access to recommended cancer screening and prevention services. Another

[293] Centers for Disease Control and Prevention (2022). Colorectal Cancer Statistics. Available at: *https://gis.cdc.gov/Cancer/USCS/#/AtAGlance/.*

[294] American Cancer Society (2023). Cancer Facts & Figures 2023. Available at: *https://www.cancer.org/research/cancer-facts-statistics/all-cancer-facts-figures/2023-cancer-facts-figures.html.*

[295] Centers for Disease Control and Prevention (2022). What Should I Know About Screening? Available at: *https://www.cdc.gov/cancer/colorectal/basic_info/screening/index.htm.*

[296] US Preventive Services Task Force (2021). Screening for Colorectal Cancer. *JAMA,* 325(19), 1965–1977. *https://doi.org/10.1001/jama.2021.6238.*

[297] Ibid.

[298] Wolf A, Fontham ETH, Church TR, et al. (2018). Colorectal cancer screening for average-risk adults: 2018 guideline update from the American Cancer Society. *CA. Cancer J. Clin.,* 2018(68), 250–281. *https://doi.org/10.3322/caac.21457.*

[299] American Society of Colon & Rectal Surgeons. Colorectal Cancer Screening and Surveillance Recommendations of U.S. Multisociety Task Force. Available at: *https://fascrs.org/healthcare-providers/education/clinical-practice-guidelines/colorectal-cancer-screening-and-surveillance-recom.*

[300] Patel SG, May FP, Anderson JC, Burke CA, et al. (2022). Updates on Age to Start and Stop Colorectal Cancer Screening: Recommendations From the U.S. Multi-Society Task Force on Colorectal Cancer. *The American Journal of Gastroenterology,* 117(1), 57–69. *https://doi.org/10.14309/ajg.0000000000001548.*

[301] Centers for Medicare & Medicaid Services. (2023). Measures Inventory Tool. Available at: *https://cmit.cms.gov/cmit/#/MeasureView?variantId=793&sectionNumber=1.*

[302] Centers for Medicare & Medicaid Services. Qualitynet Home. Available at: *https://qualitynet.cms.gov/outpatient/specifications-manuals.*

[303] Centers for Medicare & Medicaid Services (2023). Measures Inventory Tool. Available at: *https://cmit.cms.gov/cmit/#/MeasureView?variantId=793&sectionNumber=1.*

[304] Ibid.

commenter expressed that the measure modification will enable CMS to measure appropriate care more meaningfully and to better differentiate facilities with successful preventive care efforts. Another commenter supported the proposal because the commenter believes the measure modification could be key to mitigating disparities in CRC screening and early detection among different sociodemographic groups and, therefore, is supportive of CMS' health equity goals. Another commenter supported the proposal because the commenter believes the measure modification will promote timely and connected patient care.

Response: We thank commenters for supporting our proposal to modify the Colonoscopy Follow-Up Interval measure denominator to ''all patients aged 45 to 75 years'' for the Hospital OQR Program. We agree that it is important to align requirements across quality reporting programs and clinical guidelines when relevant. We believe that consistent policy across programs in terms of minimum age limits for CRC screening tests is critical to the public's understanding of evolving CRC screening recommendations. We also agree that CRC screening plays a key role in the prevention and early detection of cancer.

Comment: One commenter suggested that CMS remove the measure from the Hospital OQR Program because the commenter believes the measure should not be tracked by hospitals, but instead should be tracked by the patient's primary care physician.

Response: We support the inclusion of the Colonoscopy Follow-up Interval measure in the Hospital OQR Program and reiterate that, while this measure is suitable for clinician office settings, we continue to believe that the measure is also suitable for settings, such as HOPDs, that provide the same types of services to the same target populations for the measure. The intent of the measure is to improve the coordination of services, reduce fragmented care, encourage redesigned care processes for high quality and efficient service delivery, and incentivize higher value care. Additionally, we continue to believe this measure aligns with our goals to promote wellness and disease prevention. Under CMS' Meaningful Measures Framework 2.0, the Colonoscopy Follow-up Interval measure addresses the Meaningful Measures Area of ''Wellness and Prevention.'' Under the National Quality Strategy, the measure addresses the goals of Outcomes and Alignment under the priority area Outcomes and Alignment.

Comment: A few commenters noted that the modification to this measure would increase the patient population that is eligible for the measure and recommended that CMS maintain the same sample size to prevent increased administrative burden.

Response: The only change proposed to this measure was a change in the measure denominator to ''all patients aged 45 to 75 years.'' We understand that the measure would increase the patient population that is eligible for the measure, however, we did not propose any other changes to the measure specifications or sampling methodology for the measure, including any changes to minimum sampling size requirements. Therefore, we do not believe that the modification to the denominator increases the burden on hospitals. We refer readers to the Population and Sampling Specifications section of the Hospital OQR Program Specifications Manual for additional detail, which is available at *https://qualitynet.cms.gov/outpatient/specifications-manuals.*

After consideration of the public comments we received, we are finalizing our proposal to modify the Colonoscopy Follow-Up Interval measure as proposed. We also refer readers to the discussion of a similar proposal for the same measure as used in the ASCQR Program in section XV.B.4.c of this final rule with comment period.

3. Adoption of New Measures for the Hospital OQR Program Measure-Set

Section 1833(t)(17)(C)(i) of the Act requires the Secretary to develop measures appropriate for the measurement of the quality of care (including medication errors) furnished by hospitals in outpatient settings, that these measures reflect consensus among affected parties and, to the extent feasible and practicable, that these measures include measures set forth by one or more national consensus-based entities. We have noted in previous rulemaking, the requirement that measures reflect consensus among affected parties can be achieved in other ways aside from CBE endorsement, including through the measure development process, through broad acceptance, use of the measure(s), and through public comment (75 FR 72064).

Section 1890A of the Act requires that we establish and follow a pre-rulemaking process for selecting quality and efficiency measures for our programs, including taking into consideration input from multi-stakeholder groups. As part of this pre-rulemaking process, the CBE, with which we contract under section 1890 of the Act, convened these groups under the Measure Applications Partnership (MAP). The MAP is a public-private partnership created for the primary purpose of providing input to HHS on the selection of measures as required by section 1890(b)(7)(B) of the Act. We followed this pre-rulemaking process for the measures we proposed for adoption in the CY 2024 OPPS/ASC proposed rule (88 FR 49780 and 49790) for the Hospital OQR Program. Specifically, we proposed to: (1) re-adopt the Hospital Outpatient Department Volume Data on Selected Outpatient Surgical Procedures with modification, beginning with the voluntary CY 2025 reporting period followed by mandatory reporting beginning with the CY 2026 reporting period/CY 2028 payment determination; (2) adopt the Risk-Standardized Patient-Reported Outcome-Based Performance Measure (PRO–PM) Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA) in the HOPD Setting (THA/TKA PRO–PM), beginning with the voluntary CYs 2025 and 2026 reporting periods followed by mandatory reporting beginning with the CY 2027 reporting period/CY 2030 payment determination; and (3) adopt the Excessive Radiation Dose or Inadequate Image Quality for Diagnostic Computed Tomography (CT) in Adults measure, beginning with the voluntary CY 2025 reporting period and mandatory reporting beginning with the CY 2026 reporting period/CY 2028 payment determination. We discuss each of these measures, along with the public comments that we received on them, in subsequent sections.

a. Proposed Re-Adoption of the Hospital Outpatient Department Volume Data on Selected Outpatient Surgical Procedures Measure with Modification Beginning with the Voluntary CY 2025 Reporting Period Followed by Mandatory Reporting Beginning with the CY 2026 Reporting Period/CY 2028 Payment Determination

(1) Background

Hospital care has been gradually shifting from inpatient to outpatient settings.[305] Research indicates that volume of services performed in HOPDs will continue to grow, with some estimates projecting a 19 percent increase in patients between 2019 and

[305] Medicare Payment Advisory Commission. March 2021 Report to the Congress: Medicare Payment Policy. Chapter 3. Available at: *https://www.medpac.gov/wp-content/uploads/2021/10/mar21_medpac_report_ch3_sec.pdf.*

2029.[306] In light of this trend, it has become even more important to track volume within HOPDs. Larger facility surgical procedure volume may be associated with better outcomes due to having characteristics that improve care, such as efficient teamwork and increased surgical experience, discussed in more detail below.[307] Given the association between volume and outcomes, this information could provide valuable insight to patients when choosing a HOPD.

Although measuring the volume of procedures and other services has a long history as a quality metric, quality measurement efforts had moved away from collecting and analyzing data on volume because some considered volume simply a proxy for quality compared to directly measuring outcomes.[308] However, experts on quality and safety have recently suggested that while volume alone may not indicate or lead to better outcomes, it is still an important component of quality.[309] [310] [311] Specifically, larger facility surgical procedure volume may be associated with better outcomes due to having characteristics that improve care.[312] For example, high-volume facilities may have teams that work more effectively together, or have superior systems or programs for identifying and responding to complications.[313] This association between volume and patient outcomes may be attributable to greater experience or surgical skill, greater comfort with and, hence, likelihood of application of standardized best practices, and increased experience in monitoring and management of surgical patients for the particular procedure.

The Hospital OQR Program does not currently include a quality measure for facility-level volume data, including surgical procedure volume data, but it did so previously. In the CY 2012 OPPS/ASC final rule (76 FR 74466 through 74468), we adopted the Hospital Outpatient Department Volume Data on Selected Outpatient Surgical Procedures (HOPD Procedure Volume) measure beginning with the CY 2014 payment determination. This structural measure of facility capacity collected surgical procedure volume data on nine categories [314] of procedures frequently performed in the hospital outpatient setting: Cardiovascular, Eye, Gastrointestinal, Genitourinary, Musculoskeletal, Nervous System, Respiratory, Skin, and Other.[315] We adopted the HOPD Procedure Volume measure based on evidence that the volume of surgical procedures, particularly of high-risk surgical procedures, is related to better patient outcomes, including decreased mortality (76 FR 74466).[316] [317] We further stated our belief that publicly reporting volume data would provide patients with beneficial information to use when selecting a care provider (76 FR 74467).

In the CY 2018 OPPS/ASC final rule with comment period (82 FR 59429 and 59430), we removed the HOPD Procedure Volume measure, citing a lack of evidence to support this specific measure's link to improved clinical quality. Although there is currently increased evidence of a link between patient volume and better patient outcomes, we previously stated that we believed that there was a lack of evidence that this link was reflected in the HOPD Procedure Volume measure. At the time, we stated that measuring the number of surgical procedures did not offer insight into the facilities' overall performance or quality improvement regarding surgical procedures (82 FR 59429). Thus, we removed the HOPD Procedure Volume measure beginning with the CY 2020 payment determination based on measure removal factor 2 (that is, performance or improvement on a measure does not result in better patient outcomes), as codified under § 419.46(i)(3)(i)(B).

In the CY 2023 OPPS/ASC proposed rule (87 FR 44730 through 44732), we stated that we have been considering re-adopting the HOPD Procedure Volume measure with modification for two reasons. First, since the removal of the HOPD Procedure Volume measure, scientific literature has concluded that volume metrics serve as an indicator of which facilities are experienced with certain outpatient procedures and can assist consumers in making informed decisions about where they receive care.[318] Further supporting this position that volume metrics are an indicator of quality, one study found an inverse volume–mortality relationship related to transfemoral transcatheter aortic-valve replacement (TAVR) procedures performed from 2015 through 2017.[319] Second, as discussed above, the recent shift of more surgical procedures being performed in outpatient settings has placed greater importance on tracking the volume of outpatient procedures in different settings, including HOPDs. Given these developments, we believe that patients may benefit from the public reporting of facility-level volume measure data that reflect the procedures performed across hospitals, provide the ability to track volume changes by facility and procedure category, and can serve as an indicator for patients of which facilities are experienced with certain outpatient procedures.

In response to our request for comment in the CY 2023 OPPS/ASC proposed rule (87 FR 44730 through 44732), regarding the potential re-adoption of the Hospital Outpatient Surgical measure, several commenters expressed concern that the burden of collecting and reporting data for the

[306] Sg2 (2021). Sg2 Impact of Change Forecast Predicts Enormous Disruption in Health Care Provider Landscape by 2029. Available at: *https://www.sg2.com/media-center/press-releases/sg2-impact-forecast-predicts-disruption-health-care-provider-landscape-2029/.*

[307] Jha AK. (2015) Back to the Future: Volume as a Quality Metric. JAMA Forum Archive. Published online June 10, 2015. *https://jamanetwork.com/channels/health-forum/fullarticle/2760155.*

[308] Ibid.

[309] Ibid.

[310] Shang M, Mori M, Gan G, et al. (2022). Widening volume and persistent outcome disparity in Valve Operations: New York Statewide Analysis, 2005–2016. The Journal of Thoracic and Cardiovascular Surgery, *164*(6). *https://doi.org/10.1016/j.jtcvs.2020.11.098.*

[311] Iwatsuki M, Yamamoto H, Miyata H, et al. (2018). Effect of hospital and surgeon volume on postoperative outcomes after distal gastrectomy for gastric cancer based on data from 145,523 Japanese patients collected from a nationwide web-based data entry system. *Gastric Cancer, 22*(1), 190–201. *https://doi.org/10.1007/s10120-018-0883-1.*

[312] Jha AK. (2015) Back to the Future: Volume as a Quality Metric. JAMA Forum Archive. Published online June 10, 2015. *https://jamanetwork.com/channels/health-forum/fullarticle/2760155.*

[313] Ibid.

[314] At the time of this measure's initial adoption in the CY 2012 OPPS/ASC final rule (76 FR 74468), we finalized that HOPDs would report all-patient volume data with respect to the following eight categories: Cardiovascular, Eye, Gastrointestinal, Genitourinary, Musculoskeletal, Nervous System, Respiratory, and Skin. The category ''other'' was added following this measure's adoption. This measure collected data ranging from eight to nine procedural categories while incorporated in the OQR Program.

[315] Centers for Medicare & Medicaid Services (2016). Hospital Outpatient Specifications Manuals version 9.1. Available at: *https://qualitynet.cms.gov/outpatient/specifications-manuals#tab9.*

[316] Saito Y, Tateishi K, Kanda M, et al. (2022). Volume-outcome relationships for percutaneous coronary intervention in acute myocardial infarction. *Journal of the American Heart Association,* 11(6). *https://doi.org/10.1161/jaha.121.023805.*

[317] Vemulapalli S, Carroll J, Mack, M, et al. (2019) Procedural Volume and Outcomes for Transcatheter Aortic-Valve Replacement. *The New England Journal of Medicine,* 380(26), 2541–2550. *https://doi.org/10.1056/NEJMsa1901109.*

[318] Ogola GO, Crandall ML, Richter KM, & Shafi S. (2018). High-volume hospitals are associated with lower mortality among high-risk emergency general surgery patients. *Journal of Trauma and Acute Care Surgery,* 85(3), 560–565. *https://doi.org/10.1097/TA.0000000000001985.*

[319] Vemulapalli S, Carroll J, Mack M, et al. (2019). Procedural Volume and Outcomes for Transcatheter Aortic-Valve Replacement. *The New England Journal of Medicine,* 380(26), 2541–2550. *https://doi.org/10.1056/NEJMsa1901109.*

measure outweighs its value (87 FR 72104 and 72105). Before its removal from the Hospital OQR Program, the HOPD Procedure Volume measure was the only measure that captured facility-level volume within HOPDs and volume for Medicare and non-Medicare patients. As a result, the Hospital OQR Program currently does not capture surgical procedure volume in HOPDs. We recognize that we can determine facility volumes for procedures performed using Medicare Fee-For-Service (FFS) claims. However, the specifications for the HOPD Procedure Volume measure also include reporting data for non-Medicare patients; thus, relying solely on the use of Medicare FFS claims data to simplify reporting would limit a future volume measure to only the Medicare program payer, leading to an incomplete representation of procedural volume.[320]

In addition, in response to our request for comment in the CY 2023 OPPS/ASC proposed rule (87 FR 44730 through 44732), some commenters expressed their belief that volume is not a clear indicator of care quality and therefore procedure volume data would not be useful to consumers (87 FR 72104 and 72105). However, many studies in recent years have shown that volume does serve as an indicator of quality of care.[321] [322] For example, studies published since the CY 2018 OPPS/ASC final rule found that patients at high volume hospitals for a specific procedure had lower rates of surgical site infections, complications, and mortality compared to patients at low-volume hospitals.[323] [324] We reiterate our belief, grounded in this published scientific literature, that volume metrics serve as an indicator of which facilities have experience with certain outpatient procedures and assist consumers in making informed decisions about where they receive care, acknowledging that many studies in recent years have shown that volume does serve as an indicator of quality of care.[325] [326]

(2) Overview of Measure

(a) Data Collection, Submission, Reporting, and Measure Specifications

The HOPD Procedure Volume measure, if re-adopted with the modifications discussed below, would collect data regarding the aggregate count of selected surgical procedures. The most frequent outpatient procedures fall into one of eight categories: Cardiovascular, Eye, Gastrointestinal, Genitourinary, Musculoskeletal, Nervous System, Respiratory, and Skin.[327] Under the proposed measure, data surrounding the top five most frequently performed procedures among HOPDs in each category would be collected and publicly displayed. The top five procedures in each category would be assessed and updated annually as needed to ensure data collection of most accurate and frequently performed procedures.[328]

We also proposed that hospitals would submit aggregate-level data through the CMS web-based tool (currently, the Hospital Quality Reporting (HQR) system), consistent with what was required during the measure's initial adoption (76 FR 74467). Data received through the HQR system would then be publicly displayed on Care Compare or another CMS website. We refer readers to the CY 2009, CY 2014, and CY 2017 OPPS/ASC final rules (73 FR 68777 through 68779, 78 FR 75092, and 81 FR 79791, respectively) for our previously finalized policies regarding public display of quality measures.

In the CY 2024 OPPS/ASC proposed rule (88 FR 49782), we proposed to re-adopt the HOPD Procedure Volume measure with modification, with voluntary reporting beginning with the CY 2025 reporting period and mandatory reporting beginning with the CY 2026 reporting period/CY 2028 payment determination. At the time of this measure's initial adoption in the CY 2012 OPPS/ASC final rule with comment period, (76 FR 74468) we finalized that HOPDs would report all-patient volume data with respect to the eight categories mentioned prior. In response to commenter concerns regarding potential difficulty detecting procedural volume differentiation among these broad-based categories (76 FR 74467), the sole modification to this measure is that instead of collecting and publicly displaying data surrounding these eight broad categories, we would more granularly collect and publicly display data reported for the top five most frequently performed procedures among HOPDs within each category. We refer readers to the Center for Medicare and Medicaid Services Inventory Tool for more information on this measure: *https://cmit.cms.gov/cmit/#/*.

In the CY 2024 OPPS/ASC proposed rule (88 FR 49782), we also proposed that HOPDs submit these data to CMS during the time period of January 1 through May 15 in the year prior to the affected payment determination year. For example, for the CY 2028 payment determination, the data submission period would be January 1, 2027, to May 15, 2027, covering the performance period of January 1, 2026, to December 31, 2026. We refer readers to section XIV.E.5 of this final rule with comment period for a more detailed discussion of the requirements for data submitted via a CMS Web-based tool. We previously codified our existing policies regarding data collection and submission under the Hospital OQR Program at § 419.46.

(b) Review by the Measure Applications Partnership (MAP)

The MAP conditionally supported the HOPD Procedure Volume measure for rulemaking, pending testing indicating that the measure is reliable and valid, and endorsement by the CBE.[329] The MAP acknowledged that the measure reports the volume of procedures performed at HOPDs in select categories reflecting typical high-volume categories of procedures and stated that the measure would capture the volume for many procedures not currently monitored by the Hospital OQR Program measure set. Furthermore, the MAP expressed its belief that measuring the

[320] The specifications for the removed HOPD Procedure Volume measure are available in the Hospital Outpatient Specifications Manuals version 9.1 available at *https://qualitynet.cms.gov/outpatient/specifications-manuals#tab9.*

[321] Ogola, GO, Crandall, ML, Richter, KM, & Shafi, S. (2018). High-volume hospitals are associated with lower mortality among high-risk emergency general surgery patients. *Journal of Trauma and Acute Care Surgery,* 85(3), 560–565. *https://doi.org/10.1097/TA.0000000000001985.*

[322] Vemulapalli S, Carroll J, Mack M, et al. (2019) Procedural Volume and Outcomes for Transcatheter Aortic-Valve Replacement. *The New England Journal of Medicine, 380*(26), 2541–2550. *https://doi.org/10.1056/NEJMsa1901109.*

[323] Mufarrih SH, Ghani MOA, Martins RS, et al. (2019) Effect of hospital volume on outcomes of total hip arthroplasty: a systematic review and metaanalysis. J Orthop Surg Res 14, 468. *https://doi.org/10.1186/s13018-019-1531-0.*

[324] Saito Y, Tateishi K, Kanda M, et al. (2022). Volume-outcome relationships for percutaneous coronary intervention in acute myocardial infarction. *Journal of the American Heart Association, 11*(6). *https://doi.org/10.1161/jaha.121.023805.*

[325] Ogola GO, Crandall ML, Richter KM, Shafi, S. (2018). High-volume hospitals are associated with lower mortality among high-risk emergency general surgery patients. *Journal of Trauma and Acute Care Surgery,* 85(3), 560–565. *https://doi.org/10.1097/TA.0000000000001985.*

[326] Vemulapalli S, Carroll J, Mack M, et al. (2019). Procedural Volume and Outcomes for Transcatheter Aortic-Valve Replacement. *The New England Journal of Medicine,* 380(26), 2541–2550. *https://doi.org/10.1056/NEJMsa1901109.*

[327] Centers for Medicare & Medicaid Services (2016). Hospital Outpatient Specifications Manuals version 9.1. Available at: *https://qualitynet.cms.gov/outpatient/specifications-manuals.*

[328] Data source: Part A and B claims for Outpatient Hospitals for services January 1, 2022–December 31, 2022.

[329] Centers for Medicare & Medicaid Services. Pre-Rulemaking MUC Lists and MAP Reports. The Measures Management System. Available at: *https://mmshub.cms.gov/measure-lifecycle/measure-implementation/pre-rulemaking/lists-and-reports.*

volume of procedures would relate to the program's goals of improving the safety and quality of outpatient procedures in HOPDs.[330] The MAP added that electronic reporting of procedure volumes based on code lists should not be overly burdensome to hospitals, and the public reporting of specific procedure volumes may be useful to patients.[331]

The MAP described that there is a well-established positive correlation between the volume of procedures performed at a facility and the clinical outcomes resulting from that procedure. One systematic review highlighted by the MAP found a significant volume-outcome relationship in the vast majority (87 percent) of the 403 included studies.[332] Furthermore, the MAP included a similar review in their analysis of the HOPD Procedure Volume measure that also focused on outpatient surgeries, which found a significant volume-outcome relationship across eight studies.[333]

The MAP stated that this measure addresses a national trend where even complex surgeries are moving from inpatient to outpatient settings, and that public reporting of this measure could help CMS and the public better understand possible quality differences between settings.[334] The MAP reported that the HOPD Procedure Volume measure data from 2015 and 2016 demonstrates that the number of procedures performed by facilities in the 25th and 75th percentiles varied across the condition categories.[335] These findings support our belief that volume metrics serve as an indicator of which facilities are experienced with certain outpatient procedures and can assist consumers in making informed decisions about where they receive care.[336] [337]

In addition, the MAP noted the concurrent submission of MUC 2022–028: ASC Facility Volume Data on Selected Surgical Procedures for inclusion in the ASCQR Program. The MAP highlighted that the specifications of the volume measure proposal for the ASCQR Program are aligned with the volume measure we proposed for the Hospital OQR Program and, therefore would facilitate comparisons of equivalent procedure volumes across ambulatory surgical centers (ASCs) and HOPDs, one of the key goals of the programs.[338]

(c) Measure Endorsement

As discussed in the previous subsection of this final rule with comment period, the MAP reviewed and conditionally supported the HOPD Procedure Volume measure pending testing indicating the measure is reliable and valid, and endorsement by a national CBE as the measure was not submitted for endorsement. As we noted in previous rulemaking (75 FR 72064), the requirement that measures reflect consensus among affected parties can be achieved in ways other than from endorsement by a national CBE, including the measure development process, broad acceptance of the measure(s), use of the measure(s), and public comment.

We proposed to re-adopt the measure because we did not find any other measures of procedure volume. Additionally, this measure was previously in the Hospital OQR Program with supporters of its use. Given the support from the MAP and feedback from public comment, as well as the increasing shift from inpatient to outpatient surgical procedures and evidence that volume metrics can promote higher quality healthcare for patients, in the CY 2024 OPPS/ASC proposed rule (88 FR 49780 through 49783), we proposed the re-adoption of this measure in the Hospital OQR Program pending endorsement by a national CBE.

We invited public comment on the proposal.

Comment: Several commenters expressed support for our proposal to re-adopt with modification the HOPD Procedure Volume measure beginning with the voluntary CY 2025 reporting period followed by mandatory reporting beginning with the CY 2026 reporting period/CY 2028 payment determination. Some of these commenters expressed that this measure provides valuable insights about quality of care and supports consumer decision-making. These commenters also expressed support for the measure's more granular reporting at the procedure level for the five most frequently occurring procedures in each of the clinical categories. One commenter expressed their support of this measure's likelihood to reduce administrative burden.

Response: We thank the commenters for their support. Although we are not re-adopting the HOPD Procedure Volume measure at this time, we agree that this measure provides valuable insights into care quality and is supportive of consumer decision-making.

Comment: Many commenters did not support our proposal to re-adopt with modification the HOPD Procedure Volume measure. Some of these commenters believe there is a lack of evidence that surgical volume is an indicator of quality, specifically in the outpatient setting, and a few commenters stated that the measure does not align with CMS' Meaningful Measures 2.0 framework for this reason. Furthermore, a few commenters believe that CMS has not provided evidence for a threshold to determine at what particular volume patient outcomes improve for specific procedures. A few commenters expressed concern that procedural volume is impacted by factors outside of the hospital's control. Additionally, a few commenters cited evidence which indicates higher volume for transcatheter aortic valve replacement (TAVR) procedures is not an indicator of superior care quality.[339] [340]

Response: We disagree with commenters that volume cannot serve as an indicator of care quality along with other quality information. We reiterate

[330] Ibid.

[331] Ibid.

[332] Levaillant M, Marcilly R, Levaillant L, et al. (2021). Assessing the hospital volume-outcome relationship in surgery: A scoping review. *BMC Medical Research Methodology,* 21(1). *https://doi.org/10.1186/s12874-021-01396-6.*

[333] Stanak M, & Strohmaier C. (2020). Minimum volume standards in day surgery: A systematic review. *BMC Health Services Research,* 20(1). *https://doi.org/10.1186/s12913-020-05724-2.*

[334] Medicare Payment Advisory Commission. March 2021 Report to the Congress: Medicare Payment Policy. Available at: *https://www.medpac.gov/document/march-2021-report-to-the-congress-medicare-payment-policy/.*

[335] Centers for Medicare & Medicaid Services. Pre-Rulemaking MUC Lists and MAP Reports. The Measures Management System. Available at: *https://mmshub.cms.gov/measure-lifecycle/measure-implementation/pre-rulemaking/lists-and-reports.*

[336] Ogola GO, Crandall ML, Richter KM, & Shafi S. (2018). High-volume hospitals are associated with lower mortality among high-risk emergency general surgery patients. *Journal of Trauma and Acute Care Surgery,* 85(3), 560–565. *https://doi.org/10.1097/TA.0000000000001985.*

[337] Saito Y, Tateishi K, Kanda M, et al. (2022). Volume-outcome relationships for percutaneous coronary intervention in acute myocardial infarction. *Journal of the American Heart Association,* 11(6). *https://doi.org/10.1161/jaha.121.023805.*

[338] Centers for Medicare & Medicaid Services. Pre-Rulemaking MUC Lists and MAP Reports. The Measures Management System. Available at: *https://mmshub.cms.gov/measure-lifecycle/measure-implementation/pre-rulemaking/lists-and-reports.*

[339] Nelson AJ, Wegermann ZK, Gallup D, et al. Modeling the Association of Volume vs Composite Outcome Thresholds With Outcomes and Access to Transcatheter Aortic Valve Implantation in the US. JAMA Cardiol. 2023;8(5):492–502. *https://doi.org/10.1001/jamacardio.2023.0477.*

[340] Russo MJ, McCabe JM, Thourani VH, et al. Case Volume and Outcomes After TAVR With Balloon-Expandable Prostheses: Insights From TVT Registry. J Am Coll Cardiol. 2019;73(4):427–440. Available at: *https://doi.org/10.1016/j.jacc.2018.11.031.*

that recently published scientific literature supports the position that volume metrics can serve as an indicator of quality, denoting which facilities have experience with certain outpatient procedures and assist consumers in making informed decisions about where they receive care. Furthermore, a study found that congestive heart failure (CHF) patients who stayed in hospitals with more experience in managing CHF received higher quality care and experienced better outcomes.[341] Referencing commenter concern of a lack of evidence that surgical volume is an indicator of quality, specifically in the outpatient setting, in the CY 2024 OPPS/ASC proposed rule (88 FR 49782), we cited one study which found that patients who had total hip arthroplasties performed at high-volume hospitals had lower rates of surgical site infections, complications, and mortality compared to patients at low-volume hospitals.[342] Although we are not re-adopting the HOPD Procedure Volume measure at this time for the reasons discussed below, we will continue to assess the evidence linking volume to quality of care to ensure alignment with the Meaningful Measures 2.0 Framework goal to use ''only high-quality measures impacting key quality domains.''

With respect to the determination of volume thresholds indicating improved outcomes, while the scientific literature points to an association between volume and outcomes, we do not intend to designate volume thresholds indicating proven desired outcomes. We believe it is important for patients to have the ability to access information that can inform their decision-making when choosing a hospital. Furthermore, we acknowledge that procedural volume can be impacted by factors outside of the hospital's control. We want to provide transparency to patients and consumers with respect to volume, in the case that it helps inform patient decision-making.

We acknowledge the publication of recent research indicating that when patients were treated in high-volume hospitals versus those with best historical outcomes, there was no significant reduction in observed versus modeled adverse events.[343] [344] We believe these recent studies indicate that hospital variation in care metrics is important, but that it does not discount the conclusions of the studies mentioned above or address instances where facility volume is low. Given the potential association between volume and outcomes, we believe volume information can be useful to patients and consumers. Although we are not re-adopting the HOPD Procedure Volume measure at this time, given that there is a potential association between volume and outcome, we believe this measure provides transparency, including information about volume that may be informative to patients.

Comment: Some commenters did not support our proposal because the HOPD Procedure Volume measure was previously removed from the Hospital OQR Program measure set due to CMS' stated belief at that time that there is a lack of evidence to support this measure's link to improved clinical quality.

Response: When we removed the HOPD Procedure Volume measure from the Hospital OQR Program measure set in the CY 2018 OPPS/ASC final rule with comment period, we stated our belief at the time that performance or improvement on this measure did not result in better patient outcomes (82 FR 59429). This belief was due to the lack of evidence supporting the measure's link to improved clinical quality at the time the CY 2018 OPPS/ASC final rule (82 FR 59429) with comment period was published. As discussed in the CY 2024 OPPS/ASC proposed rule (88 FR 49781), since the measure removal, scientific literature shows that volume metrics can serve as an indicator of which facilities are experienced with certain outpatient procedures and can assist consumers in making informed decisions. More recent literature supports the use of volume as a quality-of-care indicator and we continue to believe that this information can be of benefit to Medicare beneficiaries and other consumers, especially when case volume is low. Therefore, although we are not re-adopting the HOPD Procedure Volume measure at this time, we recognize the increasing importance of volume in the HOPD setting.

Comment: Many commenters did not support our proposal because they stated that they believe the potential administrative burden of the HOPD Procedure Volume measure outweighs its potential value.

Response: The MAP noted that electronic reporting of procedure volumes based on code lists should not be overly burdensome to hospitals, and the public reporting of specific procedure volumes may be useful to patients. Furthermore, our estimates of burden indicate that each participating hospital would spend 10 minutes per year to submit the data for this measure to CMS, as noted in section XXIV.B.7 of this final rule with comment period. Although we are not re-adopting the HOPD Procedure Volume measure at this time, we believe these collection efforts would not impose undue burden on hospitals.

In addition, this measure would further advance CMS' goal of transitioning to a fully digital quality measurement landscape and promoting interoperability while helping to decrease reporting burden in the long-term. We therefore believe that the value of the measure would outweigh potential reporting burden.

Comment: A few commenters did not support our proposal because they believe adoption of the HOPD Procedure Volume measure would drive business away from high-risk public hospitals or rural care.

Response: Although we are not re-adopting the HOPD Procedure Volume measure at this time, we do not agree with the commenters' concern that public reporting of procedure volume would affect providers' business. We have not found, to date, that public reporting associated with this measure affects hospitals' service lines in any significant way. For this measure, only aggregate data is reported. We do not intend to include any qualifiers with publicly displayed data. We believe this measure provides transparency to patients, including information about volume that may be informative to patients.

Comment: Several commenters did not support our proposal because they believe the HOPD Procedure Volume measure would lead to potential misuse through ''perverse incentives'' for providers to perform non-indicated procedures to increase procedural volume.

Response: We disagree that the volume measure creates an incentive for providers to perform non-indicated procedures. The HOPD Procedure

[341] Joynt, K.E., Orav, E.J., & Jha, A.K. (2011). The association between hospital volume and processes, outcomes, and costs of care for congestive heart failure. Annals of internal medicine, 154(2), 94–102. *https://doi.org/10.7326/0003-4819-154-2-201101180-00008.*

[342] Mufarrih, S.H., Ghani, M.O.A., Martins, R.S. et al. Effect of hospital volume on outcomes of total hip arthroplasty: a systematic review and metaanalysis. J Orthop Surg Res 14, 468 (2019). Available at: *https://doi.org/10.1186/s13018-019-1531-0.*

[343] Nelson AJ, Wegermann ZK, Gallup D, et al. Modeling the Association of Volume vs Composite Outcome Thresholds With Outcomes and Access to Transcatheter Aortic Valve Implantation in the US. JAMA Cardiol. 2023;8(5):492–502. *https://doi.org/10.1001/jamacardio.2023.0477.*

[344] Russo MJ, McCabe JM, Thourani VH, et al. Case Volume and Outcomes After TAVR With Balloon-Expandable Prostheses: Insights From TVT Registry. J Am Coll Cardiol. 2019;73(4):427–440. Available at: *https://doi.org/10.1016/j.jacc.2018.11.031.*

Volume measure tracks the top five procedures performed in the outpatient setting using CPT codes. The procedures posted by volume change yearly; thus, the volume measure could not lead to potential misuse through ''perverse incentives'' for providers to perform non-indicated procedures to increase procedural volume. Furthermore, we did not identify significant changes in reported volume information that would indicate this measure engendered ''perverse incentives'' for providers to perform non-indicated procedures simply to increase reported numbers of procedures.

Comment: Several commenters did not support our proposal to adopt with modification the HOPD Procedure Volume measure because they believe volume data will be confusing to Medicare patients. Commenters explained their belief that such data are limited in value due to lack of context related to the clinical appropriateness of the procedure for each specific patient as well as the risk profile for the volume of patients. Commenters added that the measure does not provide context related to overall procedural outcomes.

Response: We disagree with the commenter's assertion that volume data will be confusing to Medicare patients. As we explained in the CY 2024 OPPS/ASC proposed rule (88 FR 49782), if the proposal was adopted in future rulemaking, we intended to publish the measure's results on the Care Compare website, which is designed to be a consumer-friendly portal for quality information on Medicare providers. We interpret commenters' concern about the clinical appropriateness of the procedure for each specific patient to indicate concern that the volume measure's calculation may appear to be inflated by medically unnecessary procedures. We disagree with this concern. We believe the HOPD Procedure Volume measure provides fundamental information to patients about the frequency with which a procedure is performed in a given HOPD. We do not believe that this information is harmful for patients, and we believe strongly that equipping patients with as much meaningful information as possible about their care builds a stronger health care system. We also do not agree that the measure lacks risk profile context. As we stated in the CY 2024 OPPS/ASC proposed rule (88 FR 49781), volume metrics serve as an indicator of which facilities have experience with certain outpatient procedures, likely leading to higher quality outcomes, and assist consumers in making informed decisions about where they receive care. We do agree that other dimensions of quality are also important to patients' outcomes in the hospital outpatient department, but we believe that the information provided through the HOPD Procedure Volume measure results provides transparency into volume as a dimension of quality, which may be informative to patients. The HOPD Procedure Volume measure is intended to be one of many metrics for determining care.

Although we are not re-adopting the HOPD Procedure Volume measure at this time, we continue to believe there is significant evidence linking volume to quality of care, and that volume metrics serve as an indicator of which facilities have experience with certain outpatient procedures and can assist consumers in making informed decisions about where they receive care. Based on comments received, we intend to reassess the measure's methodology and reconsider how the data may be publicly displayed in the most meaningful manner for consumers.

Comment: A few commenters did not support our proposal to adopt the HOPD Procedure Volume measure over challenges related to reporting volume by procedure type. One commenter raised concern over a lack of consistency in data obtained, as the measure assesses the top five most frequently performed surgical procedures, which will change from year to year. One commenter raised concern over many services and diagnoses distributed over large groups of procedures or diagnostic codes, so even if a facility regularly performs a service, a volume measure may incorrectly identify it as having little to no experience if no single code exceeds a minimum threshold. One commenter expressed concern, stating CMS only has access to Medicare/Medicaid claims populations, which will likely result in skewed data for surgical procedure volumes and outcomes. One commenter expressed that it is unclear how the measure provides meaningful information for all patients when the categories, as well as the top five procedures per category, are based upon Medicare FFS frequency and not frequency across all patients and payers. This commenter added that when utilizing claims data, reporting is delayed, making it challenging for hospitals to identify gaps and improve performance. Another commenter expressed that CMS already has access to this data through claims.

Response: To address commenter concerns over a lack of consistency in procedural data obtained year to year, we reiterate that the top five procedures in each category would be assessed and updated annually to ensure accurate data collection of the most frequently performed procedures. Instead of tracking a fixed list of a greater number of procedures, we intended to choose the methodology of tracking the top five procedures in each category to decrease reporting burden while maximizing the usefulness of the reported data. Responding to commenter's concerns over the distribution of services over large groups of procedural codes, our method is applied consistently across all medical providers. As such, all medical providers are equally likely to have procedural volume distributed over a large number of procedural codes. For this reason, this measure groups some procedural codes together within specific procedure categories.[345] We reiterate that the proposal is not being finalized for CY 2024. We will further consider this concern in future rulemaking.

We acknowledge that relying solely on the use of Medicare FFS claims data to simplify reporting would limit the measure to only this payer, which may bias the data, misrepresenting the volume of procedures performed at a given HOPD. As we note in section XIV.B.3.a(1) of this final rule with comment period, the specifications for the HOPD Procedure Volume measure include reporting data for non-Medicare patients. We would like to clarify that hospital procedural volume submitted to the CMS web-based tool would be determined by CPT codes rather than Medicare and Medicaid claims. The chosen categories and top five procedures within each category are intended to be informed by recent Medicare claims because we believe they likely mirror procedural trends in non-Medicare populations. We would like to further investigate procedural frequency trends which may mirror that of non-Medicare populations by including both FFS and Medicare Advantage data when evaluating categories and most frequently performed procedures. We are concerned that not including Medicare Advantage data in our sampling estimates could potentially imperil their accuracy, particularly as these measures are meant to show procedure volume for all patients. We intend to address this measurement subject in the future after determining the best way to accurately predict which reporting categories would be most useful to hospitals, as

[345] The specifications for the removed HOPD Procedure Volume measure are available in the Hospital Outpatient Specifications Manuals version 9.1 available at *https://qualitynet.cms.gov/outpatient/specifications-manuals#tab9.*

well as the top five most frequently performed procedures in each category.

Comment: A few commenters did not support our proposal to re-adopt with modification the HOPD Procedure Volume measure because it is not CBE endorsed. These commenters raised concern over the measure's lack of validity and reliability testing.

Response: As we noted in the CY 2011 OPPS/ASC final rule with comment period (75 FR 72064), the requirement that measures reflect consensus among affected parties can be achieved in ways other than from endorsement by a national consensus-based entity, including the measure development process, broad acceptance of the measure(s), use of the measure(s), and public comment. While the HOPD Procedure Volume measure is not CBE-endorsed, we believe this measure reflects consensus among affected parties, because the CBE, which represents interested parties, reviews and conditionally supported the measure for use in the Hospital OQR Program.

Comment: A few commenters expressed concern that if this measure is adopted into the Hospital OQR Program, it could be used in the calculation of Star Rating performance. One commenter noted the importance of lower-volume sites in providing services to underserved populations, such as Black, Hispanic, and rural patients. Another commenter raised concern that the cardiovascular procedure studies cited by CMS are outdated or inapplicable to their patient population.

Response: We acknowledge the commenter's concern over the HOPD Procedure Volume measure being used in the calculation of Star Rating performance. We reiterate that we are not finalizing our proposal to adopt this measure currently and there are currently no plans to include this measure in Star Rating calculations. Furthermore, we agree with the importance of lower-volume sites in providing services to patients, including historically underserved populations and will keep this in consideration if we re-propose this measure in the future.

We respectfully disagree that the studies cited in the CY 2024 OPPS/ASC proposed rule are outdated or inapplicable. One cardiovascular study (Saito et al. 2022) was published within the past two years and adequately shows that volume at hospitals for this procedure was inversely associated with in-hospital mortality. We would like to reiterate our belief, given the potential association between volume and outcome, that it is our duty to provide transparency to patients, rather than withhold information that may be informative.

Comment: Many commenters provided recommendations in response to our proposal to re-adopt with modification the HOPD Procedure Volume measure. A few commenters recommended that CMS work with interested parties to identify additional measures that would be useful or complementary in evaluating the shift in procedures from inpatient to outpatient setting that would be an appropriate indicator of quality of care. A few commenters recommended adoption of a quality metric that addresses equity, low-value procedures, or prevention of ambulatory care sensitive conditions that are known to result in inpatient utilization instead of the HOPD Procedure Volume measure. Furthermore, a few commenters recommended reporting all procedures in a specific category, rather than the top five performed annually. Another commenter recommended a phased-in approach, where we gradually introduce new procedure reporting categories each year. One commenter recommended only confidential-level feedback than publicly reporting this data and tying it to payment. One commenter recommended delaying re-adoption of the Volume Indicator measure in favor of more targeted quality metrics that do not discourage patients from seeking new and innovative procedures.

Response: We thank commenters for these recommendations. We agree that collaboration with interested parties, attention to advancing health equity, and refining measure specifications are important when identifying useful measures for evaluating the shift in procedures from the inpatient to outpatient setting, and will consider these recommendations in future rulemaking. We would like to clarify that the OQR Program is a pay-for-reporting program and not a value-based payment program.

After consideration of the public comments we received, we are not finalizing our proposal to re-adopt with modification the Hospital Outpatient Department Volume Data on Selected Outpatient Surgical Procedures measure beginning with the voluntary CY 2025 reporting period followed by mandatory reporting beginning with the CY 2026 reporting period/CY 2028 payment determination. We will not finalize this measure at this time, as we would like to investigate procedural frequency trends which may mirror that of non-Medicare populations by conducting analysis that includes FFS and Medicare Advantage data when evaluating categories and the most frequently performed procedures. Based on comments received, we are reassessing the measure's methodology and reconsidering how the data may be publicly displayed. We continue to believe there is significant evidence linking volume to quality of care, and that volume serves as an indicator of which facilities have experience with certain outpatient procedures and can assist consumers in making informed decisions about where they receive care. We also refer readers to the discussion of a similar proposal for the same measure as used in the ASCQR Program in section XV.B.5.a of this final rule with comment period.

b. Adoption of the Risk-Standardized Patient-Reported Outcome-Based Performance Measure (PRO–PM) Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA) in the HOPD Setting (THA/TKA PRO–PM) Beginning With Voluntary CYs 2025 and 2026 Reporting Periods Followed by Mandatory Reporting Beginning With the CY 2027 Reporting Period/CY 2030 Payment Determination

(1) Background

In the FY 2023 IPPS/LTCH PPS final rule (87 FR 49246 through 49257), we adopted the THA/TKA PRO–PM in the Hospital Inpatient Quality Reporting (IQR) Program beginning with voluntary reporting periods in CY 2025 and 2026,[346] followed by mandatory reporting for eligible elective procedures occurring July 1, 2024, through June 30, 2025, for the FY 2028 payment determination. In the CY 2024 OPPS/ASC proposed rule (88 FR 49783 through 49787), we proposed the adoption of the THA/TKA PRO–PM into the Hospital OQR Program using the same specifications as finalized for the hospital-level measure adopted into the Hospital IQR Program (87 FR 49246 through 49257), with modifications to include procedures performed in the HOPD setting.

Approximately 6 million adults aged 65 or older suffer from osteoarthritis in the United States.[347] In 2013, there were approximately 568,000 hospitalizations

[346] In the CY 2024 OPPS/ASC proposed rule (88 FR 49813 and 49814), we stated these reporting periods as FY. The IQR voluntary reporting periods for the THA/TKA PRO–PM are October 23, 2022, through June 30, 2023, for 2025 voluntary reporting and April 2, 2023, through June 30, 2024, for 2026 voluntary reporting.

[347] Arthritis Foundation (2018). Arthritis By the Numbers Book of Trusted Facts and Figures. Accessed March 8, 2019. Available at: *https://www.arthritis.org/getmedia/e1256607-fa87-4593-aa8a-8db4f291072a/2019-abtn-final-march2019.pdf.*

billed to Medicare for osteoarthritis.[348] Hip and knee osteoarthritis is one of the leading causes of disability among non-institutionalized adults,[349] [350] and roughly 80 percent of patients with osteoarthritis have some limitation in mobility.[351] [352] Elective THA and TKA are most commonly performed for degenerative joint disease or osteoarthritis, which affects more than 30 million Americans.[353] THA and TKA offer the potential for significant improvement in quality of life by decreasing pain and improving function in a majority of patients, without resulting in a high risk of complications or death.[354] [355] [356] However, not all patients experience benefit from these procedures.[357] Many patients note that their pre-operative expectations for functional improvement have not been met.[358] [359] [360] [361] In addition, clinical practice variation has been well documented in the United States,[362] [363] [364] [365] [366] readmission and complication rates vary across hospitals,[367] and international experience documents wide hospital-level variation in patient-reported outcome measure results following THA and TKA.[368]

Due to the absence of recently conducted large scale and uniformly collected patient-reported outcome (PRO) data available from patients undergoing elective primary THA/TKA, we established an incentivized, voluntary PRO data collection opportunity within the Comprehensive Care for Joint Replacement (CJR) model to support measure development.[369] Elective THA/TKAs are important, effective procedures performed on a broad population, and the patient outcomes for these procedures (such as pain, mobility, and quality of life) can be measured in a scientifically sound way,[370] [371] are influenced by a range of improvements in care,[372] and demonstrate hospital-level variation even after patient case mix adjustment.[373] [374] Further, THA/TKA procedures are specifically intended to improve function and reduce pain, making PROs a meaningful outcome metric to assess.[375]

In the CY 2021 OPPS/ASC final rule (85 FR 86146), we announced that THA and TKA procedures were removed from the Inpatient Only Procedures (IPO) list and added to the ASC covered procedures list (CPL).[376] As a result, the volume of THA and TKA procedures for Medicare beneficiaries aged 65 years and older have been increasing in outpatient settings.

We analyzed Part B Medicare FFS claims data for the number of HOPD claims with THA/TKA procedures during CY 2020, 2021, and 2022 (Table 127).

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[376] Centers for Medicare & Medicaid Services. Ambulatory Surgical Center (ASC) Payment. Available at: *https://www.cms.gov/medicare/medicare-fee-for-service-payment/ascpayment.*

TABLE 127: DISTRIBUTION OF TOTAL HIP ARTHROPLASTY (THA) AND TOTAL KNEE ARTHROPLASTY (TKA) CLAIMS PER OUTPATIENT HOSPITAL CY 2020-2021

CY Year	CPT	CPT Description	#HOPDs with THA/TKA Claims	Median # of Claims	Mean # of Claims	Std Dev	Min	Max
2020	27130	ARTHRP ACETBLR/PROX FEM PROSTC AGRFT/ALGRFT	2341	13	30.26	43.81	1	394
2020	27447	ARTHRP KNE CONDYLE&PLATU MEDIAL&LAT COMPARTMENTS	2668	23	49.57	68.65	1	644
2020	27130 and 27447	All THA/TKA	2753	31	73.77	106.50	1	978

CY	CPT	CPT Description	#HOPDs with THA/TKA Claims	Median # of Claims	Mean # of Claims	Std Dev	Min	Max
2021	27130	ARTHRP ACETBLR/PROX FEM PROSTC AGRFT/ALGRFT	2619	18	37.80	53.19	1	540
2021	27447	ARTHRP KNE CONDYLE&PLATU MEDIAL&LAT COMPARTMENTS	2901	30	60.75	86.08	1	1259
2021	27130 and 27447	All THA/TKA	2961	43	92.95	133.68	1	1400

TABLE 127: DISTRIBUTION OF TOTAL HIP ARTHROPLASTY (THA) AND TOTAL KNEE ARTHROPLASTY (TKA) CLAIMS PER OUTPATIENT HOSPITAL CY 2020-2021

CY Year	CPT	CPT Description	#HOPDs with THA/TKA Claims	Median # of Claims	Mean # of Claims	Std Dev	Min	Max
CY	CPT	CPT Description	#HOPDs with THA/TKA Claims	Median # of Claims	Mean # of Claims	Std Dev	Min	Max
2022	27130	ARTHRP ACETBLR/PROX FEM PROSTC AGRFT/ALGRFT	2756	21	42.09	63.69	1	1447
2022	27447	ARTHRP KNE CONDYLE&PLATU MEDIAL&LAT COMPARTMENTS	3001	36	70.24	98.70	1	1625
2022	27130 and 27447	All THA/TKA	3070	51	106.45	157.11	1	3072

Data source: Part B outpatient claims January 1, 2020 - December 31, 2022, with a CPT code of 27130 or 27447. Claims indicating an ED visit are excluded.

In CY 2022 OPPS/ASC proposed rule (86 FR 42251 and 42252), we requested comment on the potential future adoption of the THA/TKA PRO–PM into the Hospital OQR Program. We refer readers to the CY 2022 OPPS/ASC final rule (86 FR 63851 through 63854) for a complete summary of feedback from interested parties.

Many commenters supported inclusion of the THA/TKA PRO–PM to the Hospital OQR Program as procedures move from inpatient to outpatient settings. Commenters noted it was important to monitor quality outcomes and publicly report results. Additionally, commenters stated that the measure is aligned with patient values, being presented in a manner that is easy to understand.

Other commenters did not support expansion of the measure to the Hospital OQR Program, and expressed concern with data collection burden, patient survey fatigue, and reporting thresholds. In response, we stated that while we recognize that PRO–PMs require providers to integrate data collection into clinical workflows, this integration provides opportunity for PROs to inform clinical decision-making and benefits patients by engaging them in discussions about potential outcomes. Furthermore, we did not expect this measure to contribute to survey fatigue as the PRO instruments used to calculate pre- and post-operative scores for this THA/TKA PRO–PM were carefully selected, with extensive input from interested parties, to be low burden for patients. We refer readers to the CY 2022 OPPS/ASC final with comment period (86 FR 63851 through 63854) for a complete summary of feedback.

In the CY 2024 OPPS/ASC proposed rule (88 FR 49785), we proposed to adopt the THA/TKA PRO–PM into the

Hospital OQR Program beginning with two voluntary reporting periods, followed by mandatory reporting. The first voluntary reporting period would begin with the CY 2025 reporting period for eligible elective outpatient procedures between January 1, 2025, through December 31, 2025, and the second would begin with the CY 2026 reporting period for eligible elective outpatient procedures between January 1, 2026, through December 31, 2026. Mandatory reporting would begin with the CY 2027 reporting period/CY 2030 payment determination for eligible elective outpatient procedures occurring January 1, 2027, through December 31, 2027, impacting the CY 2030 payment determination and subsequent years. Because the proposed measure required collection of data during the 3-month pre-operative period and the greater than 1-year post-operative period, there would be a delay between when the elective THA/TKA procedures actually occur, when the results would be reported under the Hospital OQR Program, and when payment determinations occur. Therefore, we proposed a 3-year gap between the reporting period and the payment determination year (for example, CY 2027 reporting period for the CY 2030 payment determination) for the Hospital OQR Program. We refer readers to section XIV.E.7.a of this final rule with comment period for more information on the reporting requirements.

(2) Overview of Measure

(a) Data Collection, Submission, Reporting, and Measure Specifications

This measure reports the facility-level risk-standardized improvement rate (RSIR) in PROs following elective primary THA/TKA for Medicare FFS beneficiaries aged 65 years and older who were enrolled in Medicare FFS Part A and B for the 12 months prior to the date of the procedure and in Medicare Part A and B during the procedure. The measure includes only elective primary outpatient THA/TKA procedures (patients with fractures and revisions are not included) performed in HOPDs and does not include any inpatient procedures. The measure excludes patients with staged procedures (multiple elective primary THA or TKA procedures performed on the same patient during distinct encounter) that occur during the measurement period and excludes discontinued procedures (that is, procedures that were started but not completed).[377]

Substantial clinical improvement is measured by achieving a pre-defined improvement in score on one of the two validated joint-specific PRO instruments measuring hip or knee pain and functioning: (1) The Hip dysfunction and Osteoarthritis Outcome Score for Joint Replacement (HOOS, JR) for completion by THA recipients; or (2) the Knee injury and Osteoarthritis Outcome Score for Joint Replacement (KOOS, JR) for completion by TKA recipients. Improvement is measured from the pre-operative assessment (data collected 90 to 0 days before surgery) to the post-operative assessment (data collected 300 to 425 days following surgery). Improvement scores are risk-adjusted to account for differences in patient case-mix. The measure, if adopted into the Hospital OQR Program as proposed, would account for potential non-response bias through inverse probability weighting based on likelihood of response.

We refer readers to the FY 2023 IPPS/LTCH PPS final rule (87 FR 49246 through 49257), for more information on the development of the hospital-level THA/TKA PRO–PM, including background on the measure and a complete summary of measure specifications, data sources, and measure calculation.

For additional details regarding the measure specifications, we also refer readers to the Hip and Knee Arthroplasty Patient-Reported Outcomes file, available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.*

(i) Data Sources

The THA/TKA PRO–PM uses four sources of data for the calculation of the measure: (1) PRO data; (2) claims data; (3) Medicare enrollment and beneficiary data; and (4) U.S. Census Bureau survey data. As described in section XIV.B.3.b(1) of this final rule with comment period, the measure uses PRO data directly reported by the patient regarding their health, quality of life, or functional status associated with health care or treatment. These patient-reported data are collected by facilities pre-operatively and post-operatively, and limited patient-level risk factor data are collected with PRO data and identified in claims as detailed in this section of this final rule with comment period.[378] The measure includes PRO data collected with the PRO instruments described in this section of this final rule with comment period, including two joint-specific PRO instruments—the HOOS, JR for completion by THA recipients and the KOOS, JR for completion by TKA recipients—from which scores are used to assess substantial clinical improvement. For risk-adjustment by pre-operative mental health score, HOPDs would submit one of two additional PRO instruments: (1) Patient-Reported Outcomes Measurement Information System (PROMIS)-Global Mental Health subscale; or (2) Veterans RAND 12-Item Health Survey (VR–12) Mental Health subscale. The risk model also includes a one-question patient-reported assessment of health literacy—the Single Item Literacy Screener questionnaire.

Furthermore, the following data would be collected for identification of the measure cohort, for risk-adjustment purposes, and for the statistical approach to potential non-response bias. Claims data billed under OPPS would be used to identify eligible elective primary outpatient THA/TKA procedures for the measure cohort to which submitted PRO data can be matched, and to identify additional variables for risk-adjustment and in the statistical approach to account for response bias, including patient demographics and clinical co-morbidities up to 12 months prior to surgery. The Medicare Enrollment Database (EDB) identifies Medicare FFS enrollment and patient-identified race, and the Master Beneficiary Summary File allows for determination of Medicare and Medicaid dual eligibility enrollment status. Demographic information from the U.S. Census Bureau's American Community Survey allows for derivation of the Agency for Healthcare Research and Quality (AHRQ) Socioeconomic Status (SES) Index score. Race, dual eligibility, and AHRQ SES Index score are used in the statistical approach to account for potential non-response bias in the outcome calculation. We refer readers to section XIV.B.3.b(2)(a)(iii) of this final rule with comment period for further details regarding the variables required for data collection and submission.

(ii) Measure Calculation

The HOPD facility-level THA/TKA PRO–PM result would be calculated by

[377] U.S. Department of Health and Human Services (2021). Hospital Outpatient Prospective Payment System (OPPS): Use of Modifiers –52, –73, and –74 for Reduced or Discontinued Services. Available at: *https://www.hhs.gov/guidance/document/hospital-outpatient-prospective-payment-system-opps-use-modifiers-52-73-and-74-reduced-or.*

[378] Higgins JP, Thomas J, Chandler J, et al. (2019). *Cochrane handbook for systematic reviews of interventions.* John Wiley & Sons. *https://doi.org/10.1002/9781119536604.*

aggregating all patient-level results across the facility. This measure would be calculated and presented as a RSIR, producing a performance measure per facility which accounts for patient case-mix, addresses potential non-response bias, and represents a measure of quality of care following elective primary outpatient THA/TKA. Response rates for PRO data would be calculated as the percentage of elective primary THA or TKA procedures performed at HOPDs for which complete and matched pre- and post-operative PRO data have been submitted, divided by the total number of eligible THA or TKA procedures performed at each facility.

(iii) Data Submission and Reporting

In response to feedback received from interested parties in the requests for comments (RFCs) on this measure in the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 25588 through 25592) (as summarized in the FY 2022 IPPS/LTCH PPS final rule (86 FR 45408 through 45414)) and the CY 2022 OPPS/ASC proposed rule (FR 86 42251 and 42252), and as discussed in the Hospital IQR Program in the FY 2023 IPPS/LTCH PPS final rule (87 FR 49246 through 49257), we proposed to adopt the THA/TKA PRO–PM in the Hospital OQR Program utilizing flexible data submission approaches.

Under the proposal, HOPDs would submit the following variables collected pre-operatively between 90 and zero days prior to the THA/TKA procedure for each patient: Medicare provider number; Medicare health insurance claim (HIC) number/Medicare beneficiary identifier (MBI); date of birth; date of procedure; date of PRO data collection; procedure type; mode of collection; person completing the survey; facility admission date; patient reported outcome measure version; PROMIS Global (mental health subscale items) or VR–12 (mental health subscale items); HOOS, JR (for THA patients) or KOOS, JR (for TKA patients); Single-Item Health Literacy Screening (SILS2) questionnaire; BMI or weight (kg)/height (cm); chronic (≥90 day) narcotic use; total painful joint count (patient reported in non-operative lower extremity joint); and quantified spinal pain (patient-reported back pain, Oswestry index question.[379] [380])

Under the proposal, HOPDs would also submit the following variables collected post-operatively between 300 and 425 days following the THA/TKA procedure for each patient: Medicare provider number; Medicare HIC number/MBI; date of birth; procedure date, date of PRO data collection; procedure type; mode of collection; person completing the survey; facility admission date; KOOS, JR (TKA patients) or HOOS, JR (THA patients). The data submission period for the THA/TKA PRO–PM would also serve as the review and correction period, and there would be no opportunity to correct the data following the submission deadline.

In the CY 2024 OPPS/ASC proposed rule (88 FR 49787), following the two voluntary reporting periods, we proposed mandatory reporting of the THA/TKA PRO–PM beginning with the CY 2027 reporting period/CY 2030 payment determination. Under the proposal, for each voluntary and subsequent mandatory reporting period, we would collect data on the THA/TKA PRO–PM in accordance with the Health Insurance Portability and Accountability Act of 1996 (HIPAA), Privacy and Security Rules (45 CFR parts 160 and 164, subparts A, C, and E), and other applicable law.

(b) Review by Measure Applications Partnership (MAP)

We included the THA/TKA PRO–PM for the Hospital OQR in the publicly available ''2022 Measures Under Consideration List'' (MUC 2022–026).[381] The MAP Coordinating Committee supported the measure, as referenced in the 2022–2023 Final Recommendations report to HHS and CMS.[382]

The MAP members noted that a similar version of this measure has been adopted for use in the Hospital IQR Program, however, there currently is no measure that assesses PROs among THA/TKA patients in HOPDs for the Hospital OQR Program. The MAP highlighted that the key strategy for the Hospital OQR Program is to ensure that procedures done in any type of facility, including HOPDs, have equivalent quality. As such, the MAP members agreed that measures of quality of procedures in hospital settings should extend to HOPDs, to the extent feasible and appropriate, so that consumers can compare quality of a specific procedure across different facility types.[383]

In addition, the MAP members stated that the goal of the PRO–PM is to capture the full spectrum of care to incentivize collaboration and shared responsibility for improving patient health and reducing the burden of their disease. They agreed that this measure aligns with the goal of patient-centered approaches to health care quality improvement and addresses the high priority areas of patient and family engagement and communication/care coordination for the Hospital OQR Program.[384]

(c) Measure Endorsement

The CBE endorsed the hospital-level version of the THA/TKA PRO–PM (CBE #3559) in November 2020.[385] We note that the HOPD version of the THA/TKA PRO–PM would use the same specifications as the CBE-endorsed hospital-level THA/TKA PRO–PM that is currently implemented in the Hospital IQR program with modifications to capture procedures for the HOPDs. We intend to seek CBE endorsement for the HOPD version of the THA/TKA PRO–PM in a future measure endorsement cycle.

We have noted in previous rulemaking (75 FR 72064) the requirement that measures reflect consensus among affected parties can be achieved in other ways aside from CBE endorsement, including through the measure development process, through broad acceptance, use of the measure(s), and through public comment. In the CY 2024 OPPS/ASC proposed rule (88 FR 49787), we proposed this measure without CBE endorsement based upon strong MAP and public support combined with the importance of the measure for Medicare beneficiaries. In addition, there are two existing, CBE-endorsed versions of this measure, one at the clinician-group level (CBE #3639) and one for the hospital level (CBE #3559). We expect that the measure will perform similarly in the HOPD setting, and we intend on submitting the measures for CBE endorsement following data collection during voluntary reporting.

We refer readers to section XIV.E.7.a of this final rule with comment period for a discussion on the THA/TKA PRO–PM form, manner, and timing submission requirements.

We invited public comment on the proposal.

[379] Fairbank JC & Pynsent PB (2000). The Oswestry Disability Index. *Spine.* 25(22), 2940–52. *https://doi.org/10.1097/00007632-200011150-00017.*

[380] The Oswestry Disability Index is in the public domain and available for all hospitals to use.

[381] Centers for Medicare & Medicaid Services. 2022 Measures Under Consideration List. Available at: *https://mmshub.cms.gov/sites/default/files/2022-MUC-List.xlsx.*

[382] MAP MUC Preliminary Recommendations 2022–2023. Available at *https://mmshub.cms.gov/sites/default/files/2022-2023-MAP-Final-Recommendations-508.xlsx.*

[383] Ibid.

[384] Ibid.

[385] Centers for Medicaid & Medicare Services. Hospital-Level, Risk-Standardized Improvement Rate in Patient-Reported Outcomes Following Elective Primary Total Hip and/or Total Knee Arthroplasty (THA/TKA). Available at: *https://cmit.cms.gov/cmit/#/FamilyView?familyId=1618.*

Comment: Several commenters supported the use of the THA/TKA PRO–PM in the Hospital OQR Program, as well as general support for PRO–PMs in CMS quality programs that are valid, reliable, and capable of informing performance improvement.

Response: We thank commenters for their support of the THA/TKA PRO–PM for the Hospital OQR Program.

Comment: Many commenters expressed support for this measure, but recommended changes to the proposed voluntary and mandatory reporting timelines for the THA/TKA PRO–PM adoption into the Hospital OQR Program. A few commenters suggested that CMS extend the voluntary reporting timelines to support hospitals' learning and their incorporation of this PRO–PM into their workflows, and to support patients in making informed care decisions based on quality. One commenter suggested a partial year reporting before an entire year reporting requirement is instituted and suggested four years of voluntary reporting. One commenter suggested a delay of reporting timelines by a year. One commenter supported the proposed voluntary and mandatory reporting timelines but urged CMS to consider adjusting the HOPD reporting and submission deadlines to align with inpatient requirements adopted in the FY 2023 IPPS/LTCH PPS final rule (87 FR 49246 through 49257) for the Hospital IQR Program. The commenter noted that when implementing the PRO surveys, hospitals will not make a distinction between inpatient or outpatient services because tracking one set of patients on a fiscal year timeline (for the Hospital IQR Program) and another set of patients on a calendar year timeline (for the Hospital OQR Program) will be an administrative burden. Several commenters supported only the voluntary reporting timeline without mandatory reporting, citing undue burden for hospitals participating in both the Hospital IQR and Hospital OQR Programs to collect data and respond to differing measurement and reporting periods. These commenters urged CMS to not mandate THA/TKA PRO–PM measure reporting in the Hospital OQR Program until testing and consensus-based endorsement in the HOPD setting has been completed or until CMS has sufficient information from the use of this measure in the Hospital IQR Program, to ensure this measure operates as intended and is useful for providers and patients. Commenters suggested this would allow CMS to assess feasibility, validity, and response rates, particularly in light of certain patient-level characteristics that may influence response rates of this measure.

Response: We thank commenters for their support of adopting the THA/TKA PRO–PM in the Hospital OQR Program. In response to interested party feedback to revise the measure reporting timelines, we are finalizing the measure with modification by delaying implementation of mandatory reporting by one year, such that voluntary reporting would begin with the CY 2025 reporting period and continue through the CY 2027 reporting period, and mandatory reporting would begin with the CY 2028 reporting period for CY 2031 payment determination.

In response to commenters' recommendations to align performance and reporting timelines of the Hospital OQR Program with the Hospital IQR Program, we will explore the feasibility of this approach within the HQR system, but do not want to delay the start of voluntary reporting with the CY 2025 reporting period so that HOPDs and their vendors can gain experience with the measure. Any further changes to the reporting requirements would be proposed through future rulemaking.

Regarding commenters' recommendation to delay mandatory reporting until CBE endorsement, given the increasing volume of THA and TKA procedures occurring in the outpatient setting, we believe it is important to adopt this PRO–PM in Hospital OQR Program as soon as possible and intend to submit the outpatient version of this measure for CBE endorsement in a future measure cycle. We refer readers to section XIV.E.7.a of this final rule with comment period where we discuss in more detail the form, manner, and timing of reporting the THA/TKA PRO–PM.

Comment: One commenter supported the adoption of this measure into the Hospital OQR Program but recommended that CMS analyze hip and knee arthroplasty procedures separately. Specifically, this commenter noted that THA procedures have a high success rate as measured by improvement in Quality Adjusted Life Years (QALYs), while TKA does not always reach the same levels of patient satisfaction.

Response: While we acknowledge that THA and TKA procedures can have varying recovery times and may differ somewhat in anticipated patient outcomes, we developed this measure to include both THA and TKA procedures for several reasons: (1) to align with other claims-based measures that combine THA/TKA procedures; (2) to increase the number of hospitals performing enough procedures and obtaining enough completed pre- and post-operative patient-reported outcome measures (PROMs) to be included in the measure; and (3) because surgeons and their hospital care teams often provide care for patients receiving both types of procedures.

Comment: Many commenters expressed concern that the inclusion of the THA/TKA PRO–PM in the Hospital OQR Program could create financial burden at the hospital level and require additional staff resources, and impact clinical workflows at the provider level. Several commenters expressed concern that the post-operative data collection timeframe of 300 to 425 days would be costly, time consuming, and difficult to implement because many patients miss follow-up appointments or do not require follow-up care this long after their procedure. One commenter noted concern for possible bias that may arise from events outside of the provider's control during the long post-operative assessment window. Another commenter noted that many clinicians participating in The Joint Commission Advanced Total Hip and Knee Replacement Certification, which calls for 90 day pre- and post-operative (+/− 2 months) PROMs reporting, have expressed challenges with a 1-year data capture. A few commenters expressed concern that EHRs are not integrated with patient portals that would allow hospitals to collect patient-reported information. Additionally, commenters noted that many small, rural, and medically underserved hospitals exist in areas where patient portal use is unreliable, requiring infrastructure investments and adding manual burden to extrapolate data. One commenter suggested CMS institute technical support and incentives like the facility bonus used in the Quality Payment Program for smaller health systems and for those with limited infrastructure and resources and encouraged CMS to consider reimbursing hospitals for data collection.

Response: We acknowledge that collecting PROMs data may involve more burden and initial implementation resources compared to some other types of quality measures, and that small hospitals, particularly in rural areas, may lack the necessary infrastructure to collect data on this measure. However, we believe the benefit of collecting direct functional improvement information from the patients outweighs the burden. We believe that measuring patient-reported outcomes is an important aspect of patient-centered healthcare and continue to emphasize, as highlighted in our Meaningful Measures 2.0 Framework, that the

patient voice should be prioritized across healthcare systems and providers. While PRO–PMs require providers to integrate data collection into clinical workflows, this integration provides an important opportunity for patient-reported outcomes to inform clinical decision-making and benefits patients by engaging them in discussions about potential outcomes. To allow more time for initial implementation, we are extending the voluntary reporting period by an additional year and delaying implementation of mandatory reporting by one year. We believe that the additional year of voluntary reporting and delaying mandatory reporting will allow time for HOPDs to integrate data collection into their clinical workflows, as well as for CMS to monitor implementation progress with regards to data collection burden, and time for rulemaking should any improvements for mandatory reporting need to be made. Additionally, to provide more flexibility, we are not requiring HOPDs to collect data in a standardized way. HOPDs may use a variety of data collection, storage, and submission approaches, and we encourage HOPDs to use processes best suited to them. We will monitor data collection burden during the voluntary reporting period and carefully consider public comments to advance patient-centered measurement with as little burden as possible to both providers and patients.

We also acknowledge commenters' concerns about the long post-operative data collection timeline of 300 to 425 days, and the concern about potential bias that could occur due to events following the procedure to the post-operative data collection window. In developing the THA/TKA PRO–PM, the measure developer reviewed registry data capture to inform the post-operative assessment window (initially 270 to 365 days) for capture of full recovery from both THA and TKA, and to align the post-operative assessment with the typically scheduled one-year post-surgery appointments so that the collection of the post-operative data collection would not require an additional appointment. Following several years of PRO data collection through the CJR Model, clinical experts expressed concern that the initial 365-day upper limit missed patients who were scheduled or rescheduled for this one-year follow-up beyond 365 days, and they strongly advocated for shifting the post-operative data collection window to better align with clinical practice and increase PRO data collection. For additional details we refer readers to the Patient-Reported Outcomes (PROs) Following Elective Primary Total Hip and/or Total Knee Arthroplasty: Hospital-Level Performance Measure—Measure Methodology Report, available in Hip and Knee Arthroplasty Patient-Reported Outcomes folder at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.*

Regarding the commenter's concern that the long-term results of care may be connected to factors outside the facility's control, it is our belief that quality procedures, efficient processes, and best practices (such as discharge education), and care coordination are critical aspects of care directly in purview of the facility.

Regarding commenters' recommendations concerning reimbursement and incentives for reporting the THA/TKA PRO–PM data, we are not able to provide incentive payments or reimburse hospitals for data collection under the Hospital OQR Program. We note that the Hospital OQR Program is a pay-for-reporting program, and hospitals will receive credit for reporting their measure data regardless of their performance on a measure.

Comment: A few commenters expressed concern that data is not collected in a standardized way and suggested that CMS consider reducing the number of risk variables required. These commenters also suggested that CMS shorten the pre- and post-operative data collection window and propose an alternative timeframe. A commenter urged CMS to consider reducing the Hospital OQR Program measure reporting requirement of 50 percent for completed PRO data for the first two years of collection to reduce financial penalties associated with incomplete data collection. A few commenters noted that the extensive data collection required by the measure would rarely be used to guide patient care decisions and incomplete reporting penalties would require diversion of staff effort away from direct patient care toward PRO collection. One commenter urged CMS to also monitor and evaluate patient willingness to respond to requests for patient-reported information and to assist providers in best practices to improve and maintain patient responsiveness to these data collection requests.

Response: We emphasize that allowing hospitals to use a variety of data collection, storage, and submission approaches ensures flexibility and reduces burden, and we encourage hospitals to use processes best suited to their care setting and patient populations. We note that while we are not requiring hospitals to collect data in a standardized way, we are standardizing the specific data elements that need to be collected and reported to us. Further, we believe that clinicians, providers, and hospitals should determine practices that avoid duplication across care settings. We will evaluate data collection burden associated with the THA/TKA PRO–PM to inform future changes to measure specifications or reporting process improvements.

In regards to reporting thresholds requirements, we selected the 50 percent reporting threshold after considering numerous factors and the experience of the Comprehensive Care for Joint Replacement (CJR) Model participants. The proposed reporting threshold for adoption of the measure into the Hospital OQR Program is based on average response rates for both pre-operative and post-operative surveys collected by participating hospitals in the CJR Model. We note that the proposed reporting threshold for adoption of the measure into the Hospital OQR Program is lower than that currently used in the CJR Model (50 percent versus 85 percent) since hospitals participating in the CJR Model had difficulty meeting the threshold requirement. Additionally, hospitals are not held to reporting thresholds until mandatory reporting; therefore, we believe hospitals will have time to develop their data collection and reporting processes. We reiterate that hospitals in the Hospital IQR Program will already have the necessary infrastructure and several years of experience collecting measure data to meet this threshold. Lastly, we are providing three years of voluntary reporting for hospitals to integrate data collection into their workflows. We will continue to consider the appropriate pre- and post-operative matched survey response rate and reporting thresholds, evaluate our proposed approach during voluntary reporting, and consider adjustments based on feedback prior to mandatory reporting.

We also acknowledge commenters' concerns with evaluating patient willingness to respond to the PRO surveys. We anticipate data collection for this measure to present a low burden to patients thereby fostering receptiveness to survey participation. We will evaluate data collection burden and response rates associated with the THA/TKA PRO–PM and will also consider this information in future measure reevaluation.

Comment: A few commenters requested CMS explore data collection through providers because surgeons' offices or other settings commonly administer PRO surveys and suggested adoption of the measure into the Quality Payment Program as part of its specialty care-focused Merit-based Incentive Payment System (MIPS) Value Pathways (MVPs) Program, given that patient follow-up is more likely to occur through the orthopedic/surgeon practice. One commenter supported the adoption of the measure into the Hospital OQR Program if the measure is removed from the Hospital IQR Program, citing that duplicative processes would create burden. One commenter recommended streamlining or eliminating duplicative existing measures as the number of overall measures in the Hospital OQR Program increases.

Response: We agree that there is value in measurement at the clinician level; however, the hospital outpatient measure helps capture the quality of care provided in the HOPD setting and provides the opportunity for more entities to have sufficient case volume to be included in the measure. We highlight that THA/TKA procedures performed in the hospital inpatient or outpatient departments would be counted only either in the Hospital IQR Program or the Hospital OQR Program. Additionally, implementation of this measure in the HOPD setting has been recommended by interested parties as summarized in the FY 2023 IPPS/LTCH PPS final rule (87 FR 49254) and supported by interested parties as summarized in the CY 2022 OPPS/ASC final rule with comment period (86 FR 63851 and 63852).

After considering the comments received, we are finalizing adoption of the THA/TKA PRO–PM into the Hospital OQR Program with modification. In response to interested party feedback, we are delaying implementation of mandatory reporting by one year, such that voluntary reporting would begin with the CY 2025 reporting period and continue through the CY 2027 reporting period, and mandatory reporting would begin with the CY 2028 reporting period for CY 2031 payment determination. The additional year of voluntary reporting would allow time to monitor implementation progress with regards to data collection burden and response rates, as well as time for rulemaking should any improvements for mandatory reporting need to be made.

c. Adoption of the Excessive Radiation Dose or Inadequate Image Quality for Diagnostic Computed Tomography (CT) in Adults (Hospital Level—Outpatient) Measure Beginning With the Voluntary CY 2025 Reporting Period Followed by Mandatory Reporting Beginning With the CY 2026 Reporting Period/CY 2028 Payment Determination

(1) Background

The use of computed tomography (CT) scans has greatly improved the diagnosis and treatment of many conditions, and as such, over 80 million CT scans are performed each year in the U.S.[386] Most CT scans are performed as outpatient procedures.[387] CT scans expose patients to low-dose ionizing radiation which is known to contribute to the development of cancer.[388] The Biological Effects of Ionizing Radiation (BEIR) VII report by the United States National Academy of Sciences defined low-dose radiation as doses up to 100 millisieverts (mSv).[389] A low dose CT scan of the chest delivers 1.5 mSv of radiation, while a regular-dose CT chest scan delivers 7 mSv of radiation.[390] In comparison, a conventional chest x-ray delivers about 0.1 mSv of radiation.[391]

There is a large body of research that suggests that exposure to ionizing radiation within the same range that is routinely delivered by CT scans increases a person's risk of developing cancer.[392] [393] [394] [395] One study found that patients who received CT scans, particularly women and adults aged 45 years or younger, had an elevated risk of developing thyroid cancer and leukemia.[396] Another study found that patients who received CT scans had a 0.7 percent higher risk of developing cancer in their lifetime compared to the general United States population.[397] Cancer risk increased for patients who underwent multiple CT scans, ranging from 2.7 to 12 percent.[398] While the likelihood of developing cancer from a CT scan is small on an individual level, it has been estimated that the percentage of cancers attributable to CT scans in the United States may be as high as 2 percent.[399]

[386] Harvard Health Publishing (2021). Radiation Risk from Medical Imaging. Available at: *https://www.health.harvard.edu/cancer/radiation-risk-from-medical-imaging.*

[387] Food and Drug Administration. Computed Tomography. Available at: *https://www.fda.gov/radiation-emitting-products/medical-x-ray-imaging/computed-tomography-ct.*

[388] Harvard Health Publishing (2021). Radiation Risk from Medical Imaging. Available at: *https://www.health.harvard.edu/cancer/radiation-risk-from-medical-imaging.*

[389] Siegel JA, Greenspan BS, Maurer AH, et al. (2018). The BEIR VII Estimates of Low-Dose Radiation Health Risks Are Based on Faulty Assumptions and Data Analyses: A Call for Reassessment. *Journal of Nuclear Medicine,* 59 (7) 1017–1019. *https://doi.org/10.2967/jnumed.117.206219.*

[390] Ibid.

[391] Environmental Protection Agency. Radiation Sources and Doses. Available at: *https://www.epa.gov/radiation/radiation-sources-and-doses.*

[392] Berrington de Gonzalez A, Daniels RD, Cardis E, et al. (2020). Epidemiological Studies of Low-Dose Ionizing Radiation and Cancer: Rationale and Framework for the Monograph and Overview of Eligible Studies. *J Natl Cancer Inst Monogr,* 2020(56), 97–113. *https://doi.org/10.1093/jncimonographs/lgaa009.*

[393] Cao CF, Ma KL, Shan H, et al. (2022). CT Scans and Cancer Risks: A Systematic Review and Dose-response Meta-analysis. *BMC Cancer,* 22, 1238. *https://doi.org/10.1186/s12885-022-10310-2.*

[394] Hauptmann M, Daniels R, Cardis E, et al. (2020). Epidemiological Studies of Low-Dose Ionizing Radiation and Cancer: Summary Bias Assessment and Meta-Analysis. *J Natl Cancer Inst Monogr,* 2020(56), 188–200. *https://doi.org/10.1093/jncimonographs/lgaa010.*

[395] Shao YH, Tsai K, Kim S, Wu YJ, Demissie K (2020). Exposure to Tomographic Scans and Cancer Risks. *JNCI Cancer Spectr,* 4(1). *https://doi.org/10.1093/jncics/pkz072.*

[396] Ibid.

[397] Harvard Health Publishing (2021). Radiation Risk from Medical Imaging. Available at: *https://www.health.harvard.edu/cancer/radiation-risk-from-medical-imaging.*

[398] Ibid.

[399] Berrington de González A, Mahesh M, Kim KP, et al. (2009). Projected cancer risks from computed tomographic scans performed in the United States in 2007. *Archives of internal medicine,* 169(22), 2071–2077. *https://doi.org/10.1001/archinternmed.2009.440.*

CT image quality and radiation dose are related; as radiation dose increases, image quality increases until a diagnostic threshold is reached, at which point no further diagnostic benefit from image quality occurs.[400] [401] Conversely, too little radiation dose can produce inadequate image quality. Research suggests that current radiation doses utilized for CT scans may be lowered between 50 percent and 90 percent without impacting image diagnostic utility.[402] [403] [404] [405] [406] Based on the evidence of harm from excessive radiation and evidence that radiation doses could be lowered in many patients' situation without deteriorating image diagnostic utility to the point of rendering exams unacceptable, we believe it is important to promote patient safety by ensuring that patients are exposed to the lowest possible level of radiation while preserving image quality. Therefore, in the CY 2024 OPPS/ASC proposed rule, (88 FR 49789), we proposed the adoption of the Excessive Radiation eCQM as a voluntary measure for the CY 2025 reporting period followed by mandatory reporting beginning with the CY 2026 reporting period/CY 2028 payment determination.

[400] Goldman LW (2007). Principles of CT: Radiation Dose and Image Quality. *Journal of Nuclear Medicine Technology,* 35(4), 213–225. *https://doi.org/10.2967/jnmt.106.037846.*

[401] Smith-Bindman R, Chu P, Wang Y, Chung R, et al. (2020). Comparison of the Effectiveness of Single-Component and Multicomponent Interventions for Reducing Radiation Doses in Patients Undergoing Computed Tomography: A Randomized Clinical Trial. *JAMA Intern Med,* 180(5), 666–675. *https://doi.org/10.1001/jamainternmed.2020.0064.*

[402] Greffier J, Hamard A, Pereira F, et al. (2020). Image quality and dose reduction opportunity of deep learning image reconstruction algorithm for CT: a phantom study. *Eur Radiol,* 30(7), 3951–3959. *https://doi.org/10.1007/s00330-020-06724-w.*

[403] Gottumukkala RV, Kalra MK, Tabari A, Otrakji A, Gee MS (2019). Advanced CT Techniques for Decreasing Radiation Dose, Reducing Sedation Requirements, and Optimizing Image Quality in Children. *Radiographics,* 39(3), 709–726. *https://doi.org/10.1148/rg.2019180082.*

[404] Den Harder AM, Willemink MJ, van Doormaal PJ, et al. (2018). Radiation dose reduction for CT assessment of urolithiasis using iterative reconstruction: A prospective intra-individual study. *Eur Radiol,* 28(1), 143–150. *https://doi.org/10.1007/s00330-017-4929-2.*

[405] Rob S, Bryant T, Wilson I, Somani BK (2017). Ultra-low-dose, low-dose, and standard-dose CT of the kidney, ureters, and bladder: is there a difference? Results from a systematic review of the literature. *Clin Radiol,* 72(1), 11–15. *https://doi.org/10.1016/j.crad.2016.10.005.*

[406] Konda SR, Goch AM, Leucht P, et al. (2016). The use of ultra-low-dose CT scans for the evaluation of limb fractures: is the reduced effective dose using CT in orthopaedic injury (REDUCTION) protocol effective? *Bone Joint J,* 98–B(12), 1668–1673. *https://doi.org/10.1302/0301-620X.98B12.BJJ-2016-0336.R1.*

(2) Overview of Measure

The Excessive Radiation Dose or Inadequate Image Quality for Diagnostic Computed Tomography (CT) in Adults (Hospital Level—Outpatient) electronic clinical quality measure (eCQM) (the Excessive Radiation eCQM), which was developed by the University of California San Francisco and is stewarded by Alara Imaging, Inc., provides a standardized method for monitoring the performance of diagnostic CT to discourage unnecessarily high radiation doses while preserving image quality. The measure calculates the percentage of eligible CT scans that are out-of-range based on having either excessive radiation dose or inadequate image quality, relative to evidence-based thresholds based on the clinical indication for the exam.[407] This measure provides a metric toward reducing unintentional harm to patients from CT scans. Setting a standard for diagnostic CT scans to prevent unnecessarily high radiation doses while preserving image quality provides hospitals with a reliable method to assess harm reduction efforts and modify their improvement efforts. This measure also addresses high priority areas as stated in our Meaningful Measures Framework, including the transition to digital quality measures and the adoption of high-quality measures that improve patient outcomes and safety.[408] Additionally, the Excessive Radiation eCQM supports the National Quality Strategy goal of promoting safety because it works to reduce preventable harm to patients.[409] The measure was developed according to evidence and consensus-based clinical guidelines for optimizing CT radiation doses, including guidelines developed by the American College of Radiology, American College of Cardiology, Image Wisely 2020, and the American Association of Physicists in Medicine.[410] [411] [412] [413] [414]

[407] Centers for Medicare & Medicaid Services. Pre-Rulemaking MUC Lists and MAP Reports. The Measures Management System. Available at: *https://mmshub.cms.gov/measure-lifecycle/measure-implementation/pre-rulemaking/lists-and-reports.*

[408] Centers for Medicare & Medicaid Services. Meaningful Measures Framework. Available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/CMS-Quality-Strategy.*

[409] Centers for Medicare & Medicaid Services. CMS Quality Strategy. Available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Value-Based-Programs/CMS-Quality-Strategy.*

[410] American College of Radiology (2015). Development and Revision Handbook. Available at: *https://www.acr.org/-/media/ACR/Files/Practice-Parameters/DevelopmentHandbook.pdf.*

Measure testing by the measure developer across a total of 16 inpatient and outpatient hospitals and a large system of outpatient radiology practices revealed that availability, accuracy, validity, and reproducibility were high for all of the measure's required data elements and the variables that were calculated by the translation software. The measure developer further assessed the reporting burden by administering surveys to each of the participating hospitals and outpatient groups. The measure developer found the burden to be small to moderate, comparable to the burden of measure reporting for other measures. Additionally, the measure developer noted that the burden of reporting the Excessive Radiation eCQM fell to information technology personnel rather than physicians.

Measure testing found that assessing radiation doses and providing audit feedback to radiologists resulted in significant reductions in dose levels. The testing sites also noted that the assessment of their doses as specified in the measure was helpful for identifying areas for quality improvement. According to the measure developer, over 40 letters were submitted in support of the measure, including several from radiologists and medical physicists who serve as leaders of the testing sites, that confirmed the measure was feasible and that data assembly would not pose a large burden.

The Excessive Radiation eCQM was submitted to the CBE for endorsement review in the Fall 2021 cycle (CBE #3663e) and was endorsed on August 2, 2022. The measure was also included in the 2022 MUC List.[415] The MAP Hospital Workgroup reviewed the MUC List on December 13–14, 2022. The Workgroup noted that the Hospital OQR Program currently does not have any measures assessing the risk of radiation exposure from CT scans. The Workgroup also noted that the measure

[411] Hirshfeld JW, Ferrari VA, Bengel FM, et al. (2018). 2018 ACC/HRS/NASCI/SCAI/SCCT Expert Consensus Document on Optimal Use of Ionizing Radiation in Cardiovascular Imaging: *Best Practices for Safety and Effectiveness. Catheter Cardiovasc Interv,* 2018(92), E35–E97. *https://doi.org/10.1002/ccd.27659.*

[412] Image Wisely 2020. Available at: *https://www.imagewisely.org/Imaging-Modalities/Computed-Tomography/Diagnostic-Reference-Levels.*

[413] American Association of Physicists in Medicine. The Alliance For Quality Computed Tomography. Available at: *https://www.aapm.org/pubs/CTProtocols/.*

[415] Centers for Medicare & Medicaid Services. Pre-Rulemaking MUC Lists and MAP Reports. The Measures Management System. Available at: *https://mmshub.cms.gov/measure-lifecycle/measure-implementation/pre-rulemaking/lists-and-reports.*

addresses the ''Safety'' Meaningful Measures 2.0 Healthcare Priority and would encourage shared decision-making between providers and patients.[416] The MAP's Final Report on February 1, 2023, supported the Excessive Radiation eCQM for rulemaking in the Hospital OQR Program.[417]

(3) Data Sources

The Excessive Radiation eCQM uses hospitals' electronic health record (EHR) data and radiology electronic clinical data systems, including the Radiology Information System (RIS) and the Picture Archiving and Communication System (PACS). Medical imaging information such as Radiation Dose Structured Reports and image pixel data are stored according to the universally adopted Digital Imaging and Communications in Medicine (DICOM) standard. Currently, eCQMs cannot access and process data elements in their original DICOM formats.

Hospitals may choose to use any available software that performs the necessary functions to comply with measure requirements. One such example is the Alara Imaging software,[418] which fulfills these requirements by linking primary data elements, assessing CT scans for eligibility for inclusion in the measure, and generating three data elements mapped to clinical terminology for EHR consumption (CT Dose and Image Quality Category, Calculated CT Size-Adjusted Dose, and Calculated CT Global Noise) within the hospital's firewall.[419] While the Alara Imaging software and the necessary updates to the software are proprietary, these would be available to all reporting entities free of charge and accessible by creating a secure account through the measure steward's website. Alara Imaging also provides free of charge necessary education materials including step-by-step instructions on creating an account and linking their EHR and PACS data to the software. Hospitals and their vendors will be able to use the data elements created by this software to calculate the eCQM and to submit results to the Hospital OQR Program via Quality Reporting Document Architecture (QRDA) Category I files as they do for all other eCQMs.

(4) Measure Specifications

The measure numerator is diagnostic CT scans that have a size-adjusted radiation dose greater than the threshold defined for the specific CT category. The threshold is determined by the body region being imaged and the reason for the exam, which affects the radiation dose and image quality required for that exam. The numerator also includes CT scans with a noise value greater than a threshold specific to the CT category.[420]

The measure denominator is all diagnostic CT scans performed on patients ages 18 and older during the one-year measurement period which have an assigned CT category, a size-adjusted- radiation dose value, and a global noise value.[421]

The measure excludes CT scans that cannot be categorized by the area of the body being imaged or reason for imaging. These include scans that are simultaneous exams of multiple body regions outside of four commonly performed multiple region exams defined by the measure, or scans that cannot be classified based on diagnosis and procedure codes. Exams that cannot be classified are specified as LOINC code 96914–7, CT Dose and Image Quality Category, Full Body. The measure also has technical exclusions for CT scans missing information on the patient's age, Calculated CT Size-Adjusted Dose, or Calculated CT Global Noise. We refer readers to the eCQI Resource Center (*https://ecqi.healthit.gov/ecqm/oqr/pre-rulemaking/2024/cms1206v1#quicktabs-tab-tabs_pre_rule_measure-0*) for more details on the measure specifications.

(5) Data Submission and Reporting

In the CY 2024 OPPS/ASC proposed rule, we proposed the adoption of the Excessive Radiation eCQM as a voluntary measure for the CY 2025 reporting period followed by mandatory reporting beginning with the CY 2026 reporting period/CY 2028 payment determination. We stated that we would utilize the voluntary period to monitor the implementation and operationalization of the measure. We refer readers to section XIV.E.6.b of this final rule with comment period for a discussion of the Excessive Radiation eCQM reporting and data submission requirements. We refer readers to section XIV.E.6 of this final rule with comment period for a discussion of our previously finalized eCQM reporting and submission policies.

We invited public comment on the proposal.

Comment: Many commenters supported our proposal to adopt the Excessive Radiation eCQM, believing that the measure will increase patient safety by reducing unnecessary exposure to harmful radiation. Several commenters expressed their belief that the measure will mitigate risks of cancer within patients who rely on CT to monitor health conditions. Several of these commenters noted that the measure was designed with stakeholder feedback from a diverse Technical Expert Panel, was tested in diverse settings, and was endorsed by the CBE on both scientific merit and feasibility. Several of these commenters highlighted the lack of standardization in CT application that leads to using a higher radiation dose than necessary. Commenters noted that the Excessive Radiation eCQM provides a guide for acceptable dose limits.

Response: We thank commenters for their support. We agree that this measure will increase patient safety by reducing unnecessary exposure to harmful radiation.

Comment: A few commenters supported the adoption of the Excessive Radiation eCQM because they believed it aligns with the priority CMS identified in the Meaningful Measures 2.0 initiative to transition to digital quality measures. One commenter supported our proposal, citing alignment with other CMS quality programs. The commenter noted that implementing this measure will encourage synergy across entities and advance quality improvement efforts.

Response: We thank commenters for their support. We agree that adoption of the Excessive Radiation eCQM aligns with our Meaningful Measures 2.0 initiative to transition to digital quality measures. We further note the Excessive Radiation eCQM addresses the goal of Alignment under the priority area Outcomes and Alignment in CMS's National Quality Strategy.

Comment: A few commenters supported adoption of the Excessive Radiation eCQM and recommended CMS implement mandatory reporting beginning with the CY 2024 reporting period/CY 2026 payment determination.

Response: We thank commenters for their support and recommendation. When proposing this measure for adoption, we sought to balance quickly addressing the patient safety concerns presented by exposure to excessive radiation while still providing hospitals

[416] Ibid.

[417] Ibid.

[418] Alara Imaging. Available at: *https://www.alaracare.com/*.

[419] Additional information on measure software security and processes is available at *https://www.alaracare.com/our-solutions.*

[420] Centers for Medicare & Medicaid Services. Pre-Rulemaking MUC Lists and MAP Reports. The Measures Management System. Available at: *https://mmshub.cms.gov/measure-lifecycle/measure-implementation/pre-rulemaking/lists-and-reports.*

[421] Ibid.

with enough time to implement the measure. To ensure this balance remains, we are not accelerating the adoption timeline.

Comment: A few commenters stated that they were implementation testing centers and supported adoption of the Excessive Radiation eCQM. Commenters noted that the measure was highly feasible for reporting and was able to appropriately identify CT exams that were significantly above diagnostic reference level doses. One commenter indicated that the measure would significantly reduce the use of excessive radiation doses as well as inadequate, suboptimal low doses by identifying outliers and thereby increasing the awareness and importance of CT protocol optimization. Another commenter noted the successful implementation of the measure within their institution and stated that they had received, from Alara Imaging, information on their measure performance that brought to their attention some areas of opportunity to decrease radiation dose. Several commenters noted that the measure removed burden from their institutions in terms of identifying areas of improvement to reduce CT radiation dose, including the detection of outliers.

Response: We thank commenters for their support.

Comment: One commenter supported the adoption of the Excessive Radiation eCQM because the commenter believed that the measure will disincentivize use of technical parameters that are inappropriate based on a given patient's condition. Another commenter supported the adoption of the Excessive Radiation eCQM because the commenter believed that the Alara Imaging software bridges the gap between data stored outside of the EHR and eCQMs and aligns with the CMS's goals of digital quality measurement. The commenter noted that the software uses widespread standards including DICOM, HL7 v2.x and/or FHIR to minimize reporting burden. The commenter further noted that HOPDs can choose between Alara Imaging's measure calculation product or import the intermediate variables into an existing EHR for eCQM calculation. Another commenter supported the adoption of the Excessive Radiation eCQM because the commenter stated that the image noise algorithm for this measure is statistically robust and appropriately specified. Commenters noted that testing of the data in diverse settings resulted in accessible data elements that contained very little missing data.

Response: We thank commenters for their support.

Comment: Many commenters opposed the proposal's mandatory reporting requirement, stating that the software integration, maintenance, and management would impose a significant burden on HOPDs (specifically, implementation challenges with integration of the Alara Imaging software into facility EHR or EMR systems, the additional processes needed to aggregate data components, and the financial and administrative burden as a result of the implementation challenges and aggregation of data components). Another commenter noted that implementing this measure in rural hospitals and those treating underserved communities may prove insurmountable due to implementation challenges. Many of these commenters supported voluntary reporting of the measure.

Several commenters suggested that CMS delay implementation of mandatory reporting to give HOPDs additional time to integrate, appropriately test, and gain experience from the software. One commenter stated that the eCQM, once cybersecurity due diligence surrounding integration of software is completed, will take up to 18 months to build and test. Another commenter recommended that voluntary reporting be implemented sooner than 2024.

Response: We acknowledge the concerns regarding the potential issues with measure implementation. As discussed further below, we are delaying implementation of mandatory reporting as a logical outgrowth of public comments on this subject. We will continue to monitor implementation of the measure during the voluntary period and make any future adjustments to the requirement as needed in future rulemaking.

Regarding commenters' concerns about the burdens associated with the measure and software; while this measure in its current form requires the reporting of data that eCQMs cannot process directly through the software of their choice, the Alara Imaging software provided by the measure developer would address this gap. As stated in the CY 2024 OPPS/ASC proposed rule, the Alara Imaging software meets CMS compliance and security standards. Educational materials will also be made available to provide step-by-step instructions for creating secure accounts and linking hospital EHRs and PACS data to the translation software (88 FR 49789). We will take the commenters' concerns into account during the voluntary reporting period as we continue to evaluate the measure and its accompanying translation software for policy consideration in future rulemaking.

We also reiterate that the Hospital OQR Program introduced the ST-Segment Elevation Myocardial Infraction (STEMI) eCQM previously, such that HOPDs already have the capability and the knowledge to submit eCQM data. To help alleviate potential burden, this measure has been proposed in a phased approach after a period of voluntary reporting. During this time, we will continue to monitor and evaluate measure implementation and adjust as necessary in future rulemaking.

Comment: Several commenters expressed concern about the set thresholds for both ''Calculated CT Global Noise'' and ''Calculated CT Size-Adjusted Dose.'' One commenter stated their belief that Calculated CT Global Noise is not a meaningful indicator of quality, is not defined by any international or national standards organizations, and greatly oversimplifies the nature of image noise in clinical examinations. The commenter notes that the International Electrotechnical Commission has clearly defined measures for noise and dose in CT imaging, of which ''Calculated CT Global Noise'' and ''Calculated CT Size-Adjusted Dose'' are not among the definitions. The commenter further states that noise levels may vary substantially depending upon the parameters of the CT procedure. Another commenter notes that ''Calculated CT Size-Adjusted Dose'' and ''Calculated CT Global Noise'' are not widely accepted image quality measurements and have not been widely tested and validated. One commenter noted that the proposed measure does not seem to have referred to appropriate peer reviewed literature on CT dose in an earnest effort to address patient imaging concerns.

Response: We respectfully disagree that the thresholds have not been adequately tested. The data elements are scientifically and practically valid. The measure's thresholds for noise and radiation dose were developed with close input from an experienced and diverse Technical Expert Panel (TEP), which included representation from radiologists and physicists in medicine and were informed by an image quality study.[422] The measure also relies on evidence and consensus-based clinical guidelines for optimizing CT radiation doses. These include guidelines

[422] Smith-Bindman R, Yu S, Wang Y, et al. (2022). An Image Quality-informed Framework for CT Characterization. Radiology, 302(2), 380–389. *https://doi.org/10.1148/radiol.2021210591.*

developed by the American College of Radiology,[423] The Society of Interventional Radiology,[424] The Society of Cardiovascular CT,[425] cardiovascular imaging societies,[426] Image Wisely 2020,[427] and the FDA.[428] Measure testing by the measure developer across 16 inpatient and outpatient hospitals showed that availability, accuracy, validity, and reproducibility were high for all of the measure's required data elements and the variables that were calculated by the translation software. The testing sites reported that the assessment of their radiation doses as specified in the measure was helpful for identifying areas for quality improvement, and the measure received support from radiologists and medical physicists who serve as leaders of the testing sites (88 FR 49789). We also reiterate that this measure was submitted to the CBE by the measure developer for endorsement review (CBE #3663e) and was endorsed on August 2, 2022. The Excessive Radiation eCQM (MUC 2022–018) was submitted to the CBE-convened MAP for the 2022–2023 pre-rulemaking cycle and received support for rulemaking (88 FR 49789).

Comment: Another commenter asked how good image quality will be determined, and that CMS identify the threshold values for image quality and provide additional information about how they were derived. One commenter asked if the one-year measurement period is a cumulative dose for all patients, or individual patients, and if it is standardized over a year. One commenter noted their opposition to finalizing the measure until further testing in oncology settings can be conducted since the measure does not consider cumulative radiation exposure over a lifespan, as well as prior or anticipated radiation exposure history, including therapeutic irradiation for malignancies.

Response: Regarding the commenter's question about how good image quality would be determined, we wish to clarify that the image quality component, as measured by noise, was included to ensure that CT image quality does not decrease as an unintended consequence of lowering radiation doses. Noise was selected as the metric for measuring image quality because it is the most widely used measure of image quality for CT. Because the image quality component is not meant to be a comprehensive measure of image quality that can assess nuanced differences in quality across all CT scans, it does not take into account variables beyond noise.

Regarding the measure's threshold values and approach for deriving them, this information can be found in the materials that the measure developer submitted to the National Quality Forum (NQF) for endorsement review.[429] The thresholds were derived in part using data from the ACR Dose Index Registry and University of California San Francisco (UCSF) International CT Dose Registry.

With regard to the commenter's question about what the one-year measurement period is measuring, each CT scan in the one-year period is evaluated against size-adjusted dose and permissible image noise thresholds set for each CT category. There is no assessment that combines dose across time and there are no cumulative dose calculations.

We refer commenters to the measure specifications listed in measure submission materials on the NQF[430] and the eCQI Resource Center at *https://ecqi.healthit.gov/ecqm/eh/pre-rulemaking/2024/cms1074v1* for additional information on the measure's technical specifications. The framework for classifying CT scans into CT categories was published in ''An Image Quality-informed Framework for CT Characterization''.[431]

Comment: A few commenters expressed various concerns about the measure software vendor and pilot. Commenters expressed concerns about the ability of a single vendor to handle multiple organizations onboarding this measure and challenges associated with quality reporting. One commenter expressed concern about other services or features the vendor may provide outside of the free software and asked if there are any other vendors who offer software specific to the needs of this measure. One commenter expressed a belief that CMS lacks authority to require users to purchase software from a single supplier to meet Federal quality requirements associated with reimbursement. Another had questions about the survey conducted by the vendor about the pilot, including whether it was a conflict of interest for the vendor to conduct a survey about their own pilot. A few commenters expressed concern that the software has not been released for public review.

Response: In regard to the ability of a single vendor to handle multiple organizations onboarding, we acknowledge that onboarding of the measure may take time for both hospitals and vendors. In response to commenters' concerns about implementing the measure, we are delaying mandatory reporting of the measure by extending voluntary reporting by an additional year. Additionally, we are using a phased approach to mandatory reporting. This will allow the hospitals and vendors time to successfully implement the measure.

In regard to the use of Alara Imaging software and other vendor software, hospitals are not required to use the Alara Imaging software for CMS Measure Compliance. They may choose to use any software(s) that performs the necessary functions to generate the same standardized data elements necessary to calculate the measure consistent with the measure's specifications. The Alara Imaging software for CMS Measure Compliance was created under a CMS-funded grant. At this time, the Alara Imaging software is the only vendor to offer translation software that specifically performs all the necessary functions, in one software package, to generate the data elements necessary for the measure specifications. Because the software is not required and the software is free of charge, we disagree that the Federal quality requirements associated with reimbursement are relevant in this situation.

[423] American College of Radiology (2015). Development and Revision Handbook. *https://www.acr.org/-/media/ACR/Files/Practice-Parameters/DevelopmentHandbook.pdf.*

[424] Stecker MS, Balter S, Towbin RB, et al. (2009). Guidelines for Patient Radiation Dose Management. Journal of Vascular and Interventional Radiology. 20(7): S263–S273. *https://doi.org/10.1016/j.jvir.2009.04.037.*

[425] Halliburton SS, Abbara S, Chen MY, et al. (2011). Society of Cardiovascular Computed Tomography. SCCT guidelines on radiation dose and dose-optimization strategies in cardiovascular CT. J Cardiovasc Comput Tomogr. 5(4): 198–224. *https://doi.org/10.1016/j.jcct.2011.06.001.*

[426] Hirshfeld JW, Ferrari VA, Bengel FM, et al. (2018). 2018 ACC/HRS/NASCI/SCAI/SCCT Expert Consensus Document on Optimal Use of Ionizing Radiation in Cardiovascular Imaging: Best Practices for Safety and Effectiveness. Catheter Cardiovasc Interv. 92: E35–E97. *https://doi.org/10.1002/ccd.27659.*

[427] Image Wisely 2020. Available at: *https://www.imagewisely.org/.*

[428] FDA (2019). Computed Tomography (CT). *https://www.fda.gov/radiation-emitting-products/medical-x-ray-imaging/computed-tomography-ct#6.*

[429] Measure 3663e Information Form. Available at: *https://www.qualityforum.org/ProjectMeasures.aspx?projectID=86057&cycleNo=2&cycleYear=2021.*

[430] Measure 3663e Information Form. Available at: *https://www.qualityforum.org/ProjectMeasures.aspx?projectID=86057&cycleNo=2&cycleYear=2021.*

[431] Smith-Bindman, R., Yu, S., Wang, Y., Kohli, M. D., Chu, P., Chung, R., Luong, J., Bos, D., Stewart, C., Bista, B., Alejandrez Cisneros, A., Delman, B., Einstein, A. J., Flynn, M., Romano, P., Seibert, J. A., Westphalen, A. C., & Bindman, A. (2022). An Image Quality-informed Framework for CT Characterization. Radiology, 302(2), 380–389. *https://doi.org/10.1148/radiol.2021210591.*

Regarding commenter's concerns about a conflict of interest, we do not believe that a vendor conducting a survey on their own pilot poses a conflict of interest. Further, the pilot conducted was reviewed during the MAP selection process by a TEP. The TEP found that the pilot conducted met the CBE evaluation criteria for testing (reliability testing and validity testing) standards. For more information on the Excessive Radiation eCQM pilot, we refer readers to the measure submission materials on the NQF [432] and the eCQI Resource Center at *https://ecqi.healthit.gov/ecqm/eh/pre-rulemaking/2024/cms1074v1.*

Regarding commenters' concerns that the software has not been released for public review, we acknowledge that the Alara Imaging software for CMS Measure Compliance is proprietary. However, it will be available to all reporting entities free of charge and accessible by creating a secure account through the Alara Imaging website. Additionally, by delaying mandatory reporting of this measure, we are providing more opportunity for the Alara Imaging software to be publicly released and available for reporting entities prior to mandatory reporting.

Comment: Several commenters expressed concerns about software technical issues. A few commenters expressed concerns about how the measure is reported and what EHR formats are accepted. One commenter asked CMS to identify the specific requirements, if any, for maintaining the data over time, including where the information should be stored over the years. A few commenters expressed concern about data breaches and security protocols. One commenter asked if hospitals would sign into Alara Imaging and be protected by the Alara Imaging firewall thus requiring a business agreement, or if the hospital would run Alara Imaging software on their own hospital systems.

Response: The Alara Imaging software accepts a wide range of FHIR, HL7 formats for EHR data, and DICOM CT radiation dose and image data to decrease burden. Similar to other eCQMs, the measure has also been developed using proven formats: Quality Data Model (QDM) for immediate implementation and FHIR when adopted in the future, in accordance with our aim of encouraging interoperability based on the FHIR Application Programming Interface (API).

While the Alara Imaging software for CMS Measure Compliance is proprietary, it will be available to all reporting entities free of charge and accessible by creating a secure account through the Alara Imaging website. To clarify the reporting process, we note that a hospital can log in through the measure developer's secure portal and run the Alara Imaging software for CMS Measure Compliance inside the firewall. The software runs automatically to create the three intermediate data elements needed for the measure: CT Dose and Image Quality Category, Calculated CT Size-Adjusted Dose, and Calculated CT Global Noise. Once the software finishes creating these intermediate variables, hospitals can send the data to its EHR for measure calculation and reporting. The software allows additional options such as the ability to send the data to other business associates of the hospital if needed. No manual data entry is required.

We anticipate that some EHR vendors may develop solutions to ingest these calculated variables and calculate the eCQM, as they have done for other eCQMs. This burden to EHR developers should be similar to any other new eCQM adopted into the Hospital OQR Program.

The Alara Imaging software for CMS Measure Compliance has security protocols to safeguard sensitive patient information. It is installed and computes the measure within a hospital's firewall to be used for measure-related activities, including calculation, and reporting. The measure steward's security aligns with industry standards, including HIPAA and Systems and Organization Controls (SOC) 2 certification verified via ongoing third-party audits. As noted previously, while the Alara Imaging software for CMS Measure Compliance is proprietary, it will be available to all reporting entities free of charge and accessible by creating a secure account through the Alara Imaging website.

Additionally, regarding the question about requirements for data maintenance, the Excessive Radiation eCQM uses data from radiology electronic clinical data systems, including the Radiology Information System (RIS) and the Picture Archiving and Communication System (PACS), and medical imaging information such as Radiation Dose Structured Reports and image pixel data are stored according to the universally adopted DICOM standard, as described in the proposed rule (88 FR 27084). These data will need to be available at the time the hospital and/or its vendor calculates the eCQM for quality improvement and monitoring purposes as well reporting to CMS.

Further, we will post information about the software's specifications as it becomes available through routine communication channels to hospitals, vendors, and other interested parties, including but not limited to issuing memos, emails, and notices on QualityNet and the eCQI Resource Center websites.

Comment: One commenter suggested that the measure should be classified as a hybrid measure, not an eCQM.

Response: This measure is suitable for eCQM reporting. As set forth in the CMS' eCQI Resource Center at *https://ecqi.healthit.gov/glossary,* we define an eCQM as a measure specified in a standard electronic format that uses data electronically extracted from EHRs and/or health IT systems to measure the quality of health care provided. By using patients' radiology data that exist in a structured and standard electronic format that can be electronically extracted from radiology IT data systems, this measure meets the definition of an eCQM. And while radiology data are stored in health IT systems, we understand that for many hospitals the radiology data system may not be fully integrated or interoperable with the EHRs. To address this gap, the measure developer created the Alara Imaging software for CMS Measure Compliance. This software links primary data elements, assesses CT scans for eligibility for inclusion in the measure, and generates three data elements mapped to a clinical terminology for eCQM consumption: CT Dose and Image Quality Category, Calculated CT Size-Adjusted Dose, and Calculated CT Global Noise (88 FR 27084).

Comment: Several commenters expressed concern that the measure does not take the individual patient's needs into consideration, such as the type and reason for the scan, the size of the patient, etc. One commenter suggested this will require the operator to turn down the dose to an unacceptable level for high-BMI patients who often also suffer most from negative Social Determinants of Health and other challenges. A few commenters recommended that CMS reconsider the proposed measure and instead work with the medical imaging community to adopt a reference value approach—based on distributions of patients—and not a per-patient limit-based approach. One commenter commented on the lifespan accumulation of radiation exposure on the individual and

[432] Measure 3663e Information Form. Available at: *https://www.qualityforum.org/ProjectMeasures.aspx?projectID=86057&cycleNo=2&cycleYear=2021.*

suggested that this also be taken into consideration before finalizing the measure. One commenter noted that patient-centered care should encompass appropriate imaging—the right test for the right patient, and thus at times a higher radiation dose will provide greater test accuracy. This commenter expressed concern that this measure may result in unintended consequences and that those be monitored over time, such as the inappropriate shifting of care or coding/billing practices, or increased patient morbidity and mortality.

Response: We disagree that the measure does not take the individual patient's needs into consideration. The measure assesses radiation doses by clinical indication, thereby allowing consideration for the reason of imaging. Similarly, it assesses radiation dose according to thresholds determined by the underlying clinical indication for imaging. The denominator for this measure is all diagnostic CT exams performed on adults during the measurement period of one year that have an assigned CT category, a size-adjusted radiation dose value, and a global noise value. Thus, the measure considers the clinicians choice of imaging protocol (for example, whether to assign a patient to a single or multi-phase abdomen exam).

We wish to clarify that the purpose of the Excessive Radiation eCQM is to ensure that radiation dose and image quality fall within thresholds that are safe and appropriate, and it is not intended to oversimplify the relationship between noise and radiation. The image quality component is included in the measure as a balancing component to the radiation dose thresholds, to ensure that CT image quality does not decrease as an unintended consequence of the measure. We reiterate that the thresholds for radiation doses are size-adjusted to accommodate patients of all sizes. We would like to further emphasize that hospitals should use the measure as a guideline for conducting CT scans while also adjusting noise and radiation doses when necessary to provide quality patient care in special circumstances. The measure seeks to reduce harm from excessive radiation for most patients and should not replace appropriate clinical judgement if adjustments need to be made in select circumstances.

Comment: Several commenters recommended that CMS integrate reporting requirements of this measure between the Hospital OQR Program and the Hospital IQR Program, including considering a single hospital-wide rate rather than distinct inpatient and outpatient measures. A few commenters had concerns about the burden associated with reporting this eCQM as part of the Hospital OQR Program, as HOPDs do not participate individually in the Promoting Interoperability Program and thus do not have options of measures to report. Commenters noted that integrating reporting requirements between programs would reduce burden.

Response: We thank commenters for their recommendations. One of the Meaningful Measures 2.0 goals is to address measurement gaps, reduce burden, and increase efficiency by aligning measures across value-based programs and across partners, including CMS, Federal, and private entities. We note that the Act established the Hospital OQR Program as distinct from the Hospital IQR Program. While measure alignment and coordination between programs remains a priority, the Hospital OQR Program, consistent with specific statutory requirements, measures outpatient department services separate from other hospital services. We will continue to assess our measures to promote alignment between programs.

As we stated previously, the Hospital OQR Program already introduced the STEMI eCQM, and as such, HOPDs already have the capability and the knowledge to submit eCQM data. To help alleviate potential burden, this measure has been proposed in a phased approach after a period of voluntary reporting. During this time, we will continue to monitor and evaluate measure implementation and adjust as necessary in future rulemaking.

Comment: One commenter stated that CMS did not adequately consider references that express concern with the measure's benchmarking approach such as ''Benchmarking CT Radiation Doses Based on Clinical Indications: Is Subjective Image Quality Enough?'' by Mahadevappa Mahesh in Radiology.

Response: We note that this publication is an editorial and not a peer-reviewed source. Additionally, we note that the measure developer, while developing the Excessive Radiation eCQM, reviewed and considered interested party feedback. The measure developer then rigorously tested the measure across 16 inpatient and outpatient hospitals and a large system of outpatient radiology practices (88 FR 27084).

Comment: Two commenters expressed concern with the terminology used in the measure name and believe ''excessive radiation dose'' may raise undue alarm. One commenter recommended renaming the measure to avoid potential misinformation.

Response: We are not planning to change the measure's name. Keeping the measure's name as proposed will allow facilities and consumers to find information about the measure throughout the measure's life, such as the initial proposal to the MUC list.

Comment: A few commenters expressed their belief that the proposal should not be finalized because it is unnecessary due to other regulations and accreditation programs that exist to monitor radiation dose and optimize scanning protocols, including the ACR accreditation, the Joint Commission QC program, and state health department monitoring programs.

Response: We respectfully disagree that the measure is unnecessary. Other regulations and accreditation programs that exist are not standard among outpatient facilities. For example, facilities elect to become accredited by the ACR or Joint Commission QC program, etc. while each state has varying standards. Further, this measure provides additional information not contained in regulations and programs that exist to monitor radiation dose and optimize scanning protocols. First, the measure would allow consumers to compare hospital performance nationwide because the information would be available on the Care Compare website. Second, the Excessive Radiation eCQM, through the Alara Imaging software, is designed to not only monitor performance but also provide feedback to achieve a meaningful reduction in radiation doses.

After considering commenter's recommendations regarding voluntary and mandatory reporting timelines, we are finalizing our proposal to adopt the Excessive Radiation eCQM with modification to extend the Excessive Radiation voluntary reporting period by an additional year such that voluntary reporting would begin with the CY 2025 reporting period, as proposed, and mandatory reporting would begin one year later than proposed with the CY 2027 reporting period/CY 2029 payment determination. The additional year of voluntary reporting would allow time to monitor implementation progress with regards to data collection burden and response rates.

4. Previously Finalized and Newly Finalized Hospital OQR Program Measure Sets

a. Summary of Finalized Hospital OQR Program Measure Set for the CY 2026 Payment Determination

We refer readers to the CY 2023 OPPS/ASC final rule (87 FR 72100 through 72102) for a summary of the previously finalized Hospital OQR Program measure set for the CY 2025 payment determination. Table 128 summarizes the finalized Hospital OQR Program measures for the CY 2026 payment determination:

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TABLE 128: FINALIZED HOSPITAL OQR PROGRAM MEASURE SET FOR THE CY 2026 PAYMENT DETERMINATION

CBE #	Measure Name
0514	MRI Lumbar Spine for Low Back Pain†
None	Abdomen CT – Use of Contrast Material
0669	Cardiac Imaging for Preoperative Risk Assessment for Non-Cardiac, Low-Risk Surgery
0496	Median Time for Discharged ED Patients (Previously referred to as Median Time from ED Arrival to ED Departure for Discharged ED Patients)
0499	Left Without Being Seen†
0661	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	Colonoscopy Follow-Up Interval (Previously referred to as Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients)*
1536	Cataracts Visual Function (Previously referred to as Cataracts: Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery)**
2539	Facility 7-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy
3490	Admissions and Emergency Department (ED) Visits for Patients Receiving Outpatient Chemotherapy
2687	Hospital Visits after Hospital Outpatient Surgery
None	Outpatient and Ambulatory Surgery Consumer Assessment of Healthcare Providers and Systems (OAS CAHPS) – About Facilities and Staff***
None	OAS CAHPS – Communication About Procedure***
None	OAS CAHPS – Preparation for Discharge and Recovery***
None	OAS CAHPS – Overall Rating of Facility***
None	OAS CAHPS – Recommendation of Facility***
3636	COVID–19 Vaccination Coverage Among Health Care Personnel****
None	Breast Cancer Screening Recall Rates
None	ST-Segment Elevation Myocardial Infraction (STEMI) electronic clinical quality measure (eCQM)*****

†We note that CBE endorsement for this measure was removed.

* In this final rule, we are finalizing our proposal to modify the Colonoscopy Follow-Up Interval measure beginning with the CY 2024 reporting period/CY 2026 payment determination.

** In the CY 2023 OPPS/ASC final rule (87 FR 72097 through 72099), we finalized keeping data collection and submission voluntary for the Cataracts Visual Function measure for the CY 2025 reporting period and subsequent years. In this final rule, we are finalizing our proposal to standardize the surveys offered to patients pre- and post-surgery beginning with the CY 2024 reporting period.

*** In the CY 2022 OPPS/ASC final rule (86 FR 63840), we finalized voluntary reporting beginning with the CY 2023 reporting period and mandatory reporting beginning with the CY 2024 reporting period/CY 2026 payment determination.

**** In this final rule, we are finalizing our proposal to modify the COVID–19 Vaccination Coverage Among HCP measure beginning with the CY 2024 reporting period/CY 2026 payment determination.

***** The STEMI eCQM was adopted in the CY 2022 OPPS/ASC final rule (86 FR 63837 through 63840), beginning with voluntary reporting for the CY 2023 reporting period and mandatory reporting beginning with the CY 2024 reporting period/CY 2026 payment determination.

b. Summary of Finalized Hospital OQR Program Measure Set for the CY 2027 Payment Determination and Subsequent Years

Table 129 summarizes the previously finalized and newly finalized Hospital OQR Program measures beginning with the CY 2027 payment determination and subsequent years:

TABLE 129: FINALIZED HOSPITAL OQR PROGRAM MEASURE SET FOR THE CY 2027 PAYMENT DETERMINATION AND SUBSEQUENT YEARS

CBE #	Measure Name
0514	MRI Lumbar Spine for Low Back Pain†
None	Abdomen CT – Use of Contrast Material
0669	Cardiac Imaging for Preoperative Risk Assessment for Non-Cardiac, Low-Risk Surgery
0496	Median Time for Discharged ED Patients (Previously referred to as Median Time from ED Arrival to ED Departure for Discharged ED Patients)
0499	Left Without Being Seen†
0661	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
None	HOPD Procedure Volume (Previously referred to as Hospital Outpatient Department Volume Data on Selected Outpatient Surgical Procedures)*
0658	Colonoscopy Follow-Up Interval (Previously referred to as Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients)
1536	Cataracts Visual Function (Previously referred to as Cataracts: Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery)**
2539	Facility 7-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy
3490	Admissions and Emergency Department (ED) Visits for Patients Receiving Outpatient Chemotherapy
2687	Hospital Visits after Hospital Outpatient Surgery
None	OAS CAHPS – About Facilities and Staff
None	OAS CAHPS – Communication About Procedure
None	OAS CAHPS – Preparation for Discharge and Recovery
None	OAS CAHPS – Overall Rating of Facility
None	OAS CAHPS – Recommendation of Facility
3636	COVID–19 Vaccination Coverage Among Health Care Personnel
None	Breast Cancer Screening Recall Rates
None	ST-Segment Elevation Myocardial Infarction (STEMI) eCQM
None	Risk-Standardized Patient-Reported Outcome-Based Performance Measure (PRO–PM) Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA) in the HOPD Setting (THA/TKA PRO–PM)***
3663e	Excessive Radiation eCQM (Previously referred to as Excessive Radiation Dose or Inadequate Image Quality for Diagnostic Computed Tomography (CT) in Adults eCQM)****

†We note that CBE endorsement for this measure was removed.

* In this final rule, we are finalizing our proposal to re-adopt the HOPD Procedure Volume measure with modification beginning with the voluntary CY 2025 reporting period and mandatory reporting beginning with the CY 2026 reporting period/CY 2028 payment determination.

** In the CY 2023 OPPS/ASC final rule with comment period (87 FR 72097 through 72099), we finalized keeping data collection and submission voluntary for this measure for the CY 2025 reporting period and subsequent years.

***In this final rule, we are finalizing our proposal to adopt the THA/TKA PRO–PM beginning with the voluntary CY 2025 reporting period and with delayed implementation of mandatory reporting beginning with the CY 2028 reporting period/CY 2031 payment determination.

****In this final rule, we are finalizing our proposal to adopt the Excessive Radiation eCQM beginning with the voluntary CY 2025 reporting period and with delayed implementation of mandatory reporting beginning with the CY 2027 reporting period/CY 2029 payment determination.

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5. Maintenance of Technical Specifications for Quality Measures

We refer readers to the CY 2019 OPPS/ASC final rule (83 FR 59104 and 59105) and the CY 2022 OPPS/ASC final rule (86 FR 63861) for our policies regarding maintenance of technical specifications for quality measures. We maintain technical specification manuals that can be found on the CMS website at: *https://qualitynet.cms.gov/outpatient/specifications-manuals.* Technical specifications for eCQMs used in the Hospital OQR Program are contained in the CMS Annual Update for the Hospital Quality Reporting Programs (Annual Update), which are available, along with implementation guidance documents, on the eCQI Resource Center website at: *https://ecqi.healthit.gov/.*

We did not propose any changes to these policies in the CY 2024 OPPS/ASC proposed rule.

6. Public Display of Quality Measures

We refer readers to the CY 2009, CY 2014, CY 2017, and CY 2021 OPPS/ASC final rules (73 FR 68777 through 68779, 78 FR 75092, 81 FR 79791, and 85 FR 86193 through 86236 respectively) for our previously finalized policies regarding public display of quality measures.

We did not propose any changes to these policies in the CY 2024 OPPS/ASC proposed rule.

a. Public Reporting of Median Time for Discharged ED Patients—Transfer Patients and Median Time for Discharged ED Patients—Overall Rate

The Median Time from Emergency Department (ED) Arrival to ED Departure for Discharged ED Patients (Median Time for Discharged ED Patients) measure was adopted for reporting in the Hospital OQR Program beginning with the CY 2013 payment determination (75 FR 72086). The Median Time for Discharged ED Patients measure is a chart-abstracted measure that evaluates the time between the arrival to and departure from the ED, also known as ED throughput time. The Median Time for Discharged ED Patients measure is calculated in stratified subsections for certain types of patients: (1) Median Time for Discharged ED Patients-Reported Measure, which excludes psychiatric/mental health and transferred patients; (2) Median Time for Discharged ED Patients-Psychiatric/Mental Health Patients, which includes information only for psychiatric/mental health patients; and (3) Median Time for Discharged ED Patients-Transfer Patients, which includes information only for patients transferred from the ED; and (4) the Median Time for Discharged ED Patients-Overall Rate. The measure excludes patients who expired in the ED, left against medical advice, or whose discharge was not documented or unable to be determined.

In the CY 2011 OPPS/ASC final rule with comment period (75 FR 72086), we considered publicly displaying all strata; however, due to input from interested parties, we did not finalize public display of Median Time for Discharged ED Patients-Transfer Patients and Median Time for Discharged ED Patients-Overall Rate. Currently, measure data for the Median Time for Discharged ED Patients-Transfer Patients and Median Time for Discharged ED Patients-Overall Rate are not reported publicly on the Care Compare site. Measure data for the Median Time for Discharged ED Patients-Reported Measure is currently publicly displayed on the Care Compare site and in the corresponding downloadable data file for the Hospital OQR Program. We also collect and report Median Time for Discharged ED Patients—Psychiatric/Mental Health Patients for public awareness of behavioral health gaps in the transfer of such patients, and per the CY 2018 OPPS/ASC final rule with comment period (82 FR 59437), we adopted a policy to publicly report these stratified behavioral health data beginning in July 2018 using data from patient encounters during the third quarter of 2017. We now believe displaying all strata will highlight and prioritize various issues in the health care system, specifically behavioral health and continuum of care.

In the CY 2024 OPPS/ASC proposed rule (88 FR 49792), we proposed publicly reporting measure data for Median Time for Discharged ED Patients-Transfer Patients and Median Time for Discharged ED Patients-Overall Rate. Publicly reporting these measure stratifications can elucidate ED throughput performance gaps for patients requiring higher levels of specialized care above what a facility is able to or provide. Data for these measure stratifications are not currently being reported publicly on the Care Compare site.

Under the proposal, beginning with the CY 2024 reporting period, we would make data publicly available on our Care Compare website and in downloadable data files found at *data.cms.gov* for the following chart-abstracted measure strata: Median Time for Discharged ED Patients-Transfer Patients and the Median Time for Discharged ED Patients-Overall Rate which contains data for all patients.

We invited public comment on the proposal.

Comment: One commenter supported public reporting of Median Time for Discharged ED Patients-Transfer Patients and Median Time for Discharged ED Patients-Overall Rate stating that the measure stratifications can elucidate ED throughput performance gaps for patients requiring higher levels of specialized care above what a facility is able to or provide. The commenter further stated that facilities have begun to see more mental health and substance use disorder patients in relation to overall volume of patients and publicly reporting the measure gives visibility to issues in the ED.

Response: We thank the commenter for their support. We agree that public reporting of the Median Discharge Time for Patients-Transfer Patients and Median Time for Discharged ED Patients-Overall Rate will bring to light any existing performance gaps for this patient population. We believe displaying all strata will highlight and prioritize various issues in the health care system.

Comment: Several commenters did not support Public Reporting of Median Time for Discharged ED Patients-Transfer Patients and Median Time for Discharged ED Patients-Overall Rate. A few of these commenters stated that the measure could be affected by many factors (such as ED boarding) which are outside the control of ED, and therefore Median Time for Discharged ED Patients-Transfer Patients and the Median Time for Discharged ED Patients-Overall Rate should not be publicly reported. One commenter stated that CMS should not finalize the proposal to publicly report Median Time for Discharged ED Patients-Transfer Patients and Median Time for Discharged ED Patients-Overall Rate because essential hospitals may lack the reporting infrastructure and staff needed to track and submit the measure accurately and therefore these hospitals need more time to properly develop systems to collect and verify these data points before publicly reporting them on Care Compare.

Response: We thank commenters for their concern. We disagree that Median Time for Discharged ED Patients-Transfer Patients and Median Time for Discharged ED Patients-Overall Rate should not be publicly displayed on the Care Compare website and in the downloadable files. For one, HOPDs are already collecting and reporting this data. Prior to our proposal to publicly report all strata in this measure, HOPDs

had not presented CMS with this issue of lacking reporting infrastructure and staff needed to track and submit the measure accurately. Furthermore, we believe that displaying all strata will highlight and prioritize various issues in the health care system. We believe patients should have access to this data when making decisions about their care.

Comment: A few commenters suggested that CMS remove the Median Time for Discharged ED Patients measure. Commenters stated that Median Time for Discharged ED Patients should be removed due to the influence of factors beyond the control of HOPDs.

Response: One of the Meaningful Measures 2.0 goals is to address measurement gaps, reduce burden, and increase efficiency by using only high-value quality measures impacting key quality domains. As we stated in the CY 2024 OPPS/ASC proposed rule, ED performance and care continues to be a key quality domain of the Hospital OQR Program. Removal of the Median Time for Discharged ED Patients measure would result in an incomplete measure set because there would be no measures that review ED throughput. We continue to believe that the Median Time for Discharged ED Patients measure supports our Meaningful Measures 2.0 goals.

Comment: One commenter suggests that CMS provide context with public reporting of Median Time for Discharged ED Patients about ED discharge delays due to persistent lack of care options, growing workforce shortages, an inability to pay for post-discharge care and administrative delays.

Response: We thank the commenter for their recommendations and will take them into consideration.

After consideration of the public comments we received, we are finalizing our proposal as proposed.

b. Overall Hospital Star Ratings

In the CY 2021 OPPS/ASC final rule (85 FR 86193 through 86236), we finalized a methodology to calculate the Overall Hospital Quality Star Rating (Overall Star Ratings). The Overall Star Ratings utilizes data collected on hospital inpatient and outpatient measures that are publicly reported on a CMS website. We refer readers to the CY 2021 OPPS/ASC final rule (85 FR 86193 through 86236) for our previously finalized policies regarding the Overall Star Ratings.

We did not propose any changes to these policies in the CY 2024 OPPS/ASC proposed rule.

C. Hospital OQR Program Quality Measure Topics for Potential Future Consideration

1. Summary

In the CY 2024 OPPS/ASC proposed rule (88 FR 49792), we sought public comment on potential measurement topic areas for the Hospital OQR Program. The request for comment (RFC) sought input on innovative measurement approaches and data sources for use in quality measurement to inform our work and, more specifically, the focus of measure development within the Hospital OQR Program. We identified three potential priority areas and we encouraged the public to review and provide comment.

2. Background

In the CY 2024 OPPS/ASC proposed rule (88 FR 49792), we sought public comment to address: (1) quality measurement gaps in the HOPD setting, including the ED; (2) changes in outpatient care (such as shifts in volume, technology use, and case complexity); (3) growth of concerns around workforce and patient safety; (4) the transition to digital quality measurement; and (5) interest in patient-reported outcomes.

Specifically, we sought comment on quality measurement topics for the Hospital OQR Program that include:

- Promoting Safety (Patient and Workforce);
- Behavioral Health; and
- Telehealth.

We sought input on the specific questions posed in this RFC.

3. Summary of Comments on Patient and Workforce Safety as a Measurement Topic Area in the Hospital OQR Program

Launched in April 2022, the CMS National Quality Strategy outlines CMS' aim to shape a resilient, high-value healthcare system through quality outcomes, safety, equity, and accessibility for all.[433] Improving safety through levers such as quality measurement is a critical objective of the National Quality Strategy. We acknowledge that promoting safety in order to achieve zero preventable harm requires developing measures that assess and hold healthcare systems accountable to keep individuals safe through preventative and treatment processes. Therefore, in the CY 2024 OPPS/ASC proposed rule, we sought public comment on patient and workforce safety measures. We are particularly interested in sepsis care for potential future inclusion in the Hospital OQR Program as a patient safety measure.

Sepsis is a life-threatening condition which can arise from simple infections (such as pneumonia or a urinary tract infection) and requires prompt recognition and early intervention, which can often occur in an ED.[434] [435] Although sepsis can affect anyone at any age, it is more common in infants, older adults, and patients with chronic health conditions such as diabetes and immunosuppressive disorders.[436] The Centers for Disease Control and Prevention (CDC) estimates annually that there are approximately 1.7 million adults diagnosed with sepsis with 270,000 resulting deaths.[437] Therefore, preventing, diagnosing, and treating sepsis effectively has been a focus of patient safety in recent years.[438] [439]

HOPDs may play a critical role in the initial assessment and evaluation of suspected sepsis patients through lab tests, diagnostic imaging, and collection of sepsis biomarkers.[440] Timely and accurate sepsis diagnosis is essential to effective care. Research shows that performance of evidence-based time-sensitive therapies in EDs can lower the risk of organ dysfunction, reduce mortality, and mitigate the need for mechanical ventilation.[441] [442] [443] In

[433] Schreiber M, Richards AC, Moody-Williams J, et al. (2022). The CMS National Quality Strategy: A Person-Centered Approach to Improving Quality. Available at: *https://www.cms.gov/blog/cms-national-quality-strategy-person-centered-approach-improving-quality.*

[434] McVeigh SE (2020). Sepsis Management in the Emergency Department. *The Nursing clinics of North America,* 55(1), 71–79. *https://doi.org/10.1016/j.cnur.2019.10.009.*

[435] Seymour CW, Gesten F, Prescott HC, et al. (2017). Time to Treatment and Mortality during Mandated Emergency Care for Sepsis. *The New England journal of medicine,* 376(23), 2235–2244. *https://doi.org/10.1056/NEJMoa1703058.*

[436] National Institute of General Medical Sciences (2021). Sepsis. Available at: *https://nigms.nih.gov/education/fact-sheets/Pages/sepsis.aspx.*

[437] Centers for Disease Control and Prevention (2022). What is Sepsis? Available at: *https://www.cdc.gov/sepsis/what-is-sepsis.html.*

[438] Rhee C, Dantes RB, Epstein L, & Klompas M (2019). Using Objective Clinical Data to Track Progress on Preventing and Treating Sepsis: CDC's New 'Adult Sepsis Event' Surveillance Strategy. *BMJ Qual Saf,* 28(4), 305–309. *https://doi.org/10.1136/bmjqs-2018-008331.*

[439] Fay K, Sapiano MRP, Gokhale R, et al. (2020). Assessment of Health Care Exposures and Outcomes in Adult Patients with Sepsis and Septic Shock. *JAMA Netw Open,* 3(7), e206004. *https://doi.org/10.1001/jamanetworkopen.2020.6004.*

[440] Gauer R, Forbes D, & Boyer N (2020). Sepsis: Diagnosis And Management. *American Family Physician,* 101(7), 409–418. *https://www.aafp.org/pubs/afp/issues/2020/0401/p409.html.*

[441] Arabi YM, Al-Dorzi HM, Alamry A, et al. (2017). The Impact of a Multifaceted Intervention Including Sepsis Electronic Alert System and Sepsis Response Team on the Outcomes of Patients with Sepsis and Septic Shock. *Annals of intensive care,* 7(1), 57. *https://doi.org/10.1186/s13613-017-0280-7.*

addition, using an interdisciplinary sepsis-response team to coordinate care in the ED shows potential in improving sepsis care management and enhancing patient outcomes.[444] These findings highlight the role of HOPDs and EDs in the timely diagnosis and treatment of sepsis. Therefore, we believe the Hospital OQR Program may benefit from quality measures centered around sepsis care.

We also believe quality measures should align, to the extent possible, across CMS programs to minimize reporting burden. In the FY 2015 IPPS/LTCH PPS final rule (79 FR 50236 through 50241), we adopted the Severe Sepsis and Septic Shock: Management Bundle measure (CBE #0500) [445] (the Sepsis measure) into the Hospital Inpatient Quality Reporting (IQR) Program beginning with the FY 2015 reporting period/FY 2017 payment determination. In the FY 2024 IPPS/LTCH PPS proposed rule (88 FR 27027 through 27030), we proposed to adopt the Sepsis measure into the Hospital Value-Based Purchasing (HVBP) Program beginning with the FY 2026 program year. The Sepsis measure supports the efficient, effective, and timely delivery of high-quality sepsis care by providing a standard operating procedure for the early risk stratification and management of a patient with severe infection. When the care interventions in the measure are provided as a composite, health systems observe significant reductions in hospital length of stay, readmission rates, and mortality.[446] [447]

In the CY 2024 OPPS/ASC proposed rule (88 FR 49793), we requested comment on whether this measure would be appropriate and feasible for use in the Hospital OQR Program, as well as whether CMS should consider adopting an alternative measure that assesses the quality of sepsis care in the hospital outpatient setting.[448]

Additional safety measures may be needed to adequately monitor and maintain safety in the Hospital OQR Program, such as measurement of system-wide all-cause harm, in addition to the safety of observation care, procedures and services, medication errors, technology, and workforce. Patient and workforce safety are interconnected, as the safety of healthcare workers is critical to maintaining a safe and effective healthcare environment.[449]

We requested input from interested parties on the following topics: (1) safety outcome priorities specific to settings, services, transitions and transfers, and access to care; (2) general cross-outpatient setting outcomes; (3) individual harms, including methodological approaches to patient identification and data collection, technological-derived harm, and use of electronic resources to mitigate potential for harm; and (4) workforce safety. Specifically, we requested comment on the following questions:

- What are interested parties' highest priority outcomes for ensuring safety in the outpatient setting, not limited to the following: overall priorities; priorities for specific settings (for example, EDs, HOPDs) and services (for example, observation care, emergent and non-emergent surgeries, procedures, and imaging); safety related to transitions between care settings; and safety around access to care (for example, a patient who lacks access to life-saving medications such as insulin, epinephrine, albuterol)?
- What outcomes should be measured across all settings within the Hospital OQR Program?
- Individual harms (such as wrong-site surgery) occur at low frequencies, presenting a challenge for the development of risk-adjusted quality measures that can be used to compare facilities. Existing measures in the Hospital OQR Program have used approaches such as the capture of utilization (for example, the Hospital Visits After Hospital Outpatient Surgery Measure (CBE #2687)) to indicate potential harm and longer measurement periods to improve measurement reliability.

++ Are there other methodological approaches or data that we could use to identify harm to patients receiving care in the outpatient setting?

++ What approaches could we use to capture harms associated with outpatient services (HOPD procedures, ED visits, outpatient clinic visits, outpatient imaging)?

++ How could electronic data sources or monitoring systems be leveraged to gather timely data on such errors?

- What aspects of workforce safety are important for us to consider for the Hospital OQR Program?
- As new technology becomes available and is used more widely (such as artificial intelligence (AI) for diagnoses, robotic surgery, and electronic health records (EHRs)), there is a potential for these technologies or their application to cause harm to patients. For example, AI algorithms trained on data that is under representative of certain racial, ethnic, or gender groups may misdiagnosis these same populations.[450] At the same time, technology could also be leveraged to mitigate AI risks, improve safety, or facilitate quality measurement.

++ Which technologies are of the most concern in terms of potential for harm?

++ What measurable safety-related outcomes should CMS consider for the Hospital OQR Program?

++ What technologies could be leveraged to improve safety or facilitate its measurement?

We received comments on this topic.

Comment: Many commenters provided feedback and recommendations to measure and assess the quality of sepsis care in the hospital outpatient setting that could potentially support the foundation of patient safety established in the Hospital OQR Program. While these commenters did not specifically reference implementation of the Severe Sepsis and Septic Shock: Management Bundle measure (CBE #0500) in the Hospital OQR Program, commenters generally supported the intent of this measure and believed increased focus on sepsis care will help patient safety in the outpatient program.

[442] Whiles BB, Deis AS, & Simpson SQ (2017). Increased Time to Initial Antimicrobial Administration is Associated With Progression to Septic Shock in Severe Sepsis Patients. *Critical care medicine,* 45(4), 623–629. *https://doi.org/10.1097/CCM.0000000000002262.*

[443] Gavelli F, Castello LM, & Avanzi GC (2021). Management of Sepsis and Septic Shock in the Emergency Department. *Internal and emergency medicine.* 16(6), 1649–1661. *https://doi.org/10.1007/s11739-021-02735-7.*

[444] Delawder JM, & Hulton L (2020). An Interdisciplinary Code Sepsis Team to Improve Sepsis-Bundle Compliance: A Quality Improvement Project. *Journal of emergency nursing,* 46(1), 91–98. *https://doi.org/10.1016/j.jen.2019.07.001.*

[445] In previous years, we referred to the consensus-based entity by corporate name. We have updated this language to refer to the consensus-based entity more generally.

[446] Levy MM, Gesten FC, Phillips GS, et al. (2018). Mortality Changes Associated with Mandated Public Reporting for Sepsis: The Results of the New York State Initiative. *Am J Respir Crit Care Med,* 198(11), 1406–1412. *https://doi.org/10.1164/rccm.201712-2545OC.*

[447] Bauer SR, Han X, Wang XF, et al. (2020). Association Between Compliance with the Sepsis Quality Measure (SEP–1) and Hospital Readmission. *Chest,* 158(2), 608–611. *https://doi.org/10.1016/j.chest.2020.02.042.*

[448] Centers for Medicare & Medicaid Services (2023). Sepsis Bundle Project (SEP) National Hospital Inpatient Quality Measures. Available at: *https://qualitynet.cms.gov/files/6391e95676962e0016ad9199?filename=2a-b_SEP-List_v5.14.pdf.*

[449] McGaffigan P, Gerwig K, & Kingston MB (2020). Workforce Safety Key to Patient Safety. *Healthcare Executive.* 35(6), 48–50. *https://www.ihi.org/resources/Pages/Publications/workforce-safety-key-to-patient-safety.aspx.*

[450] Thomas, LB, Mastorides, SM, Viswanadhan, NA, et al. (2021). Artificial Intelligence: Review of Current and Future Applications in Medicine. *Federal practitioner: for the health care professionals of the VA, DoD, and PHS,* 38(11), 527–538. *https://doi.org/10.12788/fp.0174.*

Several commenters expressed concerns regarding the administrative burden related to chart abstraction. A few commenters stated their belief that the Sepsis measure contributes to antibiotic overuse. Other commenters noted that certain elements of the Sepsis measure are not appropriate for the outpatient setting. One commenter specifically noted that the denominator population would be too small. Another commenter opposed the measure, expressing their belief that hospitals participating in the Hospital Value-Based Purchasing program may deliberately designate some inpatient sepsis cases as outpatient to avoid incurring monetary penalties. Another commenter noted that the measure requires adherence to a standardized protocol and may not provide flexibility for individually tailored care. One commenter questioned how stays would be characterized or attributed to a setting for quality reporting purposes if hospitals were required to report on the Sepsis measure for both their inpatient and outpatient care.

A few commenters shared recommendations of alternative sepsis care measures. These recommendations included measures targeted at prevention of sepsis onset, as well as early and accurate sepsis identification. One commenter recommended that CMS more broadly measure healthcare associated infections and encouraged analysis to identify the infections most pertinent to the HOPD setting, noting that given the high volume of surgical procedures in this setting, surgical site infections may be a suitable candidate topic for a quality metric.

A few commenters shared general considerations when assessing the quality of sepsis care in the hospital outpatient setting. One commenter encouraged CMS to gather sufficient evidence from use of the Sepsis measure under the Hospital IQR Program prior to adopting the measure in the outpatient setting. Another commenter requested that CMS pay particular attention to racial disparities in regard to sepsis care. One commenter urged CMS to consider other targeted solutions that better addresses current patient safety challenges, including those exposed during the recent Public Health Emergency.

Response: We thank commenters for their input and acknowledge their concerns and recommendations. We will take commenters' feedback into consideration in future rulemaking related to quality measurement of sepsis care, including the importance of addressing health equity in the Hospital OQR Program.

Comment: Many commenters supported efforts to address patient and workforce harms through data-driven and actionable quality measurement. Commenters shared their highest priorities in developing measures targeted at patient harm in the outpatient setting, including harms associated with ED boarding, radiation exposure, and preventing low-value care. Highlighted outcomes for workforce safety included work-related illness, injury, and workplace violence. A few commenters recommended that CMS support research to better understand the implications of the COVID–19 pandemic on safety in the healthcare system overall.

Commenters also shared recommendations for potential measures to advance patient safety. A few commenters recommended measures that assess avoidable readmissions, repeat visits, and use of inappropriate services. One commenter recommended adoption of Hospital Visits after Orthopedic ASC Procedures (CBE #3470) and Hospital Visits after Urology ASC Procedures (CBE #3366). Another commenter recommended measures of DVT prophylaxis, medical errors, and in-facility accidents, such as patient falls.

In addition, commenters provided recommendations for methodological approaches to identifying patient harm in the outpatient setting. A few commenters recommended that CMS leverage the CDC's National Healthcare Safety Network (NHSN) to accurately measure hospital-acquired infection at the HOPD level. A few commenters also encouraged CMS to utilize all-payer data for more accurate measurement of patient harms. One commenter suggested capturing harm via a claims-based measure, while another commenter advocated for additional PRO–PMs. As a means of examining disparities in patient safety, one recommended stratifying patient safety measures by social risk factors.

Several commenters acknowledged harms resulting from the proliferation of AI in the healthcare space. A few commenters highlighted the potential risk of AI bias, which commenters believed can lead to improper diagnosis or inappropriate care delivery in underserved populations, further exacerbating disparities in patient outcomes. One commenter suggested that CMS dedicate more resources to understanding these disparities. In addition, several commenters suggested increased stakeholder engagement efforts, such as multi-disciplinary panels to fully consider the potential harms and benefits associated with high impact technologies. Other commenters acknowledged the role AI technology can play in improving safety and creating a more equitable system. One commenter noted that AI has been demonstrated to reduce time to care. A few comments highlighted AI's potential to offer accuracy that may reduce repeat and inappropriate care.

A few commenters urged that, when possible, CMS align its work with other proponents of patient safety and collaborate with Federal partners on safety-focused measures. A few commenters recommended that CMS explore measurement approaches in line with the Joint Commission's National Patient Safety Goals. Other commenters encouraged CMS to coordinate with the Centers for Disease Control and Prevention (CDC) and the Occupational Safety and Health Administration (OSHA) to align quality measurement efforts and advance the well-being of the healthcare workforce.

Several commenters highlighted barriers to developing and implementing quality measurement of workforce safety, including the potential administrative burden to report and track workforce safety metrics, the dearth of workplace violence data, the potential interplay of measures with Federal policies, and factors outside of the hospital's control that may contribute to workplace violence.

Response: We thank the commenters for their input and recommendations. We believe efforts to mitigate patient and workforce harms are critical to achieving our vision of shaping a high-value health care system that delivers high-quality, safe,andequitable care for all. We acknowledge the critical but complicated nature of AI technology and appreciate all input on this topic. We will consider all comments in any future rulemaking related to safety quality measurement in the Hospital OQR Program.

4. Summary of Comments on Behavioral Health and Suicide Prevention in the Hospital OQR Program

Behavioral healthcare in the outpatient setting comprises a vast array of services for patients with a wide range of conditions. Behavioral health services are delivered in multiple settings by multiple types of providers, including but not limited to HOPDs, through partial observation, and in the ED.

Quality gaps in the area of hospital outpatient behavioral health include care coordination across settings, availability of services, and barriers to accessing services. In this RFC, we are seeking comment from interested parties

on behavioral health topics based in part on work by the National Quality Forum (NQF), The National Committee for Quality Assurance (NCQA), and the CMS Behavioral Health Strategy.[451] [452] [453] Behavioral health topics under consideration for measure development in the hospital outpatient setting include: availability and access, coordination of care, patient experience, patient-centered clinical care, prevention and treatment of chronic conditions, prevention of iatrogenic harm (that is, harm resulting from medical care), equity across all domains, and suicide prevention. We are particularly interested in measuring suicide screening in the hospital outpatient setting to improve early risk detection and facilitate appropriate behavioral health treatment.

Suicide is a serious but preventable public health threat and is one of the leading causes of death in the United States.[454] In 2020, about 46,000 Americans died as a result of suicide and 12.2 million adults experienced suicidal ideation.[455] Individuals with a recorded depressive disorder are about five times more likely to die by suicide after adjusting for sociodemographic factors and other mental health diagnoses than individuals without a recorded mental health condition.[456] Many factors contribute to suicide risk, including Major Depressive Disorder (MDD) diagnosis.[457] [458] MDD is a significant risk factor for suicide, indicating that patients with MDD are a critical population for intervention efforts.[459]

Research shows that in the weeks, months, and year prior to suicide, individuals significantly utilized healthcare services, providing an opportunity for assessment and prevention in the clinical setting.[460] Nineteen percent of individuals who died by suicide with a recorded mental health diagnosis visited the ED within one year prior to their death while 7.5 percent visited the ED within 1 month.[461] HOPDs may be an opportune setting for detecting suicide risk in persons with mental health diagnoses, such as MDD, and reducing the overall suicide rate. ED-initiated suicide prevention efforts can meaningfully reduce suicide attempts in individuals that are screened and receive evidence-based care.[462]

Under the Merit-based Incentive Payment System (MIPS), we adopted the Adult Major Depressive Disorder (MDD): Suicide Risk Assessment measure (CBE #0104). This measure aims to improve clinical assessment of suicide risk where a new or recurrent episode of MDD is identified and may be beneficial in the Hospital OQR Program. In the CY 2024 OPPS/ASC proposed rule (88 FR 49795), we requested comment on this specific measure example, including whether interested parties believe this measure would be appropriate and feasible for use in the Hospital OQR Program, as well as other measures, such as a universal screening measure. More than half of those who die by suicide do not have a recorded mental health diagnosis.[463] Universal suicide screening may improve identification of individuals who may not otherwise have been identified as at risk.[464]

Additional measures may be needed to adequately promote screening and treatment of behavioral health disorders in the outpatient setting. For example, measures geared towards prevention and treatment of substance use disorders. In 2021, 17.3 percent of adults over the age of 18 met the criteria for substance use disorder for drugs or alcohol.[465] Outpatient screening of substance use disorders through tools such as SAMHSA's Screening, Brief Intervention, and Referral to Treatment (SBIRT) may aid the early intervention and treatment for persons with substance use disorders and help identify those at risk of developing such disorders.[466] [467] We sought comment on whether screening for substance use disorders would be an appropriate measure topic for the Hospital OQR Program.

Furthermore, we sought broad input on behavioral health as a measurement topic area in the Hospital OQR Program based on, but not limited to, the following matters: (1) priorities for measuring outcomes of outpatient behavioral health services, particularly by setting within the HOPD; and (2) quality measure approaches to improve behavioral health access in outpatient settings. Specifically, we requested comment from interested parties on the following questions:

- Are there additional behavioral health topic areas that we should prioritize? Of the topics outlined in this RFC (availability and access, coordination of care, patient experience, patient-centered clinical care, prevention and treatment of chronic conditions, prevention of iatrogenic harm, equity across all domains, and

[451] National Quality Forum (2022). Opioid-Related Outcomes Among Individuals with Co-occurring Behavioral Health Conditions. Available at: *https://www.qualityforum.org/Projects/n-r/Opioids_and_Behavioral_Health_Committee/2022_Final_Report.aspx#onclick=%E2%80%9D_gaq.push([%E2%80%98_trackEvent%E2%80%99,%E2%80%99Download%E2%80%99,%E2%80%99PDF%E2%80%99,this.href]);%E2%80%9DUsing.* No ''Measurement to Promote Joint Accountability and Whole-Person Care''.

[452] The National Committee for Quality Assurance (2021). Behavioral Health Quality Framework: A Roadmap for Using Measurement to Promote Joint Accountability and Whole-Person Care. Available at: *https://www.ncqa.org/wp-content/uploads/2021/07/20210701_Behavioral_Health_Quality_Framework_NCQA_White_Paper.pdf.*

[453] Centers for Medicare & Medicaid Services (2022). CMS Behavioral Health Strategy. Available at: *https://www.cms.gov/cms-behavioral-health-strategy.*

[454] Centers for Disease Control and Prevention (2022). Facts About Suicide. Available at: *http://www.cdc.gov/suicide/facts/index.html.*

[455] Centers for Disease Control and Prevention (2022). Suicide Prevention. Available at: *http://www.cdc.gov/suicide/index.html.*

[456] Yeh HH, Westphal J, Hu Y, et al. (2019). Diagnosed Mental Health Conditions and Risk of Suicide Mortality. *Psychiatric services (Washington, DC),* 70(9), 750–757. *https://doi.org/10.1176/appi.ps.201800346.*

[457] Ibid.

[458] Cai H, Xie XM, Zhang Q, et al. (2021). Prevalence of Suicidality in Major Depressive Disorder: A Systematic Review and Meta-Analysis of Comparative Studies. Frontiers in psychiatry, 12, 690130. *https://doi.org/10.3389/fpsyt.2021.690130.*

[459] Moitra M, Santomauro D, Degenhardt L, et al. (2021). Estimating the Risk of Suicide Associated with Mental Disorders: A Systematic Review and Meta-regression Analysis. *Journal of psychiatric research,* 137, 242–249. *https://doi.org/10.1016/j.jpsychires.2021.02.053.*

[460] Miller IW, Camargo CA, Arias SA, et al. (2017). Suicide Prevention in an Emergency Department Population: The ED–SAFE Study. *JAMA psychiatry,* 74(6), 563–570. *https://doi.org/10.1001/jamapsychiatry.2017.0678.*

[461] Ahmedani BK, Simon GE, Stewart C, et al. (2014). Health Care Contacts in the Year Before Suicide Death. *J Gen Intern Med,* 29, 870–877. *https://doi.org/10.1007/s11606-014-2767-3.*

[462] Miller IW, Camargo CA, Arias SA, et al. (2017). Suicide Prevention in an Emergency Department Population: The ED–SAFE Study. *JAMA psychiatry,* 74(6), 563–570. *https://doi.org/10.1001/jamapsychiatry.2017.0678.*

[463] Stone DM, Simon TR, Fowler KA, et al. (2018) Vital Signs: Trends in State Suicide Rates—United States, 1999–2016 and Circumstances Contributing to Suicide—27 States, 2015. *MMWR,* 67, 617–624. *http://dx.doi.org/10.15585/mmwr.mm6722a1.*

[464] Boudreaux ED, Camargo CA, Arias SA, et al. (2016). Improving Suicide Risk Screening and Detection in the Emergency Department. *American Journal of Preventive Medicine,* 50(4), 445–453. *https://doi.org/10.1016/j.amepre.2015.09.029.*

[465] Substance Abuse and Mental Health Services Administration (2021). Table 5.1B—Substance Use Disorder for Specific Substances in Past Year: Among People Aged 12 or Older; by Age Group, Percentages, 2021. Available at: *https://www.samhsa.gov/data/sites/default/files/reports/rpt39441/NSDUHDetailedTabs2021/NSDUHDetailedTabs2021/NSDUHDetTabsSect5pe2021.htm.*

[466] Substance Abuse and Mental Health Services Administration (2022). Screening, Brief Intervention, and Referral to Treatment (SBIRT). Available at: *https://www.samhsa.gov/sbirt.*

[467] O'Connor EA, Perdue LA, Senger, CA, et al. (2018). Screening and Behavioral Counseling Interventions to Reduce Unhealthy Alcohol Use in Adolescents and Adults: Updated Evidence Report and Systematic Review for the US Preventive Services Task Force. JAMA, 320(18), 1910–1928. *https://doi.org/10.1001/jama.2018.12086.*

suicide prevention), which are the highest priority? What are the most relevant quality gaps and outcomes related to behavioral health for hospital outpatient settings and services?

- Access is one of the biggest challenges around improving behavioral health outcomes. What measurement approaches could be used to drive improvements in access to services?
- Should CMS consider substance use disorder-related screening and counseling measures in regards to behavioral health outcomes for the outpatient setting, and, if so, what specific quality measures should CMS include?
- Should CMS consider a measure related to universal suicide risk in the ED? Are there other interventions or measurement approaches targeted at suicide prevention that CMS should consider?

We received comments on this topic.

Comment: Many commenters supported efforts to expand screening and treatment of behavioral health in the outpatient setting. Priority areas included suicide screening and prevention, access to medication assisted treatment for substance use disorder patients, referrals to appropriate follow-up care, crisis care, and patient-centered, interdisciplinary management of patients with psychiatric disorders. A few commenters underscored barriers to behavioral healthcare, such as cost, insurance coverage, and mental health provider shortages. To address these barriers to patient care, commenters recommended that CMS partner with policymakers for broader intervention.

Commenters also shared recommendations for potential measures that assess behavioral health quality. One commenter suggested that CMS monitor whether patients are referred to appropriate follow-up care. A few commenters recommended measures of patient experience and suggested that CMS convene stakeholders from all domains to inform measure development. One commenter urged CMS to focus its development on outcomes measures, including patient-reported outcome measures, rather than patient experience measures.

Commenters generally supported efforts to expand suicide screening. A few commenters believed universal suicide screening to be clinically appropriate and logistically feasible for the HOPD setting. One commenter noted their belief that the ED is often the main avenue of care for patients without primary care providers, thus a universal screening measure could improve identification and treatment of behavioral health conditions within this patient population. Another commenter recommended two suicide assessment tools believed to be clinically effective and low burden: the Safety Planning Intervention (SPI) and the Post-Discharge Telephonic Follow-up Contacts Intervention (FCI).

A few commenters recommended that CMS examine existing reporting requirements related to behavioral health to avoid duplication and advance alignment across programs. Suggestions for alignment included the National Committee for Quality Assurance's (NCQA) Healthcare Effectiveness Data and Information Set (HEDIS) and the Core Quality Measures Collaborative (CQMC). One commenter suggested research to understand how behavioral healthcare delivery has changed, so as to better tailor development of measures. The commenter recommended only adopting measures that are CBE-approved.

Regarding substance use disorder screening and counseling for the outpatient setting, one commenter expressed their belief that these measure topics are more appropriate in inpatient and primary care settings. The commenter also noted that if CMS is to further explore a disorder-related screening measure, they suggested using the Alcohol Use Disorders Identification Test (AUDIT) or AUDIT–C tool and the Drug Abuse Screening Test (DAST).

A few commenters did not believe a universal suicide screening measure to be appropriate for the HOPD setting due to commenters' desires for a more patient-specific screening approach, claims of limited evidence pointing to the measure's success, and concerns that universal screening would heighten strains in the ED. One commenter recommended that CMS narrow its detection and prevention efforts to patients for whom the Joint Commission requires such screening.

A few commenters did not believe the MDD: Suicide Risk Assessment measure to be appropriate for the HOPD setting, due to concerns of the measure's lack of CBE endorsement and beliefs that the measure is more appropriate for the ASC setting.

Response: We thank the commenters for their meaningful input and commitment to addressing quality gaps in the area of hospital outpatient behavioral health. We believe these approaches to continually improve behavioral health in outpatient settings will drive improvements in behavioral health outcomes. We will consider these comments in any future rulemaking related to outpatient behavioral health quality measurement in the Hospital OQR Program.

5. Summary of Comments on Telehealth as a Measurement Topic Area in the Hospital OQR Program

We define telehealth as the provision of healthcare services through two-way, real-time interactive telecommunications technology between patients and providers who are located at a distant site.[468] Telemedicine has the potential to improve patient experience, outcomes, and access to healthcare.[469] Telemedicine is also associated with cost-savings for both patients and healthcare systems.[470] [471] Telehealth utilization expanded greatly in the outpatient setting during the early months of the SARS–CoV–2 pandemic.[472] The number of outpatient visits conducted via telehealth has since declined but remains higher than pre-pandemic levels.[473]

While telehealth provides a variety of benefits to patients and health systems, there is variability in telehealth's effectiveness across different outpatient services as some conditions may necessitate in-person physical examination or diagnostic testing.[474] [475] There are also known disparities in the effectiveness of telehealth and its impact on outcomes as certain populations lack access to internet and digital devices, or lack familiarity with technology.[476] [477]

[468] Telehealth Services, 42 CFR 410.78. Available at: *https://www.ecfr.gov/current/title-42/chapter-IV/subchapter-B/part-410/subpart-B/section-410.78.*

[469] Corbett, JA, Opladen, JM, & Bisognano, JD (2020). Telemedicine can revolutionize the treatment of chronic disease. *International Journal of Cardiology. Hypertension,* 7, 100051. *https://doi.org/10.1016/j.ijchy.2020.100051.*

[470] American Health Association (2016). Telehealth: Helping Hospitals Deliver Cost-Effective Care. Available at: *https://www.aha.org/system/files/content/16/16telehealthissuebrief.pdf.*

[471] Patel KB, Turner K, Alishahi TA, et al. (2023). Estimated Indirect Cost Savings of Using Telehealth Among Nonelderly Patients With Cancer. *JAMA network open,* 6(1), e2250211. *https://doi.org/10.1001/jamanetworkopen.2022.50211.*

[472] Lo, J, Rae M, Amin, K, & Cox C (2022). Outpatient telehealth use soared early in the COVID–19 pandemic but has since receded. *Peterson-KFF Health System Tracker.* Available at: *https://www.healthsystemtracker.org/brief/outpatient-telehealth-use-soared-early-in-the-covid-19-pandemic-but-has-since-receded/.*

[473] Ibid.

[474] Patel SY, Mehrotra A, Huskamp HA, et al. (2021). Variation in Telemedicine Use and Outpatient Care During The COVID–19 Pandemic in the United States. *Health affairs (Project Hope),* 40(2), 349–358. *https://doi.org/10.1377/hlthaff.2020.01786.*

[475] Koonin LM, Hoots B, Tsang CA, et al. Trends in the Use of Telehealth During the Emergence of the COVID–19 Pandemic—United States, January–March 2020. *MMWR Morb Mortal Wkly Rep* 2020;69:1595–1599. *http://dx.doi.org/10.15585/mmwr.mm6943a3.*

[476] Ibid.

For the Hospital OQR Program, we are considering a measure focused on telehealth quality based on a framework developed by the CBE.[477] [478] This framework was chosen because it offers a comprehensive guide for developing telehealth measures under four domains: access, effectiveness, experience, and equity. In the CY 2024 OPPS/ASC proposed rule (88 FR 49795), we sought input from interested parties on the following topics: (1) inclusion and prioritization of areas of telehealth-related care, and in particular those priority topic areas discussed above; (2) addressing quality gaps in outpatient telehealth-related care, including across HOPD settings and services; (3) capturing utilization, and disparities resulting from utilization, of telehealth-related care for outpatient settings and services; and (4) understanding patient experience with outpatient telehealth services. Specifically, we requested comment from interested parties on the following questions:

- In reference to the telehealth-related topics outlined above, are there additional matters that we should prioritize for the Hospital OQR Program? Which subjects are of the highest priority?
- What do commenters believe are the most relevant clinical issues addressable through telehealth in outpatient settings, and gaps in care that telehealth can address?
- What are the highest priority concerns regarding disparities in access, use, or outcomes related to telehealth in the outpatient setting? Are there any settings or services that should be prioritized?
- Which existing outpatient quality measures should be stratified by telehealth as the mode of delivery?
- What are the most relevant patient-experience-related telehealth outcomes that should be measured?

We received comments on this topic.

Comment: Many commenters supported further development of measures that assess telehealth care quality in the Hospital OQR Program. Commenters believed advancing and evaluating healthcare outcomes and effectiveness of telehealth quality of care will inform broader adoption of telehealth to meet its potential to transform the health care delivery system and access to care. Priority areas highlighted by commenters included check-ins following surgery, follow-up appointments that do not require physical ''laying of hands'' via an in-person visit, remote patient monitoring, management of chronic conditions, and virtual behavioral health and substance use treatment.

Commenters also provided many recommendations for focus areas for a potential measure that assesses telehealth care quality in the Hospital OQR Program. These included recommendations regarding understanding patient experience with telehealth, including measurement of patient-centeredness of care, ease of use, timeliness, and shared decision-making. One commenter recommended that, since patient experience evaluation of telehealth should be treated the same as other care settings, the same questions on patients' experience should be asked. Additional recommendations focused on technical delivery aspects such as quality measurement of platforms used and connection issues.

Commenters additionally provided recommendations for stratifying outpatient quality measures by telehealth as mode of delivery. These included outpatient quality measures for required follow-up appointments, antibiotic prescription rates, and screening tools such as Patient Health Questionnaire-9 (PHQ9) and Generalized Anxiety Disorder-7 (GAD–7). A few commenters recommended focusing evaluation efforts on the influence of telehealth on ED visits and readmissions, wait times, time spent with providers, intermediate patient outcomes, such as rates of complications, and concordance with treatment plans.

Many commenters highlighted priority concerns regarding disparities in access, use, or outcomes related to telehealth in the outpatient setting. These focused on areas to close gaps in care using telehealth and included prioritizing access to quality maternal health during the perinatal period to decrease the number of maternal deaths among all women, addressing the variance in accessibility (internet, appropriate devices) and telehealth treatment options, focusing on rural and rural emergency settings, and addressing low digital health literacy, particularly among older adults. Other commenters encouraged focusing on utilizing frameworks and guidance available from the Americans with Disabilities Act (ADA) and the HHS Office for Civil Rights to ensure equitable care for those in need of interpretive services and ADA compliance services.

Commenters provided recommendations to address quality gaps in outpatient telehealth-related care, including across HOPD settings and services. Gaps in care highlighted included expanding access to continuous glucose monitors to patients and the supportive elements that ensure interoperability between patient devices and EHRs, as well as development of a payment structure that provides a bridge for young adults to obtain telehealth services for mental health and substance use disorders. A few commenters highlighted the ways in which telehealth closes gaps in care for their outpatient systems such as tele-stroke services, as well as how it allows facilities to scale across geography. Commenters also noted that virtual care supports rural and smaller facilities that do not have the volume or budget to support many specialty services.

Response: We thank the commenters for their input and appreciate the many thoughtful responses on practices being utilized in facilities across our nation and the commitment to delivering high quality care using telehealth in outpatient settings. We believe these efforts to continually improve access to the highest quality of care through all modes of care delivery will help inform improvements to achieve our vision of being a high-value American health care system that delivers high-quality, safe, and equitable care for all. We will consider these comments in any future rulemaking related to telehealth quality measurement in the Hospital OQR Program.

D. Administrative Requirements

1. Requirements Regarding Hospital OQR Program Participation Status

We refer readers to § 419.46(b) for our current policies regarding participation in the Hospital OQR Program, including security official and system registration requirements. In the CY 2024 OPPS/ASC proposed rule (88 FR 49796), we proposed to amend our participation regulation codified at § 419.46(b)(1) and (2) to replace references to ''QualityNet'' with ''CMS-designated information system'' or ''CMS website,'' and to make other conforming technical edits, to accommodate recent and future systems requirements and mitigate confusion for program participants.

We invited public comment on the proposal.

We received no comments on the proposal. We are finalizing our proposal as proposed.

[477] Roberts ET & Mehrotra A (2020). Assessment of Disparities in Digital Access Among Medicare Beneficiaries and Implications for Telemedicine. *JAMA internal medicine,* 180(10), 1386–1389. *https://doi.org/10.1001/jamainternmed.2020.2666.*

[478] National Quality Forum (2021). Rural Telehealth and Healthcare System Readiness Measurement Framework—Final Report. Available at: *https://www.qualityforum.org/Publications/2021/11/Rural_Telehealth_and_Healthcare_System_Readiness_Measurement_Framework_-_Final_Report.aspx.*

2. Modified Requirements Regarding Hospital OQR Program Withdrawal

We refer readers to § 419.46(c) for our policies regarding requirements for withdrawal from the Hospital OQR Program. In the CY 2024 OPPS/ASC proposed rule (88 FR 49796), we proposed to amend our withdrawal policy codified at § 419.46(c) to replace references to ''QualityNet'' with ''CMS-designated information system'' or ''CMS website,'' and to make other conforming technical edits, to accommodate recent and future systems requirements and mitigate confusion for program participants.

We invited public comment on the proposal.

We received no comments on the proposal. We are finalizing our proposal as proposed.

E. Form, Manner, and Timing of Data Submitted for the Hospital OQR Program

Previously finalized quality measures and information collections discussed in this section were approved by the Office of Management and Budget (OMB) under control number 0938–1109 (expiration date February 28, 2025).[479] An updated PRA package reflecting the updated information collection requirements related to the finalized proposals set forth in this final rule will be submitted for approval under the same OMB control number.

1. Hospital OQR Program Annual Submission Deadlines

We refer readers to § 419.46(d) for our policies regarding clinical data submission deadlines. In the CY 2023 OPPS/ASC final rule (87 FR 72110 through 72112), we finalized alignment of the patient encounter quarters for chart-abstracted measures with the calendar year beginning with the CY 2024 reporting period/CY 2026 payment determination. To facilitate this process, we finalized transitioning to the new timeframe for the CY 2026 payment determination and subsequent years and use only three quarters of data for chart-abstracted measures in determining the CY 2025 payment determination as illustrated in the Tables 130 and 131 (87 FR 44734).

TABLE 130: FINALIZED CY 2025 PAYMENT DETERMINATION*(FUTURE STATE—TRANSITION PERIOD)

Patient Encounter Quarter	Clinical Data Submission Deadline
Q2 2023 (April 1 - June 30)	11/1/2023**
Q3 2023 (July 1 – September 30)	2/1/2024**
Q4 2023 (October 1 - December 31)	5/1/2024**

* 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.

**The August 1st, November 1st, February 1st, and May 1st deadlines are recurring.

TABLE 131: FINALIZED CY 2026 PAYMENT DETERMINATION* (FUTURE STATE)

Patient Encounter Quarter	Clinical Data Submission Deadline
Q1 2024 (January 1 - March 31)	8/1/2024**
Q2 2024 (April 1 - June 30)	11/1/2024**
Q3 2024 (July 1 – September 30)	2/1/2025**
Q4 2024 (October 1 - December 31)	5/1/2025**

*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.

**The August 1st, November 1st, February 1st, and May 1st deadlines are recurring.

In the CY 2024 OPPS/ASC proposed rule (88 FR 49797), we proposed to amend our submission deadline codified at § 419.46(d)(2) to replace references to ''QualityNet'' with ''CMS-designated information system'' or ''CMS website,'' and to make other conforming technical edits, to accommodate recent and future systems requirements and mitigate confusion for program participants.

We invited public comment on the proposal.

We received no comments on the proposal. We are finalizing our proposal as proposed.

2. Requirements for Chart-Abstracted Measures Where Patient-Level Data are Submitted Directly to CMS

We refer readers to the CY 2013 OPPS/ASC final rule (77 FR 68481 through 68484) and the CMS website, currently available at *https://qualitynet.cms.gov,* for a discussion of

[479] Office of Management and Budget. Office of Information and Regulatory Affairs. Available at: *https://www.reginfo.gov/public/do/PRAOMBHistory?ombControlNumber=0938-1109.*

the requirements for chart-abstracted measure data submitted via the HQR System (formerly referred to as the QualityNet Secure Portal) for the CY 2014 payment determination and subsequent years.

We did not propose any changes to these policies in the CY 2024 OPPS/ASC proposed rule.

3. Claims-Based Measure Data Requirements

We refer readers to the CY 2019 OPPS/ASC final rule with comment period (83 FR 59106 and 59107), where we established a 3-year reporting period for the Facility 7-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy measure beginning with the CY 2020 payment determination. We refer readers to the CY 2022 OPPS/ASC final rule with comment period (86 FR 63863) where we finalized a 3-year reporting period for the Breast Cancer Screening Recall Rates measure.

We did not propose any changes to these policies in the CY 2024 OPPS/ASC proposed rule.

4. Data Submission Requirements for the Outpatient and Ambulatory Surgery Consumer Assessment of Healthcare Providers and Systems (OAS CAHPS) Survey-Based Measure

We refer readers to the CYs 2017, 2018, and 2022 OPPS/ASC final rules with comment period (81 FR 79792 through 79794; 82 FR 59432 and 59433; and 86 FR 63863 through 63866, respectively) for a discussion of the previously finalized requirements related to survey administration and vendors for the OAS CAHPS Survey-based measure. For more information about the modes of administration, we refer readers to the OAS CAHPS Survey website: *https://oascahps.org/.*

We did not propose any changes to these policies in the CY 2024 OPPS/ASC proposed rule.

5. Data Submission Requirements for Measures Submitted via a Web-Based Tool

a. Background

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 website, currently at available at *https://qualitynet.cms.gov,* for a discussion of the requirements for measure data submitted via the HQR System (formerly referred to as the QualityNet Secure Portal) for the CY 2017 payment determination and subsequent years. The information collections finalized in the aforementioned final rules were approved under OMB control number 0938–1109 (expiration date February 28, 2025).[480] The HQR System is safeguarded in accordance with the HIPAA Privacy and Security Rules to protect submitted patient information. See 45 CFR parts 160 and 164, subparts A, C, and E, for more information.

We did not propose any changes to these policies in the CY 2024 OPPS/ASC proposed rule.

b. HOPD Procedure Volume Measure Reporting and Data Submission Requirements

In section XIV.B.3.a of this final rule with comment period, we did not finalize our proposal to re-adopt the HOPD Procedure Volume measure with modification, beginning with the voluntary CY 2025 reporting period followed by mandatory reporting beginning with the CY 2026 reporting period/CY 2028 payment determination. We proposed that hospitals would submit these data to CMS during the time period of January 1 to May 15 in the year prior to the affected payment determination year. For example, for the CY 2025 reporting period, the submission period to report the data to CMS through the HQR System would be January 1, 2026, to May 15, 2026, covering the performance period of January 1, 2025, to December 31, 2025. Following a 30-day preview period, CMS would publicly display data surrounding the top five most frequently performed procedures among HOPDs in each of the following eight categories: Cardiovascular, Eye, Gastrointestinal, Genitourinary, Musculoskeletal, Nervous System, Respiratory, and Skin.[481] This data would be publicly displayed on the Care Compare website or another CMS website. We would assess and update the top five procedures in each category annually, as needed. We proposed that hospitals would submit aggregate-level data through the CMS web-based tool within the HQR System. We refer readers to the CY 2009, CY 2014, and CY 2017 OPPS/ASC final rules (73 FR 68777 through 68779, 78 FR 75092, and 81 FR 79791, respectively) for our previously finalized policies regarding public display of quality measures. We previously codified our existing policies regarding data collection and submission under the Hospital OQR Program at § 419.46.

We invited public comment on the proposal.

We refer readers to section XIV.B.3.a of this final rule with comment period received on the Re-adoption with Modification of the Hospital Outpatient Department Volume Data on Selected Outpatient Surgical Procedures measure. Based on comments received, we are reassessing the measure's methodology and reconsidering how the data is publicly displayed. Furthermore, we plan to update and refine procedural categories to ensure data collection of the most accurate and frequently performed procedures.

c. Proposed Modification of Survey Instrument Use for the Cataracts Visual Function Measure Reporting and Data Submission Requirements

In section XIV.B.2.b of this final rule with comment period, we finalized our proposal to modify the Cataracts Visual Function measure survey instrument use, beginning with the voluntary CY 2024 reporting period. The modified measure will refine data collection by standardizing survey instruments that HOPDs can use, which will limit the allowable survey instruments to those listed below:

- The National Eye Institute Visual Function Questionnaire-25 (NEI VFQ–25)
- The Visual Functioning Patient Questionnaire (VF–14)
- The Visual Functioning Index Patient Questionnaire (VF–8R)

Hospitals will submit data from the above three survey instrument options to CMS during the time period of January 1 to May 15 in the year prior to the affected payment determination year. For example, for the voluntary CY 2024 reporting period, the data submission period would be January 1, 2025, to May 15, 2025, covering the performance period of January 1, 2024, to December 31, 2024. Specifically, for data collection, we finalized our proposal that hospitals submit aggregate-level data through the CMS web-based tool within the HQR System. We previously codified our existing policies regarding data collection and submission under the Hospital OQR Program at § 419.46.

We invited public comment on the proposal.

We refer readers to section XIV.B.2.b of this final rule with comment period regarding our discussion of the Cataracts Visual Function measure, including summaries of the comments we received on our proposal and our responses

[480] Ibid.

[481] Centers for Medicare & Medicaid Services (2016). Hospital Outpatient Specifications Manuals version 9.1. Available at: *https://qualitynet.cms.gov/outpatient/specifications-manuals#tab9.*

thereto. We did not receive public comments on the form, manner, and timing for the Cataracts Visual Function measure; as such, we are finalizing our proposal to begin collection of the modified Cataracts Visual Function measure beginning with the voluntary CY 2024 reporting period and subsequent years.

d. Data Submission Requirements for Measures Submitted via the Centers for Disease Control and Prevention (CDC) National Healthcare Safety Network (NHSN) Website

We refer readers to the CY 2014 OPPS/ASC final rule with comment period (78 FR 75097 through 75100) for a discussion of the previously finalized requirements for measure data submitted via the CDC NHSN website. In addition, we refer readers to the CY 2022 OPPS/ASC final rule (86 FR 63866), where we finalized the adoption of the COVID–19 Vaccination Coverage Among HCP measure beginning with the CY 2022 reporting period/CY 2024 payment determination. In section XIV.B.2.a of this final rule with comment period, we discuss the modification of the COVID–19 Vaccination Coverage Among HCP measure beginning with the CY 2024 reporting period/CY 2026 payment determination. The requirements for measure data submitted via the CDC NHSN website will remain as previously finalized.

We did not propose any changes to these policies in the CY 2024 OPPS/ASC proposed rule.

6. eCQM Reporting and Submission Requirements

a. Background

We refer readers to the CY 2014 OPPS/ASC final rule with comment period (78 FR 75106 and 75107), the CY 2015 OPPS/ASC final rule with comment period (79 FR 66956 through 66961), the CY 2016 OPPS/ASC final rule (80 FR 70516 through 70518), the CY 2017 OPPS/ASC final rule with comment period (81 FR 79785 through 79790), the CY 2018 OPPS/ASC final rule with comment period (82 FR 59435 through 59438), the CY 2022 OPPS/ASC final rule with comment period (86 FR 63867 through 63870), and the CY 2023 OPPS/ASC final rule with comment period (87 FR 72113 through 72114) for more details on previous discussion regarding future measure concepts related to eCQMs and electronic reporting of data for the Hospital OQR Program, including support for the introduction of eCQMs into the Program.

We refer readers to the CY 2022 OPPS/ASC final rule with comment period (86 FR 63867 and 63868), where we finalized the adoption of the STEMI eCQM reporting and data submission requirements. For the CY 2024 reporting period/CY 2026 payment determination, hospitals must submit one self-selected quarter of STEMI eCQM data.

We did not propose any changes to these policies in the CY 2024 OPPS/ASC proposed rule.

b. Excessive Radiation Dose or Inadequate Image Quality for Diagnostic Computed Tomography (CT) in Adults eCQM Reporting and Data Submission Requirements

In section XIV.B.3.c of the CY 2024 OPPS/ASC proposed rule (88 FR 49787 through 49790), we discuss the adoption of the Excessive Radiation eCQM beginning with the voluntary CY 2025 reporting period followed by mandatory reporting beginning with the CY 2026 reporting period/CY 2028 payment determination. In the CY 2024 OPPS/ASC proposed rule (88 FR 49798), we proposed a progressive increase in the number of quarters for which hospitals report Excessive Radiation eCQM data. We proposed that hospitals that submit Excessive Radiation eCQM data during the CY 2025 voluntary period may submit up to all four quarter(s) of data.

Under our proposal, beginning with the CY 2026 mandatory reporting period/CY 2028 payment determination, we proposed that hospitals report two self-selected calendar quarters of data for the Excessive Radiation eCQM. Beginning with the CY 2027 reporting period/CY 2029 payment determination, we proposed to require hospitals to report all four calendar quarters (one calendar year) of data for the Excessive Radiation eCQM. We believe that a phased implementation approach would allow facilities the ability to make the necessary adjustments for data submission over time and would produce more comprehensive and reliable quality measure data for patients and providers. Furthermore, we believe that aligning the schedule with the STEMI measure will allow for a seamless transition from voluntary to mandatory reporting of all calendar quarters.

We also refer readers to Table 132 for a summary of the proposed quarterly data increase in eCQM reporting beginning with the CY 2025 reporting period.

TABLE 132: PROPOSED PROGRESSIVE INCREASE IN ECQM REPORTING BEGINNING WITH THE CY 2025 REPORTING PERIOD AND FOR SUBSEQUENT YEARS

Calendar Year Period	Calendar Quarters of Reporting	Reporting Requirement
CY 2025 Reporting Period	Any quarter(s)	Voluntary
CY 2026 Reporting Period/CY 2028 Payment Determination	Two self-selected quarters	Mandatory
CY 2027 Reporting Period/CY 2029 Payment Determination	Four quarters (one calendar year)	Mandatory

We also proposed to require Excessive Radiation eCQM data submission by May 15 in the year prior to the affected payment determination year. 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 non-workday for Federal employees by statute or Executive Order would be extended to the first day thereafter. For example, for the CY 2026 reporting period/CY 2028 payment determination, hospitals must report two self-selected quarters of data and would be required to submit eCQM data by May 15, 2027. This data submission deadline will follow our policies on submission deadlines for eCQM data defined in section XIV.E.6.e of this final rule with comment period.

We invited public comment on our proposals.

We refer readers to section XIV.B.3.c of this final rule with comment period for the discussion of public comments received regarding the reporting and submission requirements for the Excessive Radiation eCQM. After consideration of public comments, we are finalizing our proposal to begin voluntary reporting of the Excessive Radiation eCQM beginning with the CY 2025 reporting period. We are finalizing our proposal with modification to begin mandatory reporting of the Excessive Radiation eCQM beginning with the CY 2027 reporting period/CY 2029 payment determination.

Under our finalized proposal, beginning with the CY 2027 mandatory reporting period/CY 2029 payment determination, hospitals will report two self-selected calendar quarters of data for the Excessive Radiation eCQM. Beginning with the CY 2028 reporting period/CY 2030 payment determination, hospitals will be required to report all four calendar quarters (one calendar year) of data for the Excessive Radiation eCQM.

Data submission for the Excessive Radiation eCQM is required by May 15 in the year prior to the affected payment determination year. For example, for the CY 2027 reporting period/CY 2029 payment determination, hospitals must report two self-selected quarters of data and would be required to submit eCQM data by May 15, 2028. 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 non-workday for Federal employees by statute or Executive Order would be extended to the first day thereafter. The data submission deadline will follow our policies on submission deadlines for eCQM data defined in section XIV.E.6.e of this final rule with comment period.

We also refer readers to Table 133 for a summary of the finalized quarterly data increase in eCQM reporting beginning with the CY 2025 reporting period.

TABLE 133: FINALIZED PROGRESSIVE INCREASE IN ECQM REPORTING BEGINNING WITH THE CY 2025 REPORTING PERIOD AND FOR SUBSEQUENT YEARS

Calendar Year Period	Calendar Quarters of Reporting	Reporting Requirement
CY 2025 Reporting Period	Any quarter(s)	Voluntary
CY 2026 Reporting Period	Any quarter(s)	Voluntary
CY 2027 Reporting Period/CY 2029 Payment Determination	Two self-selected quarters	Mandatory
CY 2028 Reporting Period/CY 2030 Payment Determination	Four quarters (one calendar year)	Mandatory

c. Electronic Clinical Quality Measure Certification Requirements for eCQM Reporting

(1) Use of the 2015 Edition Cures Update Certification Criteria

We refer readers to the CY 2022 OPPS/ASC final rule with comment period (86 FR 63868 and 63869) for our policies regarding the requirement that hospitals participating in the Hospital OQR Program utilize certified technology updated consistent with the 2015 Edition Cures Update as finalized in the Office of the National Coordinator for Health Information Technology (ONC) 21st Century Cures Act final rule (85 FR 25642 through 25961) beginning with the CY 2023 reporting period/CY 2025 payment determination.

We did not propose any changes to these policies in the CY 2024 OPPS/ASC proposed rule.

d. File Format for eCQM Data, Zero Denominator Declarations, and Case Threshold Exemptions

(1) File Format for eCQM Data

We refer readers to the CY 2022 OPPS/ASC final rule with comment period (86 FR 42262) for our policies regarding the file format for eCQM data.

We did not propose any changes to these policies in the proposed rule.

(2) Zero Denominator Declarations

We refer readers to the CY 2022 OPPS/ASC final rule with comment period (86 FR 63869) for our policies regarding zero denominator declarations.

We did not propose any changes to these policies in the CY 2024 OPPS/ASC proposed rule.

(3) Case Threshold Exemptions

We refer readers to the CY 2022 OPPS/ASC final rule with comment period (86 FR 63869) for our policies regarding case threshold exemptions.

We did not propose any changes to these policies in the CY 2024 OPPS/ASC proposed rule.

e. Submission Deadlines for eCQM Data

We refer readers to the CY 2022 OPPS/ASC final rule with comment period (86 FR 63870) for our policies regarding submission deadlines for eCQM data.

We did not propose any changes to these policies in the CY 2024 OPPS/ASC proposed rule.

7. Data Submission and Reporting Requirements for Patient-Reported Outcome-Based Performance Measures (PRO–PMs)

In section XIV.B.3.b of this final rule with comment period, we finalized our proposal to adopt the hospital-level THA/TKA PRO–PM into the Hospital OQR Program measure set. In this section of this final rule with comment period, we are finalizing our proposal of the reporting and submission requirements for PRO–PM as a new type of measure to the Hospital OQR Program.

a. Submission of PRO–PM Data

(1) Data Submission Generally

In section XIV.B.3.b of the CY 2024 OPPS/ASC proposed rule (88 FR 49799 through 49801), we proposed to adopt the THA/TKA PRO–PM into the Hospital OQR Program beginning with voluntary CYs 2025 and 2026 reporting periods and mandatory reporting period beginning with the CY 2027/CY 2030 payment determination. We proposed that hospitals and vendors use the HQR System for data submission for the THA/TKA PRO–PM, which would enable us to incorporate this new requirement into the infrastructure we have developed and use to collect other quality data. HOPDs may choose to: (1) send their data to CMS directly; or (2) utilize an external entity, such as through a vendor or registry, to submit data on behalf of the facility to CMS. We would provide hospitals with additional detailed information and instructions for submitting data using the HQR System through CMS' existing websites, through outreach, or both. Use of the HQR system leverages existing CMS infrastructure already utilized for other quality measures. The HQR System allows for data submission using multiple file formats (such as CSV, XML) and a manual data entry option, allowing facilities and vendors additional flexibility in data submission.

(2) Data Submission Reporting Requirements

(a) Voluntary Reporting Requirements for the Proposed THA/TKA PRO–PM

In the CY 2024 OPPS/ASC proposed rule (88 FR 49800), for hospitals participating in voluntary reporting for the THA/TKA PRO–PM, we proposed that hospitals submit preoperative PRO data, as well as matching post-operative PRO data, for at least 50 percent of their eligible elective primary THA/TKA procedures.

For the THA/TKA PRO–PM, we proposed that the first voluntary reporting period for CY 2025 would include pre-operative PRO data collection from 90 to 0 days before the procedure (for eligible elective THA/TKA procedures performed from January 1, 2025, through December 31, 2025) and post-operative PRO data collection from 300 to 425 days after the procedure. Therefore, during the first voluntary reporting period for CY 2025, hospitals would submit pre-operative data by May 15, 2026, and post-operative data by May 15, 2027, and we intend to provide hospitals with their results in confidential feedback reports in CY 2028. 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 non-workday for Federal employees by statute or Executive order would be extended to the first day thereafter. After the initial submission of pre-operative data for the first voluntary period, hospitals would submit both pre-operative data for the second voluntary period and post-operative data for the first voluntary period by the same data submission deadline, but for the different voluntary reporting periods. For example, hospitals would need to submit: (1) post-operative data for the first voluntary reporting (for procedures performed between January 1, 2025, and December 31, 2025); and (2) pre-operative data for the second voluntary reporting (for procedures performed between January 1, 2026, and December 31, 2026) of the THA/TKA PRO–PM by May 15, 2027.

For the THA/TKA PRO–PM, we proposed that the second voluntary reporting period for the CY 2026 reporting period would include pre-operative PRO data collection from 90 to 0 days before the procedure (for eligible elective THA/TKA procedures performed from January 1, 2026, through December 31, 2026) and post-operative PRO data collection from 300 to 425 days after the procedure. Hospitals would submit pre-operative data for the second voluntary reporting period by May 15, 2027, and post-operative data for the second voluntary reporting period by May 15, 2028. We intend to provide hospitals with their results in confidential feedback reports in CY 2029. HOPDs that voluntarily submit data for this measure would receive confidential feedback reports that detail submission results from the reporting period. Results of voluntary reporting would not be made publicly available. If feasible, we would calculate and provide each participating facility with their RSIR as part of the confidential feedback reports. This would provide each facility with an indication of their performance relative to the other facilities that participate in the voluntary reporting period.

While we did not propose to publicly report the data we receive during the voluntary reporting periods for the THA/TKA PRO–PM facility-level RSIR, we proposed to publicly report which facilities choose to participate in voluntary reporting and/or the percent of pre-operative data submitted by participating facilities for the first voluntary reporting period, and their percent of pre-operative and post-operative matched PRO data submitted for subsequent voluntary reporting periods. For example, if out of 100 eligible procedures a facility submits 45 pre-operative cases that match to post-operative cases, then we would report that the facility submitted 45 percent of matched pre-operative and post-operative PRO surveys during voluntary reporting.

We refer readers to Table 134 for an overview of the proposed performance period, pre- and post-operative data collection timeframes, and data submission deadlines during the voluntary reporting periods for THA/TKA PRO–PM.

TABLE 134: PROPOSED PRE-OPERATIVE AND POST-OPERATIVE PERIODS FOR THA/TKA PRO–PM VOLUNTARY REPORTING

Reporting Cycle	THA/TKA Procedures Performed	Pre-Procedure Data Collection (0 to 90 days before the procedure)	Pre-Procedure Data Submission Date	Post-Procedure Data Collection (300 to 425 days after the procedure)	Post-Procedure Data Submission	Preview/ Public Reporting
Voluntary Reporting CY 2025	January 1, 2025-December 31, 2025	October 3, 2024-December 31, 2025	May 15, 2026	October 28, 2025-February 28, 2027	May 15, 2027*	CY 2028
Voluntary Reporting CY 2026	January 1, 2026-December 31, 2026	October 3, 2025-December 31, 2026	May 15, 2027	October 28, 2026-February 28, 2028	May 15, 2028	CY 2029

*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 non-workday for Federal employees by statute or Executive Order would be extended to the first day thereafter.

**Public reporting of information on facility participation in the voluntary reporting periods would occur in CY 2028 for the CY 2025 reporting period and CY 2029 for the CY 2026 reporting period.

(b) Mandatory Reporting

Following the voluntary reporting periods, we proposed that mandatory reporting of the THA/TKA PRO–PM would begin with reporting PRO data for eligible elective THA/TKA procedures from January 1, 2027, through December 31, 2027 (the CY 2027 performance period), impacting the CY 2030 payment determination. This initial mandatory reporting would include pre-operative PRO data collection from 90 days preceding the applicable performance period and from 300 to 425 days after the performance period. For example, pre-operative data from October 3, 2026, through December 31, 2027 (for eligible elective primary THA/TKA procedures from January 1, 2027, through December 31, 2027) and post-operative PRO data collection from October 28, 2027, to February 28, 2029. Pre-operative data submission would occur by May 15, 2028, and post-operative data submission would occur by May 15, 2029.

We intend to provide hospitals with their results in CY 2030 before publicly reporting results on the Compare tool hosted by HHS, currently available at *https://www.medicare.gov/care-compare,* or its successor website. We will provide confidential feedback reports during the voluntary period which would include the risk-standardized improvement rate (RSIR); as well as other results that support understanding of their performance prior to public reporting. For this first mandatory reporting period, hospitals that fail to meet the reporting requirements would receive a reduction of their Annual Payment Update (APU) in the CY 2030 payment determination. We proposed that hospitals would be required to submit 50 percent of eligible, complete pre-operative data with matching eligible, complete post-operative data as a minimum amount of data for mandatory reporting in the Hospital OQR Program.

We refer readers to Table 135 for an overview of the proposed performance period, pre- and post-operative data collection timeframes, and data submission deadlines during the first year of mandatory reporting.

TABLE 135: PROPOSED PRE-OPERATIVE AND POST-OPERATIVE PERIODS FOR THA/TKA PRO–PM FOR MANDATORY REPORTING

Reporting Cycle	THA/TKA Procedures Performed	Pre-Procedure Data Collection (0 to 90 days before the procedure)	Pre-Procedure Data Submission Date	Post-Procedure Data Collection (300 to 425 days after the procedure)	Post-Procedure Data Submission	Preview and Public Reporting
Mandatory Reporting CY 2027	January 1, 2027-December 31, 2027	October 3, 2026-December 31, 2027	May 15, 2028	October 28, 2027-February 28, 2029	May 15, 2029	2030*

*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 non-workday for Federal employees by statute or Executive order would be extended to the first day thereafter.

*Public reporting of information on facility results in the Mandatory Reporting periods would occur in CY 2030 for CY 2027 reporting period/CY2030 payment determination.

We invited comment on these proposals.

We refer readers to section XIV.B.3.b of this final rule with comment period received on the Adoption of the Risk Standardized Patient-Reported Outcome-Based Performance Measure (PRO–PM) Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA) in the HOPD Setting (THA/TKA PRO–PM) regarding the reporting and submission requirements for the THA/TKA PRO–PM. After considering commenter's recommendation regarding voluntary and mandatory reporting timelines received in section XIV.B.3.b of this final rule with comment period, we note that we have extended the voluntary reporting period for the THA/TKA PRO–PM by an additional year. We are finalizing our proposal to begin voluntary reporting beginning with CY 2025 as proposed. We are finalizing with delayed implementation mandatory reporting beginning with the CY 2028 reporting period/CY 2031 payment determination.

We refer readers to Table 136 for an overview of the finalized performance period, pre- and post-operative data collection timeframes, and data submission deadlines during the voluntary reporting periods for THA/TKA PRO–PM.

TABLE 136: FINALIZED PRE-OPERATIVE AND POST-OPERATIVE PERIODS FOR THA/TKA PRO–PM VOLUNTARY REPORTING

Reporting Cycle	THA/TKA Procedures Performed	Pre-Procedure Data Collection (0 to 90 days before the procedure)	Pre-Procedure Data Submission Date *	Post-Procedure Data Collection (300 to 425 days after the procedure)	Post-Procedure Data Submission *
Voluntary Reporting CY 2025	January 1, 2025-December 31, 2025	October 3, 2024-December 31, 2025	May 15, 2026	October 28, 2025-March 1, 2027	May 15, 2027*
Voluntary Reporting CY 2026	January 1, 2026-December 31, 2026	October 3, 2025-December 31, 2026	May 15, 2027	October 28, 2026- February 29, 2028	May 15, 2028
Voluntary Reporting CY 2027	January 1, 2027-December 31, 2027	October 3, 2026-December 31, 2027	May 15, 2028	October 28, 2027- February 28, 2029	May 15, 2029

*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 non-workday for Federal employees by statute or Executive Order would be extended to the first day thereafter.

Following the voluntary reporting periods, we are finalizing that mandatory reporting of the THA/TKA PRO–PM would begin with reporting PRO data for eligible elective THA/TKA procedures from January 1, 2028, through December 31, 2028 (the CY 2028 performance period), impacting the CY 2031 payment determination. This initial mandatory reporting would include pre-operative PRO data collection from 90 days preceding the applicable performance period and from 300 to 425 days after the performance period. For example, pre-operative data from October 3, 2027, through December 31, 2028 (for eligible elective primary THA/TKA procedures from January 1, 2028, through December 31, 2028) and post-operative PRO data collection from October 27, 2028 to March 1, 2030. Pre-operative data submission would occur by May 15, 2029, and post-operative data submission would occur by May 15, 2030.

We refer readers to Table 137 for an overview of the finalized performance period, pre- and post-operative data collection timeframes, and data submission deadlines during the mandatory reporting periods for THA/TKA PRO–PM.

TABLE 137: FINALIZED PRE-OPERATIVE AND POST-OPERATIVE PERIODS FOR THA/TKA PRO–PM FOR MANDATORY REPORTING

Reporting Cycle	THA/TKA Procedures Performed	Pre-Procedure Data Collection (0 to 90 days before the procedure)	Pre-Procedure Data Submission Date *	Post-Procedure Data Collection (300 to 425 days after the procedure)	Post-Procedure Data Submission *	Preview and Public Reporting
Mandatory Reporting CY 2028	January 1, 2028- December 31, 2028	October 3, 2027- December 31, 2028	May 15, 2029	October 27, 2028- March 1, 2030	May 15, 2030	2031**

*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 non-workday for Federal employees by statute or Executive order would be extended to the first day thereafter.

**Public reporting of information on facility results in the Mandatory Reporting periods would occur in CY 2031 for CY 2028 reporting period/CY2031 payment determination.

8. Population and Sampling Data Requirements for the CY 2023 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 and 74483) for our policies regarding population and sampling data requirements.

We did not propose any changes to these policies in the CY 2024 OPPS/ASC proposed rule.

9. 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) for our policies regarding a review and corrections period for chart-abstracted-measures in the Hospital OQR Program.

We did not propose any changes to these policies in the CY 2024 OPPS/ASC proposed rule.

b. Web-Based Measures

We refer readers to the CY 2021 OPPS/ASC final rule with comment period (85 FR 86184) for our policies regarding a review and corrections period for web-based measures in the Hospital OQR Program.

We did not propose any changes to these policies in the CY 2024 OPPS/ASC proposed rule.

c. Electronic Clinical Quality Measures (eCQMs)

We refer readers to the CY 2022 OPPS/ASC final rule with comment period (86 FR 63870) for our policies regarding a review and corrections period for eCQMs in the Hospital OQR Program. We refer readers to the CMS website (currently available at: *https://qualitynet.cms.gov/outpatient/measures/eCQM*) and the eCQI Resource Center (available at: *https://ecqi.healthit.gov/*) for more resources on eCQM reporting.

We did not propose any changes to these policies in the CY 2024 OPPS/ASC proposed rule.

d. OAS CAHPS Measures

We refer readers to the CY 2022 OPPS/ASC final rule with comment period (86 FR 63870) and the CY 2017 OPPS/ASC final rule with comment period (81 FR 79793) for our policies regarding a review and corrections period for OAS CAHPS measures in the Hospital OQR Program.

We did not propose any changes to these policies in the CY 2024 OPPS/ASC proposed rule.

10. Hospital OQR Program Validation Requirements

a. Background

We refer readers to the CY 2011 OPPS/ASC final rule with comment period (75 FR 72105 and 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 and 66965), the CY 2016 OPPS/ASC final rule with comment period (80 FR 70524), the CY 2018 OPPS/ASC final rule with comment period (82 FR 59441 through 59443), the CY 2022 OPPS/ASC final rule with comment period (86 FR 63870 through 63873), the CY 2023

OPPS/ASC final rule with comment period (87 FR 72115 and 72116), and § 419.46(f) for our policies regarding validation.

We did not propose any changes to these policies in the CY 2024 OPPS/ASC proposed rule.

b. Use of Electronic File Submissions for Chart-Abstracted Measure Medical Records Requests

We refer readers to the CY 2022 OPPS/ASC final rule with comment period (86 FR 63870) for additional information on the use of electronic file submissions for chart-abstracted measure medical records requests.

We did not propose any changes to these policies in the CY 2024 OPPS/ASC proposed rule.

c. Time Period for Chart-Abstracted Measure Data Validation

We refer readers to the chart-abstracted validation requirements and methods we adopted in the CY 2014 OPPS/ASC final rule (78 FR 75117 and 75118) and codified at § 419.46(f)(1) for the CY 2025 payment determination and subsequent years. We refer readers to § 419.46(f)(1) for our policies regarding the time period for chart-abstracted measure data validation.

We did not propose any changes to these policies in the CY 2024 OPPS/ASC proposed rule.

d. Targeting Criteria

We refer readers to the CY 2012 OPPS/ASC final rule with comment period (76 FR 74485), where we finalized a validation selection process in which we select a random sample of 450 hospitals for validation purposes and select an additional 50 hospitals based on specific criteria; the CY 2013 OPPS/ASC final rule (77 FR 68485 and 68486), where we finalized that a hospital will be preliminarily selected for validation based on targeting criteria if it fails the validation requirement that applies to the previous year's payment determination, and for a discussion of finalized policies regarding our medical record validation procedure requirements; the CY 2018 OPPS/ASC final rule with comment period (82 FR 59441), where we clarified that an ''outlier value'' for purposes of the targeting criterion; the CY 2022 OPPS/ASC final rule with comment period (86 FR 63872), where we finalized the addition of two targeting criteria: (1) any hospital that has not been randomly selected for validation in any of the previous three years; or (2) any hospital that passed validation in the previous year and had a two-tailed confidence interval that included 75 percent; and the CY 2023 OPPS/ASC final rule with comment period (87 FR 72115 and 72116), where we finalized an additional targeting criteria: any hospital with a two-tailed confidence interval that is less than 75 percent, and that had less than four quarters of data due to receiving an ECE for one or more quarters. We refer readers to § 419.46(f)(3) for our policies regarding the validation selection process and targeting criteria.

We did not propose any changes to these policies in the CY 2024 OPPS/ASC proposed rule.

e. Educational Review Process and Score Review and Correction Period for Chart-Abstracted Measures

We refer readers to § 419.46(f)(4) for our policies regarding the educational review process, including validation score review and correction, for chart-abstracted measures.

We did not propose any changes to these policies in the CY 2024 OPPS/ASC proposed rule.

11. Extraordinary Circumstances Exception (ECE) Process

We refer readers to § 419.46(e) for our policies regarding the extraordinary circumstances exception (ECE) process under the Hospital OQR Program. In the CY 2024 OPPS/ASC proposed rule (88 FR 49802), we proposed to amend our exception policy codified at § 419.46(e)(1) to replace references to ''QualityNet'' with ''CMS-designated information system'' or ''CMS website.'' and to make other conforming technical edits, to accommodate recent and future systems requirements and mitigate confusion for program participants.

We invited public comment on the proposal.

We received no comments on the proposal. We are finalizing our proposal as proposed.

12. Hospital OQR Program Reconsideration and Appeals Procedures

We refer readers to § 419.46(g) for our policies regarding reconsideration and appeals procedures. In the CY 2024 OPPS/ASC proposed rule (88 FR 49802), we proposed to amend our submission deadline codified at § 419.46(g)(1) to replace references to ''QualityNet'' with ''CMS-designated information system'' or ''CMS website,'' and to make other conforming technical edits, to accommodate recent and future systems requirements and mitigate confusion for program participants.

We invited public comment on the proposal.

We received no comments on the proposal. We are finalizing our proposal as proposed.

F. Payment Reduction for Hospitals That Fail To Meet the Hospital OQR Program Requirements for the CY 2024 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 and 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/ASC final rule with comment period, 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 rule with comment period 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 and 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 CY 2023 OPPS/ASC proposed rule (87 FR 44533 and 44534).

2. Reporting Ratio Application and Associated Adjustment Policy for CY 2024

We proposed 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 2024 annual payment update factor. For the CY 2024 OPPS/ASC proposed rule, the proposed reporting ratio was 0.9805, which, when multiplied by the proposed full conversion factor of $87.488, 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 $85.782. We proposed to continue to apply the reporting ratio to all services calculated using the OPPS conversion factor. We proposed 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 assignments of ''S'' and ''T''). We proposed to continue to exclude services paid under New Technology APCs. We proposed 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 proposed 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 proposed 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 proposed 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 2024, the proposed reporting ratio was 0.9805, which, when multiplied by the proposed full conversion factor of $87.488, equaled a proposed conversion factor for hospitals that fail to meet the requirements of the Hospital OQR Program (that is, the reduced conversion factor) of $85.782.

We did not receive any public comments on our proposal. For this final rule with comment period, the final reporting ratio is 0.9806, which, when multiplied by the final full conversion factor of $87.382, equals a final conversion factor for hospitals that fail to meet the requirements of the Hospital OQR Program (that is, the reduced conversion factor) of $85.687. We are finalizing our proposal 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. We are also finalizing our proposals to implement the policy through the use of a reporting ratio, and 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 hospitals that fail to meet the Hospital OQR Program requirements for CY 2024 payment.

XV. Requirements for the Ambulatory Surgical Center Quality Reporting (ASCQR) Program

A. Background

1. Overview

We seek to promote higher quality, more efficient, and equitable healthcare for Medicare beneficiaries. Consistent with these goals, we have implemented quality reporting programs for multiple care settings, including the Ambulatory Surgical Center Quality Reporting (ASCQR) Program for ambulatory surgical center care.

2. Statutory Authority for the ASCQR Program

Section 1833(i)(7)(A) authorizes the Secretary to reduce any annual increase under the revised ambulatory surgical center (ASC) payment system by 2.0 percentage points for such year that an ASC that fails to submit required data on quality measures specified by the Secretary in accordance with section 1833(i)(7)(B) of the Act. Section 1833(i)(7)(B) of the Act states that, except as the Secretary may otherwise provide, several of the statutory provisions governing the Hospital Outpatient Quality Reporting (OQR) Program, specifically section 1833(t)(17)(B) through (E) of the Act, also apply to the services of ASCs under the ASCQR Program in a similar manner to the manner in which they apply to the services of hospital outpatient departments under the Hospital OQR Program. Sections 1833(t)(17)(B) through (E) of the Act generally govern the development and replacement of quality measures, the form and manner of submission of data to CMS, and procedures for making the data submitted to CMS available to the public.

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 authority of the ASCQR Program.

3. Regulatory History of the ASCQR Program

We refer readers to the following final rules for detailed discussions of the regulatory history of the ASCQR Program:

- CY 2012 OPPS/ASC final rule (76 FR 74492 through 74517);
- FY 2013 IPPS/LTCH PPS final rule (77 FR 53637 through 53644);
- CY 2013 OPPS/ASC final rule (77 FR 68492 through 68500);
- CY 2014 OPPS/ASC final rule (78 FR 75122 through 75141);
- CY 2015 OPPS/ASC final rule (79 FR 66966 through 66987);
- CY 2016 OPPS/ASC final rule (80 FR 70526 through 70538);
- CY 2017 OPPS/ASC final rule (81 FR 79797 through 79826);
- CY 2018 OPPS/ASC final rule (82 FR 59445 through 59476);
- CY 2019 OPPS/ASC final rule (83 FR 59110 through 59139);
- CY 2020 OPPS/ASC final rule (84 FR 61420 through 61434);
- CY 2021 OPPS/ASC final rule (85 FR 86187 through 86193);
- CY 2022 OPPS/ASC final rule (86 FR 63875 through 63911); and
- CY 2023 OPPS/ASC final rule (87 FR 72117 through 72136).

We have codified certain requirements under the ASCQR Program at 42 CFR part 416, subpart H (§§ 416.300 through 416.330). We refer readers to section XV.E of this final rule with comment period for a detailed discussion of the payment reduction for ASCs that fail to meet program requirements.

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 and 68494) for a detailed discussion of the priorities we consider for quality measure selection for the ASCQR Program.

We did not propose any changes to these policies in the CY 2024 OPPS/ASC proposed rule.

2. Retention of Previously Adopted ASCQR Program Measures

We previously finalized and codified at § 416.320(a) our policy regarding retention of quality measures adopted for the ASCQR Program. Specifically, our regulation at § 416.320(a) provides that we will retain quality measures previously adopted for the ASCQR Program as part of its measure set unless we remove, suspend, or replace the measure.

We did not propose any changes to this policy in the CY 2024 OPPS/ASC proposed rule.

3. Removal, Replacement, or Suspension of Quality Measures

a. Immediate Removal of Program Measures

We refer readers to § 416.320(b) for our policies regarding immediate removal of a measure for the ASCQR Program based on evidence that the continued use of the measure as specified raises patient safety concerns. In the CY 2024 OPPS/ASC proposed rule (88 FR 49804), we proposed to amend our measure removal policy codified at § 416.320(b) to replace references to ''QualityNet'' with ''CMS-designated information system'' or ''CMS website,'' and to make other conforming technical edits, to accommodate recent and future systems requirements and mitigate confusion for program participants.

We invited public comment on the proposal.

We received no comments on the proposal. We are finalizing our proposal as proposed.

b. Removal, Replacement, or Suspension of Program Measures

We previously finalized and codified at § 416.320(c) our policies regarding removal of quality measures adopted for the ASCQR Program. Specifically, our regulation at § 416.320(c) provides that, unless a measure raises specific safety concerns, we will use the regular rulemaking process, allowing public comment, to remove, suspend, or replace quality measures in the ASCQR Program. Our regulation at § 416.320(c)(2) further provides that we will weigh whether to remove measures based on eight factors, including whether a measure is ''topped-out'' (§ 416.320(c)(2)(i)), based on criteria set forth in our regulation at § 416.320(c)(3).

However, as provided in our regulation at § 416.320(c)(4), we will assess the benefits of removing a measure on a case-by-case basis and will not remove a measure solely on the basis of it meeting any of specific factor or criterion.

We did not propose any changes to these policies in the CY 2024 OPPS/ASC proposed rule.

4. Modifications to Previously Adopted Measures

In the CY 2024 OPPS/ASC proposed rule (88 FR 49804 through 49810), we proposed to modify three previously adopted measures beginning with the CY 2024 reporting period/CY 2026 payment determination: (1) COVID–19 Vaccination Coverage Among Healthcare Personnel (HCP) measure; (2) Cataracts: Improvement in Patient's Visual Function Within 90 Days Following Cataract Surgery measure survey instrument use; and (3) Endoscopy/Polyp Surveillance: Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients measure. We discuss each of these measures, along with the public comments that we received on them, in subsequent sections.

a. Modification of the COVID–19 Vaccination Coverage Among Health Care Personnel (HCP) Measure Beginning With the CY 2024 Reporting Period/CY 2026 Payment Determination

(1) Background

On January 31, 2020, the Secretary of the Department of Health and Human Services (HHS) declared a public health emergency (PHE) for the United States in response to the global outbreak of SARS–CoV–2, a then novel coronavirus that causes a disease named ''coronavirus disease 2019'' (COVID–19).[482] Subsequently, the COVID–19 Vaccination Coverage Among Health Care Personnel (HCP) measure was adopted across multiple quality reporting programs, including the ASCQR Program (86 FR 63875 through 63883).[483] The Secretary renewed the PHE on April 21, 2020 and then every 3 months thereafter, with the final renewal on February 9, 2023.[484] The PHE ended on May 11, 2023; however, the public health response to COVID–19, which includes vaccination efforts, remains a public health priority.[485] As we noted in the CY 2024 OPPS/ASC proposed rule (88 FR 49805), there had been more than 102.7 million COVID–19 cases and 1.1 million COVID–19 deaths in the United States as of February 13, 2023; in reviewing these numbers for this final rule, as of September 15, 2023 there have been more than 103.4 million COVID–19 cases and 1.1 million COVID–19 deaths in the United States.[486] [487]

As stated in the CY 2022 OPPS/ASC final rule with comment period (86 FR 63876) and in our ''Revised Guidance for Staff Vaccination Requirements,'' vaccination is a critical part of the nation's strategy to effectively counter the spread of COVID–19.[488] [489] [490] We continue to believe it is important to incentivize and track HCP vaccination through quality measurement across care settings, including the ASC setting, to protect health care workers, patients, and caregivers, and to help sustain the ability of HCP in each of these care settings to continue serving their communities. Studies indicate higher levels of population-level vaccine effectiveness in preventing COVID–19 infection among HCP and other frontline workers in multiple industries, with vaccines having a 90 percent effectiveness in preventing symptomatic and asymptomatic infection from December 2020 through August 2021.[491] Since the Food and Drug Administration (FDA) issued emergency use authorizations (EUAs) for selected initial and primary vaccines for adults, vaccines have been highly effective in real-world conditions at preventing COVID–19 in HCP with up to 96 percent efficacy for fully vaccinated HCP, including those at risk for severe infection and those in racial and ethnic groups disproportionately affected by COVID–19.[492] [493] [494] [495] Overall, data demonstrate that COVID–19 vaccines are effective and prevent severe disease, hospitalization, and death from the COVID–19 infection.[496]

When we adopted the COVID–19 Vaccination Coverage Among HCP measure in the CY 2022 OPPS/ASC final rule with comment period (86 FR 63875 through 63883), we acknowledged that the measure did not address booster shots for COVID–19 vaccination (86 FR 63881), although the FDA authorized, and the Centers for Disease Control and Prevention (CDC) recommended, additional doses and booster doses of

[482] U.S. Dept of Health and Human Services, Office of the Assistant Secretary for Preparedness and Response (2020). Determination that a Public Health Emergency Exists. Available at: *https://www.phe.gov/emergency/news/healthactions/phe/Pages/2019-nCoV.aspx.*

[483] The Hospital Inpatient Quality Reporting Program (86 FR 45374 through 45382), the Hospital OQR Program (86 FR 63824 through 63833), the Inpatient Psychiatric Facility Quality Reporting Program (86 FR 42633 through 42640), the PPS-Exempt Cancer Hospital Quality Reporting Program (86 FR 45428 through 45434), the Long-Term Care Hospital Quality Reporting Program (86 FR 45438 through 45446), the Skilled Nursing Facility Quality Reporting Program (86 FR 42480 through 42489), the End-Stage Renal Disease Quality Incentive Program (87 FR 67244 through 67248), and the Inpatient Rehabilitation Facility Quality Reporting Program (86 FR 42385 through 42396).

[484] U.S. Dept. of Health and Human Services. Office of the Assistant Secretary for Preparedness and Response (2023). Renewal of Determination that a Public Health Emergency Exists. Available at: *https://aspr.hhs.gov/legal/PHE/Pages/COVID19-9Feb2023.aspx.*

[485] U.S. Dept. of Health and Human Services. Fact Sheet: COVID–19 Public Health Emergency Transition Roadmap. February 9, 2023. Available at: *https://www.hhs.gov/about/news/2023/02/09/fact-sheet-covid-19-public-health-emergency-transition-roadmap.html.*

[486] World Health Organization. United States of America. Accessed September 15, 2023. Available at: *https://covid19.who.int/region/amro/country/us.*

[487] Centers for Disease Control and Prevention. COVID Data Tracker. Accessed February 13, 2023. Available at: *https://covid.cdc.gov/covid-data-tracker/#datatracker-home.*

[488] Centers for Medicare & Medicaid Services (October 26, 2022). Revised Guidance for Staff Vaccination Requirements. Available at: *https://www.cms.gov/medicareprovider-enrollment-and-certificationsurveycertificationgeninfopolicy-and-memos-states-and/revised-guidance-staff-vaccination-requirements.*

[489] Centers for Disease Control and Prevention (September 24, 2021). Morbidity and Mortality Weekly Report (MMWR). Comparative Effectiveness of Moderna, Pfizer-BioNTech, and Janssen (Johnson & Johnson) Vaccines in Preventing COVID–19 Hospitalizations Among Adults Without Immunocompromising Conditions—United States, March–August 2021. Available at: *https://cdc.gov/mmwr/volumes/70/wr/mm7038e1.htm?s_cid=mm7038e1_w.*

[490] Centers for Medicare & Medicaid Services (2022). Revised Guidance for Staff Vaccination Requirements. Available at: *https://www.cms.gov/files/document/qs0-23-02-all.pdf.*

[491] Centers for Disease Control and Prevention (August 27, 2021). Morbidity and Mortality Weekly Report (MMWR). Effectiveness of COVID–19 Vaccines in Preventing SARS–COV–2 Infection Among Frontline Workers Before and During B.1.617.2 (Delta) Variant Predominance—Eight U.S. Locations, December 2020–August 2021. Available at: *https://www.cdc.gov/mmwr/volumes/70/wr/mm7034e4.htm.*

[492] Pilishivi T, Gierke R, Fleming-Dutra KE, et al. (2022). Effectiveness of mRNA Covid–19 Vaccine among U.S. Health Care Personnel. *New England Journal of Medicine,* 385(25), e90. *https://doi.org/10.1056/NEJMoa2106599.*

[493] Centers for Disease Control and Prevention (2021). Morbidity and Mortality Weekly Report (MMWR). Monitoring Incidence of COVID–19 Cases, Hospitalizations, and Deaths, by Vaccination Status—13 U.S. Jurisdictions, April 4–July 17, 2021. Available at: *https://www.cdc.gov/mmwr/volumes/70/wr/mm7037e1.htm.*

[494] Centers for Medicare & Medicaid Services (2022). Revised Guidance for Staff Vaccination Requirements QSO–23–02–ALL. Available at: *https://www.cms.gov/files/document/qs0-23-02-all.pdf.*

[495] Food and Drug Administration (2020). FDA Takes Key Action in Fight Against COVID–19 By Issuing Emergency Use Authorization for First COVID–19 Vaccine. Available at: *https://www.fda.gov/news-events/press-announcements/fda-takes-key-action-fight-against-covid-19-issuing-emergency-use-authorization-first-covid-19.*

[496] McGarry BE et al. (January 2022). Nursing Home Staff Vaccination and Covid–19 Outcomes. New England Journal of Medicine. 2022 Jan 27;386(4):397–398. Available online at: *https://pubmed.ncbi.nlm.nih.gov/34879189/.*

the COVID–19 vaccine for certain individuals, particularly those who are immunocompromised due to age or condition or who are living or working in high-risk settings, such as HCP (86 FR 63881). However, we also stated that we believed the numerator of the measure was sufficiently broad to include potential future boosters as part of a ''complete vaccination course'' (86 FR 63881).

Since then, new variants of SARS–CoV–2 have emerged around the world and within the United States. Specifically, the Omicron variant (and its related subvariants) is listed as a ''variant of concern'' by the CDC because it spreads more easily than earlier variants.[497] Vaccine manufacturers have responded to the Omicron variant by developing bivalent COVID–19 vaccines, which include a component of the original virus strain to provide broad protection against COVID–19 and a component of the Omicron variant to provide better protection against COVID–19 caused by the Omicron variant.[498] Booster doses of the bivalent COVID–19 vaccine have proven effective at increasing immune response to SARS–CoV–2 variants, including Omicron, particularly in individuals who are more than 6 months removed from receipt of their primary series.[499] Updated COVID–19 vaccines are associated with a greater reduction in infections among HCP and their patients relative to those who only received primary series vaccination, with a rate of breakthrough infections among HCP who received only the two-dose regimen of 21.4 percent compared to a rate of 0.7 percent among boosted HCP.[500] [501] In the CY 2024 OPPS/ASC proposed rule (88 FR 49774 through 49776), we stated that data from the existing COVID–19 Vaccination Coverage Among HCP measure demonstrate clinically significant variation in booster dose vaccination rates across ASCs, but are clarifying here that literature has indicated disparities in COVID–19 booster vaccine uptakes across healthcare personnel irrespective of specific care setting.[502]

We believe that vaccination remains the most effective means to prevent the worst consequences of COVID–19, including severe illness, hospitalization, and death. Given the availability of vaccine efficacy data, EUAs, and Biologics License Application approvals issued by the FDA for updated 2023–2024 formulations of the vaccine, the continued presence of SARS–CoV–2 in the United States, and variance among rates of updated vaccinations, we believe it is important to modify the COVID–19 Vaccination Coverage Among HCP measure for HCP to receive primary series and updated vaccine doses in a timely manner per the CDC's recommendation that bivalent COVID–19 vaccine booster doses might improve protection against SARS–CoV–2 Omicron sublineages, including the most recent September 2023 Omicron variant that came to light after the publication of the CY 2024 OPPS/ASC proposed rule.[503] [504]

In the CY 2024 OPPS/ASC proposed rule (88 FR 49805 through 49807), we proposed to modify the COVID–19 Vaccination Coverage Among HCP measure to utilize the term ''up to date'' in the HCP vaccination definition. We also proposed to update the numerator to specify the timeframes within which an HCP is considered up to date with CDC recommended COVID–19 vaccines, including updated vaccine doses, beginning with the CY 2024 reporting period/CY 2026 payment determination for the ASCQR Program.

As noted in the CY 2022 OPPS/ASC final rule with comment period (86 FR 63877), the COVID–19 Vaccination Coverage Among HCP measure is a process measure that assesses HCP vaccination coverage rates and not an outcome measure for which ASCs are held responsible for a particular outcome. We adopted the same modification to versions of the measure that we have adopted for other quality reporting programs.[505]

(2) Overview of Measure

The COVID–19 Vaccination Coverage Among HCP measure is a process measure developed by the CDC to track COVID–19 vaccination coverage among HCP in various settings. ASCs report the required data for this measure via the CDC's National Healthcare Safety Network (NHSN). We refer readers to the CY 2022 OPPS/ASC final rule with comment period (86 FR 63877 through 63878) for more information on the initial review of the measure by the Measure Applications Partnership (MAP).[506]

We included an updated version of the measure on the Measures Under Consideration (MUC) list for the 2022–2023 pre-rulemaking cycle for consideration by the MAP. In the CY 2024 OPPS/ASC proposed rule (88 FR 49806), we noted that when reviewed by the MAP, reporting for contract personnel providing care or services not specifically included in the measure denominator was fully optional, whereas this reporting is now required to complete NHSN data entry, but is not included in the measure calculation.

In December 2022, during the MAP's Hospital Workgroup discussion, the workgroup stated that the revision of the current measure captures up to date vaccination information in accordance

[497] Centers for Disease Control and Prevention (August 2021). Variants of the Virus. Available at: *https://www.cdc.gov/coronavirus/2019-ncov/variants/index.html.*

[498] Food and Drug Administration (November 2022). COVID–19 Bivalent Vaccine Boosters. Available at: *https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-authorizes-moderna-pfizer-biontech-bivalent-covid-19-vaccines-use.* (In the CY 2024 OPPS/ASC proposed rule, we cited this information to: *https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/covid-19-bivalent-vaccines.* However, after review, the information appears to have moved. Thus, we have updated the citation.)

[499] Chalkias, S et al. (October 2022). A Bivalent Omicron-Containing Booster Vaccine against Covid–19. N Engl J Med 2022; 387:1279–1291. Available online at: *https://www.nejm.org/doi/full/10.1056/NEJMoa2208343.*

[500] Prasad N et al. (May 2022). Effectiveness of a COVID–19 Additional Primary or Booster Vaccine Dose in Preventing SARS–CoV–2 Infection Among Nursing Home Residents During Widespread Circulation of the Omicron Variant—United States, February 14–March 27, 2022. Morbidity and Mortality Weekly Report (MMWR). 2022 May 6;71(18):633–637. Available online at: *https://pubmed.ncbi.nlm.nih.gov/35511708/.*

[501] Oster Y et al. (May 2022). The effect of a third BNT162b2 vaccine on breakthrough infections in health care workers: a cohort analysis. Clin Microbiol Infect. 2022 May;28(5):735.e1–735.e3. Available online at: *https://pubmed.ncbi.nlm.nih.gov/35143997/.*

[502] Wigdan F. et al (April 2023). Who is getting boosted? Disparities in COVID–19 vaccine booster uptake among health care workers. Available at: *https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9918311/pdf/main.pdf.*

[503] Link-Gelles et al. (February 2023). Early Estimates of Bivalent mRNA Booster Dose Vaccine Effectiveness in Preventing Symptomatic SARs–CoV–2 Infection Attributable to Omicron BA.5- and XBB/XBB.1.5-Relating Sublineages Among Immunocompetent Adults—Increasing Community Access to Testing Program, United States, December 2022–January 2023. Morbidity and Mortality Weekly Report (MMWR). February 3;72(5);119–124. Available online at: *https://www.cdc.gov/mmwr/volumes/72/wr/mm7205e1.htm#suggestedcitation.*

[504] Food and Drug Administration (June 2023). FDA Briefing Document: Vaccines and Related Biological Products Advisory Committee Meeting. Food and Drug Administration. Available Online: *https://www.fda.gov/media/169378/download.*

[505] The Hospital Inpatient Quality Reporting Program, the Long-Term Care Hospital Quality Reporting Program and the PPS-Exempt Cancer Hospital Quality Reporting Program (88 FR 27074) as well as the Inpatient Psychiatric Facility Quality Reporting Program (88 FR 21290), the Skilled Nursing Facility Quality Reporting Program (88 FR 21332), the End-Stage Renal Disease Quality Incentive Program (87 FR 67244), and the Inpatient Rehabilitation Facility Quality Reporting Program (88 FR 20985).

[506] Interested parties convened by the consensus-based entity will provide input and recommendations on the Measures under Consideration (MUC) list as part of the pre-rulemaking process required by section 1890A of the Act. We refer readers to *https://p4qm.org/PRMR-MSR* for more information.

with the CDC's updated recommendations for additional and booster doses since the measure's initial development. Additionally, the Hospital Workgroup appreciated that the revised measure's target population is broader and simplified from seven categories of HCP to four.[507] During the MAP's Health Equity Advisory Group review, the group highlighted the importance of COVID–19 vaccination measures and questioned whether the proposed revised version of the measure excludes individuals with contraindications to FDA authorized or approved COVID–19 vaccines, and if the measure would be stratified by demographic factors. The measure developer confirmed that HCP with contraindications to the vaccines are excluded from the measure denominator, but stated that the measure would not be stratified since the data are submitted at an aggregate rather than an individual level. The MAP Rural Health Advisory Group expressed concerns about data collection burden, citing that collection is performed manually.[508] In the CY 2024 OPPS/ASC proposed rule (88 FR 49806), we noted that, when reviewed by the MAP, reporting for contract personnel providing care or services not specifically included in the measure denominator was fully optional, whereas this reporting is now required to complete NHSN data entry, but is not included in the measure calculation.

The developer also noted that the model used for this measure is based on the Influenza Vaccination Coverage Among HCP measure (CBE #0431).[509] We refer readers to sections XXIV.C and XXVI of this final rule with comment period for additional detail on the burden and impact of this finalized proposal.

The proposed revised measure received conditional support for rulemaking from the MAP pending (1) testing indicating the measure is reliable and valid, and (2) endorsement by the consensus-based entity (CBE). The MAP noted that the previous version of the measure received endorsement from the CBE (CBE #3636)[510] and that the measure steward (CDC) intends to submit the updated measure for endorsement.[511]

(a) Measure Specifications

This measure is calculated quarterly by averaging the ASC's most recently submitted and self-selected one week of data. The measure includes at least one week of data collection a month for each of the three months in a quarter. The denominator is calculated as the aggregated number of HCP eligible to work in the ASC for at least one day during the week of data collection, excluding denominator-eligible individuals with contraindications as defined by the CDC for all three months in a quarter.[512] Facilities report vaccination information for the following four, separate categories of HCP to NHSN:

- *Employees:* This includes all persons who receive a direct paycheck from the reporting facility (that is, on the facility's payroll), regardless of clinical responsibility or patient contact.
- *Licensed independent practitioners (LIPs):* This includes only physicians (MD, DO), advanced practice nurses, and physician assistants who are affiliated with the reporting facility, but are not directly employed by it (that is, they do not receive a paycheck from the reporting facility), regardless of clinical responsibility or patient contact. Post-residency fellows are also included in this category if they are not on the facility's payroll.
- *Adult students/trainees and volunteers:* This includes medical, nursing, or other health professional students, interns, medical residents, or volunteers aged 18 or older who are affiliated with the facility but are not directly employed by it (that is, they do not receive a paycheck from the facility), regardless of clinical responsibility or patient contact.
- *Other contract personnel:* Contract personnel are defined as persons providing care, treatment, or services at the facility through a contract who do not fall into any of the previously discussed denominator categories.[513] This also includes vendors providing care, treatment, or services at the facility who may or may not be paid through a contract. We note that the other contract personnel category is required for data submission to NHSN but is not included as part of the proposed COVID–19 Vaccination Coverage Among HCP measure.[514]

As stated in the CY 2024 OPPS/ASC proposed rule (88 FR 49807), we did not propose to modify the denominator exclusions. The numerator is calculated as the cumulative number of HCP in the denominator population who are considered up to date with CDC recommended COVID–19 vaccines. The term ''up to date'' is defined as meeting the CDC's set of criteria on the first day of the applicable reporting quarter. The current definition of ''up to date'' for COVID–19 vaccination can be found at: *https://www.cdc.gov/nhsn/pdfs/hps/covidvax/UpToDateGuidance-508.pdf.*

As proposed in the CY 2024 OPPS/ASC proposed rule (88 FR 49807), public reporting of the modified version of the COVID–19 Vaccination Coverage Among HCP measure for the ASCQR Program would begin with the Fall 2024 Care Compare refresh, or as soon as technically feasible.

(b) CBE Endorsement

The current version of the measure in the ASCQR Program received CBE endorsement (CBE #3636) on July 26, 2022.[515] The measure steward (CDC) intends to pursue CBE endorsement for the modified version of this measure.

(3) Data Submission and Reporting

We refer readers to the CY 2022 OPPS/ASC final rule with comment period (86 FR 63879 through 63883) for information on data submission and reporting of this measure. We did not propose any changes to the data submission or reporting process in the CY 2024 OPPS/ASC proposed rule (88 FR 49807). However, we did propose that reporting of the updated, modified version of this measure would begin with the CY 2024 reporting period for the ASCQR Program. Under the data submission and reporting process, which would remain unchanged under these proposals, ASCs collect the numerator and denominator for the COVID–19 Vaccination Coverage

[507] Pre-rulemaking MUC lists and map reports. The Measures Management System. (n.d.). Available at: *https://mmshub.cms.gov/measure-lifecycle/measure-implementation/pre-rulemaking/lists-and-reports.*

[508] Ibid.

[509] In previous years, we referred to the consensus-based entity (CBE) by corporate name. We have updated this language to refer to the CBE more generally.

[510] Centers for Medicare and Medicaid Services Measures Inventory Tool. (n.d.). Available at: *https://cmit.cms.gov/cmit/#/MeasureView?variantId=11670&sectionNumber=1.*

[511] The measure steward owns and maintains a measure while a measure developer develops, implements, and maintains a measure. In this case, the CDC serves as both the measure steward and measure developer. For more information on measure development, we refer readers to: Centers for Medicare and Medicaid Services (2023). Roles in Measure Development. Available at: *https://mmshub.cms.gov/about-quality/new-to-measures/roles.*

[512] Centers for Disease Control and Prevention (2022). Contraindications and precautions. Available at: *https://www.cdc.gov/vaccines/covid-19/clinical-considerations/interim-considerations-us.html#contraindications.*

[513] For more details on the reporting of other contract personnel, we refer readers to the NHSN COVID–19 Vaccination Protocol, Weekly COVID–19 Vaccination Module for Healthcare Personnel available at: *https://www.cdc.gov/nhsn/pdfs/hps/covidvax/protocol-hcp-508.pdf.*

[514] Ibid.

[515] Centers for Medicare & Medicaid Services. Measure Specifications for Hospital Workgroup for the 2022 MUC List. Available at: *https://mmshub.cms.gov/sites/default/files/map-hospital-measure-specifications-manual-2022.pdf.*

Among HCP measure for at least one self-selected week during each month of the reporting quarter and submit the data to the NHSN Healthcare Personnel Safety (HPS) Component before the quarterly deadline to meet ASCQR Program requirements. If an ASC submits more than one week of data in a month, the most recent week's data are used to calculate the measure. For example, if both the first- and third-weeks of data for an ASC are submitted, the third week data will be used for measure calculation and public reporting. Each quarter, the CDC calculates a single quarterly COVID–19 HCP vaccination coverage rate for each ASC, which is then calculated by taking the average of the data from the three weekly rates submitted by the ASC for that quarter. We publicly report each quarterly COVID–19 HCP vaccination coverage rate as calculated by the CDC (86 FR 63878).

We refer readers to section XIV.B.2.a of this final rule with comment period for the same proposal for the Hospital OQR Program.

We invited public comment on the proposal.

Comment: Some commenters supported the proposed modification to the COVID–19 Vaccination Coverage Among HCP measure and noted the importance of maintaining alignment across programs and with current CDC guidelines. A few commenters highlighted the significance of vaccination in preventing greater spread of COVID–19 and the potential for continued vaccination to prevent future large-scale outbreaks. One commenter expressed the importance of ''up to date'' guidelines to ensure patients have accurate information to support their choice of provider.

Response: We thank commenters for their support. We agree that maintaining alignment across programs and the current CDC guideline is important, as is the new definition of ''up to date'' due to the changing nature of the virus's transmission and community spread. We agree that vaccination plays a critical part of HHS's strategy to effectively counter the spread of COVID–19 and will continue to support it as the most effective means to prevent the worst consequences of COVID–19, including severe illness, hospitalization, and death. Additionally, we continue to believe it is important to incentivize and track HCP vaccination through quality measurement across care settings, including the outpatient and ASC settings. We believe that HCP vaccinations will protect healthcare workers, patients, and caregivers and help sustain the ability of HCP in each of these care settings to continue serving their communities.

Comment: Many commenters did not support modifying the COVID–19 Vaccination Coverage Among HCP measure due to concerns that the frequent changes to the CDC's definition of ''up to date'' combined with uncertainty around future vaccination schedules creates unnecessary burden for facilities. Many commenters expressed concern that changing definitions and guidance exacerbates staffing and resource challenges and requires updates to facility or system-level vaccination policies, adding burden and confusion.

Response: We acknowledge commenters' concerns around data collection, burden, and staffing and resource challenges for reporting the COVID–19 Vaccination Coverage Among HCP measure. As evidenced by the increased cases and hospitalizations in August 2023 due to new variants, we believe that COVID–19 remains a relevant and evolving situation requiring monitoring of vaccination rates to ensure the safety of patients, caregivers and providers, and that the burden of reporting is outweighed by the benefits of collecting and regularly publishing these data to inform care decision-making. Additionally, the data submission and reporting requirements provide flexibility for facilities with staffing and resource challenges as this measure only requires facilities to collect data for one self-selected week during each month of the reporting quarter at minimum.

When we finalized the adoption of the COVID–19 Vaccination Coverage Among HCP measure in the CY 2022 OPPS/ASC final rule with comment period (86 FR 63875), we received several comments encouraging us to update the measure as new evidence on COVID–19 is identified. While we acknowledge that the definition of ''up to date'' may change in the future, our intention is to continue to work with partners, including the FDA and CDC, to consider and align any updates to the measure specifications in future rulemaking as appropriate to ensure the safety of patients, providers, and caregivers in facilities of care.

Comment: Many commenters recommended that CMS reduce the required reporting frequency from quarterly to annually to reduce reporting burden for facilities. Some of these commenters observed that annual reporting would mirror the reporting schedule for the Influenza Vaccination Coverage Among HCP measure, which has been adopted into some quality reporting programs. One commenter recommended that the chosen week for data reporting be determined by individuals unaffiliated with the ASC to avoid bias. One commenter recommended that CMS educate stakeholders on the evolving COVID–19 vaccination requirements.

Response: We thank commenters for their recommendations on data collection reporting frequency, and support for the COVID–19 Vaccination Coverage Among HCP measure. As stated in the CY 2024 OPPS/ASC proposed rule (88 FR 49806), the measure developer based this measure on the Influenza Vaccination Coverage Among HCP measure (CBE #0431), which is reported annually. The measure developer (the CDC) intends to adopt a similar approach to the modified COVID–19 Vaccination Coverage Among HCP measure if vaccination strategy becomes seasonal. While monitoring and surveillance are ongoing, we do not currently have data demonstrating seasonal trends in the circulation of SARS–CoV–2. In addition, we do not believe that ASC-selection of the week for reporting on this measure introduces significant bias as the sampling is taken from within the same facility over time.

Comment: Several commenters did not support updating the specifications for the COVID–19 Vaccination Coverage Among HCP measure because the PHE has expired. Several commenters expressed their opinion that the end of Federal vaccination requirements does not justify the continued data collection for this measure. Several of these commenters recommended the removal of the measure for these reasons.

Response: As we acknowledged in the CY 2024 OPPS/ASC proposed rule (88 FR 49805), the PHE expired on May 11, 2023. While some state and Federal reporting requirements have since changed, the expiration of the PHE for COVID–19 has no bearing on the use of this measure for quality reporting because vaccination continues to be an essential tool in preventing COVID–19 transmission. Monitoring and surveillance of vaccination rates through measure performance is important as it provides patients, beneficiaries, and their caregivers with information to support informed decision-making.

We believe this measure continues to align with our goals to promote wellness and disease prevention, especially in light of new variants and an increase in COVID–19 infection and hospitalizations as of September 2023. Under CMS' Meaningful Measures Framework 2.0, the COVID–19 Vaccination Coverage Among HCP

measure addresses the quality priorities of ''Immunizations'' and ''Public Health'' through the Meaningful Measures Area of ''Wellness and Prevention.'' Under the National Quality Strategy, the measure addresses the goal of Safety under the priority area Safety and Resiliency. As part of the Administration's continued response to COVID–19, and in light of the presence of new variants that have resulted in higher rates of infection and hospitalizations as of September 2023,[516] we will continue to work to protect individuals and communities from the virus and its worst impacts.

Comment: A few commenters did not support inclusion of the COVID–19 Vaccination Coverage Among HCP measure in the ASCQR Program measure set due to conflict between state and local mandates and Federal quality reporting requirements. One commenter recommended that the measure specifications have proper exclusion criteria in alignment with Federal and state vaccination exemption policies.

Response: We recognize commenters' concerns regarding potential discrepancies between local, state, and Federal requirements for COVID–19 vaccination. However, we reiterate that the ASCQR Program is a quality reporting program, separate from state and local policies as well as other Federal policies, including those related to vaccination exemption. We also note that neither the proposed modified measure nor the current version of the measure mandates vaccination, and the elimination of the Federal vaccine mandate is immaterial to the adoption and use of the measure for quality reporting purposes.

Comment: One commenter recommended that we continually monitor this measure for unintended consequences since it has not undergone full validity and reliability testing. Another commenter recommended that ASCs stratify the measure data to identify sub-populations of HCP that have lower vaccine uptake.

Response: As part of the MAP review process, all MUC list measures were required to submit testing results and be subject to review by workgroup and MAP members, as well as be open for public commentary. The current version of the measure received CBE endorsement (CBE #3636, ''Quarterly Reporting of COVID–19 Vaccination Coverage among Healthcare Personnel'') on July 26, 2022. While the modified measure has not undergone this endorsement process, the measure steward, CDC, has signaled intention to submit the modified measure for CBE endorsement, which we believe will support the appropriateness of this measure for the ASC setting, similar to the current measure. In addition, though the modified measure was not explicitly tested in this setting, it was considered a reliable and valid measurement for other care settings, and the MAP recommended its use for ensuring quality care within the ASC setting. We thank the commenters for their recommendations regarding monitoring and use of measure information. Regarding the recommendation to stratify this measure, as we stated in the CY 2024 OPPS/ASC proposed rule, the measure cannot be stratified since the data are submitted at an aggregate rather than an individual level (86 FR 49806).

After consideration of the public comments we received, we are finalizing our proposed modification to the COVID–19 Vaccination Coverage Among HCP Measure in the ASCQR Program as proposed.

b. Modification of the Survey Instrument Used for the Cataracts: Improvement in Patient's Visual Function Within 90 Days Following Cataract Surgery Measure Beginning With the Voluntary CY 2024 Reporting Period

(1) Background

In the CY 2014 OPPS/ASC final rule with comment period (78 FR 75129), we finalized the adoption of the Cataracts: Improvement in Patient's Visual Function Within 90 Days Following Cataract Surgery (Cataracts Visual Function) measure beginning with the CY 2014 reporting period/CY 2016 payment determination. This measure assesses the percentage of patients aged 18 years and older who had cataract surgery and had improvement in visual function within 90 days following the cataract surgery via the administration of pre-operative and post-operative survey instruments (78 FR 75129). A ''survey instrument'' is an assessment tool that has been appropriately validated for the population for which it is being used.[517] For purposes of this modification to the Cataracts Visual Function measure, the survey instruments we considered and proposed assess the visual function of a patient pre- and post-operatively to determine whether the patient's visual function changed within 90 days of cataract surgery. Examples of survey instruments assessing visual function include, but are not limited to, the National Eye Institute Visual Function Questionnaire (NEI–VFQ), the Visual Function (VF–14), the modified (VF–8R), the Activities of Daily Vision Scale (ADVS), the Catquest, and the modified Catquest-9. While the measure has been available for voluntary reporting in the ASCQR Program since the CY 2015 reporting period, a number of ASCs have reported data consistently using the survey instrument of their choice (87 FR 72119). We refer readers to the Cataracts Visual Function measure's section of the ASCQR Program Specifications Manual for additional detail, which is available at: *https://qualitynet.cms.gov/asc/specifications-manuals.*

In the CY 2015 OPPS/ASC final rule with comment period (79 FR 66984), we expressed concerns that clinicians' use of varying survey instruments would lead to inconsistent measure results. However, a study conducted a comparison among the 16 survey instruments currently accepted for use by ASCs in collecting data for this measure and found them to be scientifically valid, detected clinically important changes, and provided comparable results.[518] While all 16 survey instruments in this study demonstrate usefulness for detecting clinically important change in cataract patients, some survey instruments had detection sensitivity scores higher than others.[519]

Several commenters responding to the CY 2022 OPPS/ASC proposed rule (86 FR 63846) requested additional guidance from CMS regarding measure specifications and survey instruments for this Cataracts Visual Function measure in the Hospital OQR Program. We have considered this comment on this measure, and we agree that survey instruments for the assessment of visual function pre- and post-cataract surgery should be clarified to standardize acceptable survey instruments, while minimizing collecting and reporting burden, and to improve measure reliability. Thus, in the CY 2024 OPPS/ASC proposed rule (88 FR 49807 through 49809), we proposed to clarify which specific survey instruments may be used for the assessment of visual function pre- and post-cataract surgery

[516] Centers for Disease Control and Prevention (August 23, 2023). Risk Assessment Summary for SARS CoV–2 Sublineage BA.2.86 Available at: *https://www.cdc.gov/respiratory-viruses/whats-new/covid-19-variant.html.*

[517] Ambulatory Surgical Center Specification Manual. (n.d.). Qualitynet. Retrieved March 21, 2023, from *https://qualitynet.cms.gov/asc/specifications-manuals.*

[518] McAlinden C, Gothwal VK, Khadka J, et al. (2011). A head-to-head comparison of 16 cataract surgery outcome questionnaires. *Ophthalmology.*118(12):2374–81. *https://doi.org/10.1016/j.ophtha.2011.06.008.*

[519] Ibid.

for the Cataracts Visual Function measure in both the Hospital OQR Program and the ASCQR Program, to ensure alignment of this measure's specifications across our quality reporting programs. We proposed to limit the survey instruments that an ASC may use to assess changes in a patient's visual function for purposes of the Cataracts Visual Function measure to those listed below:

- The National Eye Institute Visual Function Questionnaire-25 (NEI VFQ–25)
- The Visual Functioning Patient Questionnaire (VF–14)
- The Visual Functioning Index Patient Questionnaire (VF–8R)

(2) Considerations for the Standardization of Survey Instruments Assessing Improvement in Patient's Visual Function Within 90 Days Following Cataract Surgery

We considered several factors when identifying which specific survey instruments would be acceptable for ASCs to use when collecting data for the Cataracts Visual Function measure, such as comprehensiveness, validity, reliability, length, and burden. We stated our belief that the three survey instruments listed above would allow ASCs to select the length of the survey instrument to be administered while ensuring adequate validity and reliability.[520] [521] [522] All three of the survey instruments are based upon the 51-item National Eye Institute Visual Function Questionnaire (NEI VFQ–51) survey instrument, which was the first survey instrument originally developed for assessing a patient's visual function before and after cataract surgery. Each of the three survey instruments have progressively fewer numbers of questions than the NEI VFQ–51: 25 questions for the NEI VFQ–25, 14 questions for the VF–14, and eight questions for the VF–8R. Even with fewer questions, all three of the survey instruments have been validated as providing results comparable to the NEI VFQ–51. In addition, all three of the survey instruments are readily available for ASCs to access and use.

In the CY 2024 OPPS/ASC proposed rule (88 FR 49808), we proposed to allow ASCs to use the NEI VFQ–25 for administering and calculating this Cataracts Visual Function measure due to its comprehensiveness, its adequate validity and reliability, as well as its potential to reduce language barriers for patients. The NEI VFQ–25 is a shorter version of the NEI VFQ–51, being comprised of 25 items across 12 vision-specific domains (general health, general vision, ocular pain, near activities, distance activities, social functioning, mental health, role difficulties, dependency, driving, color vision, and peripheral vision).[523]

The NEI VFQ–25, similar to the VF–14 and VF–8R, has adequate reliability and validity.[524] The NEI VFQ–25 composite, near activities, and distance activities subscales demonstrated good internal consistency reliability, test-retest reliability, convergent validity, and known-groups validity.[525] Furthermore, the NEI VFQ–25's high internal consistency, indicates that items of the NEI VFQ–25 are highly related to each other and to the scale as a whole.[526]

In addition, the survey instrument is publicly available on the RAND website at no cost and has been translated to many languages, which is a valuable benefit for patients with limited English proficiency. The NEI VFQ–25 was chosen over other survey instruments to reduce potential language barriers, as, for example, the currently available Activities of Daily Vision Scale (ADVS) is dependent on English language skills.[527] More information on the NEI VFQ–25 can be found at: *https://www.rand.org/health-care/surveys_tools/vfq.html.*

While the NEI VFQ–25 was shortened significantly from the original NEI VFQ–51, it has been criticized for its still lengthy test-time. However, the inclusion of this survey instrument in this measure's specifications would allow for a more detailed assessment of cataract surgery outcomes as it was designed to include questions which are most important for persons who have chronic eye diseases.[528] Further, if an ASC finds the NEI VFQ–25 particularly burdensome to administer, the ASC may choose from the other two survey instruments proposed for inclusion in this measure's specifications for ASCs to use for this measure, as both of these have even fewer survey questions to administer.

In the CY 2024 OPPS/ASC proposed rule (88 FR 49809), we also proposed to allow ASCs to use the 14-item VF–14 and the 8-item VF–8R for administering and calculating this Cataracts Visual Function measure. Each can be administered in a shorter timeframe than the NEI VFQ–25 with high precision.[529] [530] Thus, the succinct formats of the VF–14 and VF–8R may ease ASCs' burden in administering the survey instruments, and potentially increase the rate of patient responses for this measure, as compared with other survey instrument options we considered. We believe these survey instruments achieve results comparable with the longer NEI VFQ–25 and NEI VFQ–51 survey instruments with substantially fewer questions to administer.

Furthermore, in the CY 2024 OPPS/ASC proposed rule (88 FR 49809), we proposed inclusion of the VF–14 because currently it is the most commonly used survey instrument and we believe it would be beneficial to allow the majority of physicians who have already been using the VF–14 to continue to have the option to do so.[531] The VF–14 is comprised of 14 items relating to daily living activities and function, such as reading, writing, seeing steps, stairs or curbs, and operating a motor vehicle.[532] Studies using this survey instrument generally

[520] Sivaprasad, S., Tschosik, E., Kapre, A., Varma, R., Bressler, N. M., Kimel, M., Dolan, C., & Silverman, D. (2018). Reliability and construct validity of the NEI VFQ–25 in a subset of patients with geographic atrophy from the Phase 2 mahalo study. *American Journal of Ophthalmology, 190,* 1–8. *https://doi.org/10.1016/j.ajo.2018.03.006.*

[521] Hecht, I., Kanclerz, P., & Tuuminen, R. (2022). Secondary outcomes of Lens and cataract surgery: More than just ''best-corrected visual acuity.'' Progress in Retinal and Eye Research, 101150. *https://doi.org/10.1016/j.preteyeres.2022.101150.*

[522] Orizonartstudios (2023). 2023 MIPS measure #303: Cataracts: Improvement in patient's visual function within 90 days following cataract surgery. MDinteractive. Retrieved March 13, 2023, from *https://mdinteractive.com/mips_quality_measure/2023-mips-quality-measure-303.*

[523] U.S. Department of Health and Human Services. (n.d.). *Visual function questionnaire 25.* National Eye Institute. Retrieved March 13, 2023, from *https://www.nei.nih.gov/learn-about-eye-health/outreach-campaigns-and-resources/outreach-materials/visual-function-questionnaire-25.*

[524] Sivaprasad, S., Tschosik, E., Kapre, A., Varma, R., Bressler, N. M., Kimel, M., Dolan, C. & Silverman, D. (2018). Reliability and construct validity of the NEI VFQ–25 in a subset of patients with geographic atrophy from the Phase 2 mahalo study. American Journal of Ophthalmology, 190, 1–8. *https://doi.org/10.1016/j.ajo.2018.03.006.*

[525] Ibid.

[526] Ibid.

[527] Mangione CM, Phillips RS, Seddon JM, et al. Development of the 'Activities of Daily Vision Scale'. A measure of visual functional status. Med Care. 1992;30(12):1111–1126. *https://doi.org/10.1097/00005650-199212000-00004.*

[528] Hecht, I., Kanclerz, P., & Tuuminen, R. (2022). Secondary outcomes of Lens and cataract surgery: More than just ''best-corrected visual acuity.'' Progress in Retinal and Eye Research, 101150. *https://doi.org/10.1016/j.preteyeres.2022.101150.*

[529] Ibid.

[530] Orizonartstudios (2023). 2023 MIPS measure #303: Cataracts: Improvement in patient's visual function within 90 days following cataract surgery. MDinteractive. Retrieved March 13, 2023, from *https://mdinteractive.com/mips_quality_measure/2023-mips-quality-measure-303.*

[531] Hecht, I., Kanclerz, P., & Tuuminen, R. (2022). Secondary outcomes of Lens and cataract surgery: More than just ''best-corrected visual acuity.'' Progress in Retinal and Eye Research, 101150. *https://doi.org/10.1016/j.preteyeres.2022.101150.*

[532] Ibid.

report significant and clinically important improvement following cataract surgery.[533] The VF–14 additionally has achieved adequate reliability and validity, proving it to be a dependable survey instrument for cataract outcomes.[534] [535]

In the CY 2024 OPPS/ASC proposed rule (88 FR 49809), we also proposed the VF–8R, as it is the most concise of the three survey instruments, while still achieving adequate validity and reliability.[536] The VF–8R consists of questions related to reading, fine handwork, writing, playing board games, and watching television.[537] Given its conciseness compared to the majority of currently available survey instruments and its adequate psychometric properties, we stated our belief that the VF–8R would be beneficial for measuring cataract surgery outcomes without prompting further patient survey fatigue.[538]

For these reasons, we believe that the NEI VFQ–25, VF–14, and VF–8R are the most appropriate survey instruments for ASCs to use to assess a patient's visual function pre- and post-cataract surgery for purposes of calculating and submitting data for the Cataracts Visual Function measure in the ASCQR Program.

To standardize survey instrument administration for the Cataracts Visual Function measure, in the CY 2024 OPPS/ASC proposed rule (88 FR 49807 through 49809), we proposed to limit the survey instruments that can be used to administer this measure, beginning with the voluntary CY 2024 reporting period, to these three survey instruments: (1) NEI VFQ–25; (2) VF–14; and (3) VF–8R. We believe the use of these three survey instruments to report data on the Cataracts Visual Function measure will allow for a more standardized approach to data collection. Having a limited number of allowable survey instruments would also address several commenters' request for additional guidance on survey instruments as well as improve measure reliability.

(3) Considerations for Data Collection Modes for the Cataracts: Improvement in Patient's Visual Function Within 90 Days Following Cataract Surgery Measure Beginning With the Voluntary CY 2024 Reporting Period

As summarized in the CY 2023 OPPS/ASC final rule with comment period (87 FR 72118 through 72120), many commenters expressed concern about the high administrative burden of reporting the Cataracts Visual Function measure, as the measure uniquely requires coordination among clinicians of different specialties (that is, opticians and ophthalmologists). In an effort to decrease administrative burden surrounding in-office time constraints, we reiterate that, while we recommend the patient's physician or optometrist administer, collect, and report the survey results to the ASC, the survey instruments required for this measure can be administered by the ASC itself via phone, by the patient via regular or electronic mail, or during clinician follow-up.

Scientific literature supports the conclusion that self-administered survey instruments produce statistically reliable results.[539] [540] Furthermore, scientific literature indicates that regular mail and electronic mail surveys respectively, are preferred by varying subgroups of patients. The inclusion of both options ensures that patients will be able to respond to survey instruments in their preferred format.[541] [542] These findings support the inclusion of varying survey instrument-collection methods for patient and provider convenience.

We invited public comment on the proposal.

Comment: Many commenters supported our proposal to modify the survey instruments allowable for the Cataracts Visual Function measure beginning with the voluntary CY 2024 reporting period. Several commenters concurred with CMS that this modification would standardize data collection and ensure comparability of the measure across ASCs. Several commenters also expressed support for the modification because the three survey instruments demonstrate adequate reliability, validity, and decrease burden. One commenter believed this modification would facilitate better comparability across providers and support care decision-making. Another commenter expressed support for CMS' efforts to create program alignment.

Response: We thank commenters for their support. We agree that limiting the allowable survey instruments used to report on the Cataracts Visual Function measure to three survey instruments of different lengths will allow for a less burdensome, and more standardized approach to data collection and improve measure reliability. We emphasize that all three surveys demonstrate adequate reliability and validity, which demonstrates that they are dependable survey instruments for measuring functionality following cataract surgery. Further, by adopting this modification for this measure, we will be promoting alignment with the Hospital OQR Program.

Comment: Several commenters recommended that the Cataracts Visual Function measure either remain voluntary or be removed from the program due to the high administrative burden. One commenter believed the measure should remain voluntary until a digital version is developed. Another commenter recommended that, in addition to removing the Cataracts Visual Function measure, CMS instead adopt the Toxic Anterior Segment Syndrome (TASS) measure.[543] One commenter recommended CMS provide additional best practices as more facilities adopt the use of these three surveys during the voluntary measurement period.

Response: We are retaining this measure as voluntary for the CY 2024 reporting period/CY 2026 payment determination. We will continue to evaluate this measure moving forward. We respectfully disagree that this measure should be removed from the ASCQR Program as we believe the benefits of the measure outweigh the reporting burden.

Cataract surgery is one of the most commonly performed procedures in

[533] Ibid.

[534] Ibid.

[535] Orizonartstudios (2023). 2023 MIPS measure #303: Cataracts: Improvement in patient's visual function within 90 days following cataract surgery. MDinteractive. Retrieved March 13, 2023, from *https://mdinteractive.com/mips_quality_measure/2023-mips-quality-measure-303.*

[536] Ibid.

[537] Pre-Cataract Surgery—Visual Functioning Index (VF–8R): Available at: *https://www.aao.org/practice-management/coding/updates-resources.* (In the CY 2024 OPPS/ASC proposed rule, we cited this information to: *https://eyecaresite.com/wp-content/uploads/2020/02/Visual-Functioning-Index-Pre-Cat-SX.pdf.* However, after review, the information appears to have moved. Thus, we have updated the citation in this final rule.)

[538] Ibid.

[539] Bhandari, N.R., Kathe, N., Hayes, C., & Payakachat, N. (2018). Reliability and validity of SF–12V2 among adults with self-reported cancer. *Research in Social and Administrative Pharmacy, 14*(11), 1080–1084. *https://doi.org/10.1016/j.sapharm.2018.01.007.*

[540] Stolwijk, C., van Tubergen, A., Ramiro, S., Essers, I., Blaauw, M., van der Heijde, D., Landewe, R., van den Bosch, F., Dougados, M., & Boonen, A. (2014). Aspects of validity of the self-administered comorbidity questionnaire in patients with ankylosing spondylitis. *Rheumatology, 53*(6), 1054–1064. *https://doi.org/10.1093/rheumatology/ket354.*

[541] Kelfve, S., Kivi, M., Johansson, B., & Lindwall, M. (2020). Going web or staying paper? the use of web-surveys among older people. *https://doi.org/10.21203/rs.3.rs-21136/v4.*

[542] Meyer, V.M., Benjamens, S., Moumni, M.E., Lange, J.F., & Pol, R.A. (2020). Global overview of response rates in patient and health care professional surveys in surgery. *Annals of Surgery, 275*(1). *https://doi.org/10.1097/sla.0000000000004078.*

[543] *https://www.ascquality.org/qualitymeasures.*

ASCs and there is currently no other patient-reported outcome measure for this procedure for the ASCQR Program. As a patient reported outcome measure, this measure aligns with the CMS National Quality Strategy (NQS) ''Foster Engagement'' goal, which seeks to increase engagement between individuals and their care teams to improve quality, establish trusting relationships, and bring the voices of people and caregivers to the forefront. The Meaningful Measures 2.0 goals also prioritize patient-reported measures and promoting better collection and integration of patient voices across CMS' quality programs.

We believe that the value of the information this measure provides to consumers about quality of care justifies the potential administrative burden for ASCs that voluntarily report on it. As some facilities have been voluntarily reporting this measure successfully while it has not been required, we believe this indicates that the measure is not overly burdensome, and that standardizing the allowable survey instruments will further improve its usability and reliability in the ASC setting. We wish to reiterate that when selecting allowable surveys, we considered a variety of factors, such as accessibility, feasibility, and prevalence. We also reiterate that we proposed to limit the allowable surveys to the NEI–VFQ–25, VF–14, and VF–8R as they are commonly adopted survey instruments that are readily available online for entities to access and use.

We note that while it is recommended that the facility obtain the survey results from the appropriate physician or optometrist, the surveys can be administered by the facility via phone, mail, email, or during clinician follow-up. Patients can also self-administer the surveys and submit them directly to the facility via mail or email.

Finally, we appreciate the commenter's suggestion to adopt the Toxic Anterior Segment Syndrome (TASS) measure. We note that the TASS measure is used to assess the number of ophthalmic anterior segment surgery patients diagnosed with TASS within 2 days of surgery. The Cataracts Visual Function measure assesses the percentage of patients aged 18 years and older who had cataract surgery and had improvement in visual function achieved within 90 days following the cataract surgery. Therefore, the TASS measure could not seamlessly replace the Cataracts Visual Function measure, as they measure two different outcomes. We will consider the adoption of new measures in future rulemaking.

Additionally, we will consider developing best practices based on facility use of these surveys during the voluntary measurement period.

Comment: Some commenters suggested that the Cataract Visual Function measure be made mandatory.

Response: We have continued to evaluate and consider community feedback on this measure's specifications and implementation since the measure was originally adopted in CY 2014. As previously noted, we are retaining this measure as voluntary for the CY 2024 reporting period/CY 2026 payment determination. We acknowledge that this measure requires cross-setting coordination among clinicians of different specialties (that is, surgeons and ophthalmologists), increasing burden. If we determine that the value of mandatory reporting justifies increased burden on ASCs, we will propose to transition the measure to mandatory reporting through rulemaking.

Comment: One commenter recommended that the Cataracts Visual Function measure be included instead under the Quality Payment Program, as patients are likely to receive ongoing care following the procedure outside of the facility where the surgery was performed.

Response: This measure is already included under the Quality Payment Program's Merit-based Incentive Payment System (MIPS) (Measure #303) for MIPS eligible clinicians (as defined in 42 CFR 414.1305) to report. Even though individual clinicians may report this measure in MIPS, we continue to view this measure as appropriate for assessing facility-level of care as the procedures are provided in a facility.

After consideration of the public comments we received, we are finalizing our proposal to modify the Cataracts Visual Function measure as proposed. We also refer readers to the discussion of a similar proposal for the same measure as used in the Hospital OQR Program in section XIV.B.2.b of this final rule with comment period.

c. Modification of Endoscopy/Polyp Surveillance: Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients Measure Denominator Change To Align With Current Clinical Guidelines Beginning With the CY 2024 Reporting Period/CY 2026 Payment Determination

(1) Background

In 2019, colorectal cancer (CRC) accounted for the 4th highest rate of new cancer cases and 4th highest rate of cancer deaths in the United States.[544] The American Cancer Society (ACS) estimates that in 2023, 153,020 individuals will be newly diagnosed with CRC and 52,550 individuals will die from CRC in the United States.[545] The CDC advises, ''[c]olorectal cancer almost always develops from precancerous polyps (abnormal growths) in the colon or rectum. Screening tests can find precancerous polyps, so that they can be removed before they turn into cancer. Screening tests can also find colorectal cancer early, when treatment works best. Regular screening, beginning at age 45, is the key to preventing colorectal cancer and finding it early.'' [546]

In May 2021, the United States Preventive Services Task Force (USPSTF) issued a revised Final Recommendation Statement on CRC Screening.[547] This replaced the prior USPSTF 2016 Final Recommendation Statement and included a number of updated policy recommendations based on new evidence and understandings of CRC and CRC screening. The USPSTF recommended that adults who do not have signs or symptoms of CRC and who are at average risk for CRC begin screening at age 45 instead of the previous recommendation of age 50.[548] In addition, multiple professional organizations, including the ACS, American Society of Colon and Rectal Surgeons, and the U.S. Multi-Society Task Force on Colorectal Cancer (which represents the American College of Gastroenterology, the American Gastroenterological Association, and the American Society for Gastrointestinal Endoscopy), recommend that people of average risk of CRC start regular screening at age 45.[549] [550] [551] Based on

[544] Centers for Disease Control (2022). Colorectal Cancer Statistics. Available at: *https://gis.cdc.gov/Cancer/USCS/#/AtAGlance/.*

[545] American Cancer Society (2023). Cancer Facts & Figures 2023. Available at: *https://www.cancer.org/research/cancer-facts-statistics/all-cancer-facts-figures/2023-cancer-facts-figures.html.*

[546] Centers for Disease Control (2022). What Should I Know About Screening?. Available at: *https://www.cdc.gov/cancer/colorectal/basic_info/screening/index.htm.*

[547] US Preventive Services Task Force (2021). Screening for Colorectal Cancer. *JAMA,* 325(19), 1965–1977. *https://doi.org/10.1001/jama.2021.6238.*

[548] Ibid.

[549] Wolf A, Fontham ETH, Church TR, et al. (2018). Colorectal cancer screening for average-risk adults: 2018 guideline update from the American Cancer Society. *CA. Cancer J. Clin.,* 2018(68), 250–281. *https://doi.org/10.3322/caac.21457.*

[550] American Society of Colon & Rectal Surgeons. Colorectal Cancer Screening and Surveillance Recommendations of U.S. Multisociety Task Force. Available at: *https://fascrs.org/healthcare-providers/education/clinical-practice-guidelines/colorectal-cancer-screening-and-surveillance-recom.*

the recent changes in clinical guidelines to begin CRC screening at age 45 instead of age 50, in the CY 2024 OPPS/ASC proposed rule (88 FR 49809 and 49810), we proposed to modify the Endoscopy/Polyp Surveillance: Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients (the ''Colonoscopy Follow-Up Interval'') measure to follow these clinical guideline changes.

(2) Overview of Measure

We refer readers to the CMS Measures Inventory Tool (CMIT) and the ASCQR Specification Manual for more information on the Colonoscopy Follow-Up Interval measure, including background on the measure and a complete summary of measure specifications.[552] [553] Currently, the Colonoscopy Follow-Up Interval measure assesses the ''percentage of patients aged 50 years to 75 years receiving a screening colonoscopy without biopsy or polypectomy who had a recommended follow-up interval of at least 10 years for repeat colonoscopy documented in their colonoscopy report.'' [554] In the CY 2024 OPPS/ASC proposed rule (88 FR 49810), we proposed to amend the measure's denominator language by replacing the phrase ''aged 50 years'' with the phrase ''aged 45 years.'' Under the proposal, the measure denominator would be modified to ''all patients aged *45 years to 75 years* receiving screening colonoscopy without biopsy or polypectomy'' from ''all patients aged *50 years to 75 years* receiving screening colonoscopy without biopsy or polypectomy.'' [555] We did not propose any changes to the measure numerator, other measure specifications, exclusions, or data collection for the Colonoscopy Follow-Up Interval measure.

In the CY 2023 Physician Fee Schedule final rule with comment period (87 FR 69760 through 69767), we adopted the modified Colonoscopy Follow-Up Interval measure, which we proposed for the ASCQR Program, for the Merit-based Incentive Payment System (MIPS). We have considered the importance of aligning the minimum age requirement for CRC screening across quality reporting programs and clinical guidelines, and as a result, in the CY 2024 OPPS/ASC proposed rule (88 FR 49810), we proposed to modify the Colonoscopy Follow-Up Interval measure denominator to ''all patients aged 45 to 75 years'' for the ASCQR Program. We proposed the modification of the Colonoscopy Follow-Up Interval measure beginning with the CY 2024 reporting period/CY 2026 payment determination.

We invited public comment on the proposal.

Comment: Many commenters supported CMS's proposal to modify the Colonoscopy Follow-Up Interval measure beginning with the CY 2024 reporting period/CY 2026 payment determination. Some commenters supported the proposal because the modification to the denominator aligns with clinical guidelines. Some of these commenters supported the proposal because the modification to the denominator provides alignment across quality programs. One commenter supported the proposal, noting that rates of CRC have been increasing in people under 50 years of age and stating a belief that the denominator change will promote appropriate and important preventative services. Another commenter supported the proposal stating a belief that the change in denominator will have far-reaching impacts on improving access to CRC screening and reduce CRC mortality.

Response: We thank commenters for supporting our proposal to modify the Colonoscopy Follow-Up Interval measure denominator to ''all patients aged 45 to 75 years'' for the ASCQR Program. We agree that it is important to align requirements across quality reporting programs and clinical guidelines when relevant. We believe that establishing consistent policy across our programs in terms of minimum age limits for CRC screening tests is critical to the public's understanding of evolving CRC screening recommendations.

Comment: One commenter noted that the modification to this measure would increase the patient population that is eligible for the measure and recommended that CMS maintain the same sample size to prevent increased administrative burden.

Response: We clarify that the only change proposed to this measure was a change in the measure denominator to ''all patients aged 45 to 75 years.'' We understand that the measure would increase the patient population that is eligible for the measure, however, we did not propose any other changes to the measure specifications or sampling methodology for the measure, including any changes to minimum sampling size requirements. Therefore, we do not believe that the modification to the denominator increases the burden on ASCs. We refer readers to the Sampling Specifications section of the ASCQR Program Specifications Manual for additional detail, which is available at: *https://qualitynet.cms.gov/asc/specifications-manuals.*

After consideration of the public comments we received, we are finalizing our proposal to modify the Colonoscopy Follow-Up Interval measure as proposed. We also refer readers to the discussion of a similar proposal for the same measure as used in the Hospital OQR Program in section XIV.B.2.c of this final rule with comment period.

5. Adoption of New Measures for the ASCQR Program Measure-Set

Section 1833(i)(7)(B) of the Act states that, except as the Secretary may otherwise provide, the provisions of section 1833(t)(17)(B) through (E) of the Act apply with respect to ASC services in a similar manner to the manner in which they apply to hospitals for the Hospital OQR Program. Section 1833(t)(17)(C)(i) of the Act requires the Secretary to develop measures appropriate for the measurement of the quality of care (including medication errors) furnished by hospitals in outpatient settings, that these measures reflect consensus among affected parties and, to the extent feasible and practicable, that these measures include measures set forth by one or more national consensus-based entities. We have noted in previous rulemaking (76 FR 74494) the requirement that measures reflect consensus among affected parties can be achieved in other ways aside from CBE endorsement, including through the measure development process, through broad acceptance, use of the measure(s), and through public comment.

Section 1890A of the Act requires that we establish and follow a pre-rulemaking process for selecting quality and efficiency measures for our programs, including taking into consideration input from multi-stakeholder groups. As part of this pre-rulemaking process, the CBE, with which we contract under section 1890 of the Act, convened these groups under the Measure Applications Partnership

[551] Patel SG, May FP, Anderson JC, Burke CA, et al. (2022). Updates on Age to Start and Stop Colorectal Cancer Screening: Recommendations From the U.S. Multi-Society Task Force on Colorectal Cancer. *The American Journal of Gastroenterology,* 117(1), 57–69. *https://doi.org/10.14309/ajg.0000000000001548.*

[552] Centers for Medicare & Medicaid Services (2023). Measures Inventory Tool. Available at: *https://cmit.cms.gov/cmit/#/MeasureView?variantId=793&sectionNumber=1.*

[553] Qualitynet Home. (n.d.). Retrieved March 21, 2023, from *https://qualitynet.cms.gov/asc/specifications-manuals#tab6.*

[554] Centers for Medicare & Medicaid Services (2023). Measures Inventory Tool. Available at: *https://cmit.cms.gov/cmit/#/MeasureView?variantId=793&sectionNumber=1.*

[555] Ibid.

(MAP). The MAP is a public-private partnership created for the primary purpose of providing input to HHS on the selection of measures as required by section 1890(b)(7)(B) of the Act, including measures for the ASCQR Program. We followed this pre-rulemaking process for the measures we proposed for adoption in the CY 2024 OPPS/ASC proposed rule for the ASCQR Program as detailed therein (88 FR 49810 through 49818) and under this section of this final rule with comment period.

Specifically, in the CY 2024 OPPS/ASC proposed rule (88 FR 49810 through 49818), we proposed to: (1) re-adopt with modification the ASC Facility Volume Data on Selected ASC Surgical Procedures measure, with voluntary reporting in the CY 2025 reporting period followed by mandatory reporting beginning with the CY 2026 reporting period/CY 2028 payment determination; and (2) adopt the Risk-Standardized Patient-Reported Outcome-Based Performance Measure (PRO–PM) Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA) in the ASC Setting (THA/TKA PRO–PM), with voluntary reporting beginning with the CYs 2025 and 2026 reporting periods followed by mandatory reporting beginning with the CY 2027 reporting period/CY 2030 payment determination.

We discuss each of these measures, along with the public comments that we received on them, in subsequent sections.

a. Proposed ASC Facility Volume Data on Selected ASC Surgical Procedures Measure With Modification Beginning With the Voluntary CY 2025 Reporting Period Followed by Mandatory Reporting Beginning With the CY 2026 Reporting Period/CY 2028 Payment Determination

(1) Background

Hospital care has been gradually shifting from inpatient to outpatient settings.[556] Further, research indicates that volume of services performed in ASCs will continue to grow, with some estimates projecting a 25 percent increase in patients between 2019 and 2029.[557] In addition, as further discussed herein, larger facility surgical procedure volume may be associated with better outcomes due to having characteristics that improve care, such as efficient team work and increased surgical experience.[558] In light of these trends in facility volume and more recent studies finding that volume is an indicator of quality, it is now especially important to track volume within ASCs, as it could provide valuable insight into the quality of ASCs' services for CMS and patients.

Although measuring the volume of procedures and other services has a long history as a quality metric, quality measurement efforts had moved away from collecting and analyzing data on volume because some considered volume simply a proxy for quality compared to directly measuring outcomes.[559] However, experts on quality and safety have recently suggested that, while volume may not alone indicate better outcomes, it is still an important component of quality.[560] [561] [562] Specifically, larger facility surgical procedure volume may be associated with better outcomes due to having characteristics that improve care.[563] For example, high-volume facilities may have teams that work more effectively together, or have superior systems or programs for identifying and responding to complications.[564] This association between volume and patient outcomes may be attributable to greater experience or surgical skill, greater comfort with and, hence, higher likelihood of application of standardized best practices, and increased experience in monitoring and management of surgical patients for the particular procedure.

The ASCQR Program does not currently include a quality measure for facility-level volume data, including surgical procedure volume data, but did so previously. In the CY 2012 OPPS/ASC final rule with comment period (76 FR 74507 through 74509), we adopted the ASC Facility Volume Data on Selected ASC Surgical Procedures (ASC Procedure Volume) measure beginning with the CY 2015 payment determination. This structural measure of facility capacity collected surgical procedure volume data on seven categories [565] of procedures frequently performed in the ASC setting: Gastrointestinal, Eye, Nervous System, Musculoskeletal, Skin, Respiratory, and Genitourinary.[566] We adopted the ASC Procedure Volume measure based on evidence that the volume of surgical procedures, particularly of high-risk surgical procedures, is related to better patient outcomes, including decreased mortality (76 FR 74507).[567] [568] We further stated our belief that publicly reporting volume data would provide patients with beneficial information to use when selecting a care provider (76 FR 74507).

In the CY 2018 OPPS/ASC final rule with comment period (82 FR 59449 and 59450), we stated our belief at that time that other measures in the ASCQR Program on specific procedure types, such as the Unplanned Anterior Vitrectomy measure, could provide patients with more valuable ASC quality of care information than the ASC Procedure Volume measure. Thus, we removed the ASC Procedure Volume measure beginning with the CY 2019 payment determination based on the availability of other measures that are ''more strongly associated with desired patient outcomes for the particular topic'' (currently Factor 6 in our regulation at § 416.320(c)(2)(vi)) (82 FR 59449).

[556] Medicare Payment Advisory Commission. March 2021 Report to the Congress: Medicare Payment Policy. Chapter 3. Available at: *https://www.medpac.gov/wp-content/uploads/2021/10/mar21_medpac_report_ch3_sec.pdf.*

[557] SG2 impact of Change Forecast predicts enormous disruption in health care provider landscape by 2029. Sg2. (2021). Retrieved March 28, 2023, from *https://www.sg2.com/media-center/press-releases/sg2-impact-forecast-predicts-disruption-health-care-provider-landscape-2029/.*

[558] Jha AK (2015) Back to the Future: Volume as a Quality Metric. JAMA Forum Archive. Published online June 10, 2015. *https://jamanetwork.com/channels/health-forum/fullarticle/2760155.*

[559] Ibid.

[560] Ibid.

[561] Shang, M., Mori, M., Gan, G., Deng, Y., Brooks, C., Weininger, G., Sallam, A., Vallabhajosyula, P., & Geirsson, A. (2022). Widening volume and persistent outcome disparity in Valve Operations: New York Statewide Analysis, 2005–2016. The Journal of Thoracic and Cardiovascular Surgery, *164*(6). *https://doi.org/10.1016/j.jtcvs.2020.11.098.*

[562] Iwatsuki, M., Yamamoto, H., Miyata, H., Kakeji, Y., Yoshida, K., Konno, H., Seto, Y., & Baba, H. (2018). Effect of hospital and surgeon volume on postoperative outcomes after distal gastrectomy for gastric cancer based on data from 145,523 Japanese patients collected from a nationwide web-based data entry system. *Gastric Cancer, 22*(1), 190–201. *https://doi.org/10.1007/s10120-018-0883-1.*

[563] Jha AK (2015) Back to the Future: Volume as a Quality Metric. JAMA Forum Archive. Published online June 10, 2015. *https://jamanetwork.com/channels/health-forum/fullarticle/2760155.*

[564] Ibid.

[565] At the time of this measure's initial adoption in the CY 2012 OPPS/ASC final rule (76 FR 74509), we finalized that ASCs would report all-patient volume data with respect to six categories: Gastrointestinal, Eye, Nervous System, Musculoskeletal, Skin, and Genitourinary. The seventh category ''Respiratory'' was added following this measure's adoption. This measure collected data ranging from six to eight procedural categories while incorporated in the ASCQR Program.

[566] ASC Specifications Manual version 5.1. Available at: *https://qualitynet.cms.gov/asc/specifications-manuals#tab6.*

[567] Saito, Y., Tateishi, K., Kanda, M., Shiko, Y., Kawasaki, Y., Kobayashi, Y., & Inoue, T. (2022). Volume-outcome relationships for percutaneous coronary intervention in acute myocardial infarction. *Journal of the American Heart Association, 11*(6). *https://doi.org/10.1161/jaha.121.023805.*

[568] Vemulapalli, S., Carroll, J., & Mack, M. et al. (2019) Procedural Volume and Outcomes for Transcatheter Aortic-Valve Replacement. The New England Journal of Medicine, 380(26), 2541–2550. *https://doi.org/10.1056/NEJMsa1901109.*

However, a commenter who opposed the removal of the ASC Procedure Volume measure at the time emphasized the measure data's usefulness for comparative research, outcomes research, immediate consumer value, and strategic planning (82 FR 59449). One commenter also expressed concern that non-availability of these data would interfere with the acceptance of ASC-based procedures, asserting that this measure helps to demonstrate the value of ASC-based procedures (82 FR 59449). These commenters further noted that the measure was not overly burdensome and, therefore, should not be removed (82 FR 59449). At the time, while we recognized the value of the measure and these concerns, we believed, overall, that the administrative burden and maintenance costs associated with this measure outweighed the benefits of keeping the measure in the ASCQR Program (82 FR 59449 and 59450).

In the CY 2023 OPPS/ASC final rule with comment period (87 FR 72127 through 72130), we stated that we have been considering re-adopting the ASC Procedure Volume measure for two reasons. First, since the removal of the ASC Procedure Volume measure, scientific literature has concluded that volume serves as an indicator of which facilities are experienced with certain outpatient procedures and can assist consumers in making informed decisions about where they receive care.[569] Further supporting this position that volume metrics are an indicator of quality, one study found an inverse volume–mortality relationship related to transfemoral transcatheter aortic-valve replacement (TAVR) procedures performed from 2015 through 2017.[570] Second, as discussed above, the recent shift of more surgical procedures being performed in outpatient settings has placed greater importance on tracking the volume of outpatient procedures in different settings, including ASCs. We believe that patients and their caregivers may benefit from the public reporting of facility-level volume measure data because the volume data illuminate which procedures are performed across ASCs, provide the ability to track volume changes by facility and procedure category, and can serve as an indicator for patients of which facilities are experienced with certain outpatient procedures. The ASC Procedure Volume measure was the only measure in the ASCQR Program measure set that captured facility-level volume within ASCs for both Medicare beneficiaries and non-Medicare patients. As a result of this measure's removal in the CY 2018 OPPS/ASC final rule, the ASCQR Program currently does not capture outpatient surgical procedure volume in ASCs.

In response to our request for comment in the CY 2023 OPPS/ASC proposed rule (87 FR 44748 through 44750) regarding the potential inclusion of a volume measure in the ASCQR Program, a few commenters suggested that we can determine facility volumes for procedures performed using Medicare Fee-For-Service (FFS) claims (87 72129 and 72130). However, we note that the ASC Procedure Volume measure included the submission of both Medicare and non-Medicare volume data; thus, relying solely on the use of Medicare FFS claims data to simplify reporting would limit a future volume measure to only the Medicare program payer, leading to an incomplete representation of ASCs' procedural volume.[571]

Additionally, in response to our request for comment in the CY 2023 OPPS/ASC proposed rule (87 FR 44748 through 44750), a few commenters stated that they believe there is a lack of evidence supporting the correlation between volume and quality as meaningful (87 FR 72129 and 72130). However, many studies in recent years have shown that volume does serve as an indicator of quality of care.[572] [573] For example, studies published since the CY 2018 OPPS/ASC final rule with comment period found that patients at high volume hospitals for a specific procedure had lower rates of surgical site infections, complications, and mortality compared to patients at low-volume hospitals.[574] [575] We reiterate our belief, grounded in this published scientific literature, that volume metrics serve as an indicator of which facilities are experienced with certain outpatient procedures and assist consumers in making informed decisions about where they receive care.[576] [577]

(2) Overview of Measure

(a) Data Collection, Submission, Reporting, and Measure Specifications

In the CY 2024 OPPS/ASC proposed rule (88 FR 49812), we noted that the ASC Procedure Volume measure, if re-adopted with the modifications discussed below, would collect data regarding the aggregate count of selected surgical procedures. Most ASC procedures fall into one of eight categories: Cardiovascular, Eye, Gastrointestinal, Genitourinary, Musculoskeletal, Nervous System, Respiratory, and Skin.[578] Under the proposed measure, data surrounding the top five most frequently performed procedures among ASCs in each category would be collected and publicly displayed. The top five procedures in each category would be assessed and updated annually as needed to ensure data collection of most accurate and frequently performed procedures.[579]

We also proposed that ASCs would submit aggregate-level data through the CMS web-based tool (currently the Hospital Quality Reporting (HQR) system), consistent with what was required during the measure's initial adoption (76 FR 74508). Data received through the HQR system would then be publicly displayed on the *data.cms.gov* website or another CMS website. We refer readers to § 416.315 for our codified policies regarding public

[569] Ogola GO, Crandall ML, Richter KM, & Shafi S (2018). High-volume hospitals are associated with lower mortality among high-risk emergency general surgery patients. *Journal of Trauma and Acute Care Surgery,* 85(3), 560–565. *https://doi.org/10.1097/TA.0000000000001985.*

[570] Vemulapalli S, Carroll J, Mack M, et al. (2019). Procedural Volume and Outcomes for Transcatheter Aortic-Valve Replacement. *The New England Journal of Medicine,* 380(26), 2541–2550. *https://doi.org/10.1056/NEJMsa1901109.*

[571] The specifications for the removed ASC Procedure Volume measure are available in the ASC Specifications Manual version 5.1 available at: *https://qualitynet.cms.gov/asc/specifications-manuals#tab6.*

[572] Ogola, Gerald O. Ph.D., MPH; Crandall, Marie L. MD, MPH; Richter, Kathleen M. MS, MBA, MFA; & Shafi, Shahid MD, MPH. (2018) High-volume hospitals are associated with lower mortality among high-risk emergency general surgery patients. Journal of Trauma and Acute Care Surgery: September 2018—Volume 85—Issue 3—p 560–565. *https://doi.org/10.1097/TA.0000000000001985.*

[573] Vemulapalli, S., Carroll, J., & Mack, M. et al. (2019) Procedural Volume and Outcomes for Transcatheter Aortic-Valve Replacement. *The New England Journal of Medicine, 380*(26), 2541–2550. *https://doi.org/10.1056/NEJMsa1901109.*

[574] Mufarrih, S.H., Ghani, M.O.A., Martins, R.S. et al. (2019) Effect of hospital volume on outcomes of total hip arthroplasty: a systematic review and meta-analysis. J Orthop Surg Res 14, 468. *https://doi.org/10.1186/s13018-019-1531-0.*

[575] Saito, Y., Tateishi, K., Kanda, M., Shiko, Y., Kawasaki, Y., Kobayashi, Y., & Inoue, T. (2022). Volume-outcome relationships for percutaneous coronary intervention in acute myocardial infarction. *Journal of the American Heart Association, 11*(6). *https://doi.org/10.1161/jaha.121.023805.*

[576] Ogola GO, Crandall ML, Richter KM, Shafi, S (2018). High-volume hospitals are associated with lower mortality among high-risk emergency general surgery patients. *Journal of Trauma and Acute Care Surgery,* 85(3), 560–565. *https://doi.org/10.1097/TA.0000000000001985.*

[577] Vemulapalli S, Carroll J, Mack M, et al. (2019). Procedural Volume and Outcomes for Transcatheter Aortic-Valve Replacement. *The New England Journal of Medicine,* 380(26), 2541–2550. *https://doi.org/10.1056/NEJMsa1901109.*

[578] ASC Specifications Manual version 1.0b. Available at: *https://qualitynet.cms.gov/asc/specifications-manuals#tab6.*

[579] Data source: Clinical Data Warehouse; CMS ASC Part B claims for encounters January 1, 2022–December 31, 2022.

reporting of data under the ASCQR Program.

In the CY 2024 OPPS/ASC proposed rule (88 FR 49812), we proposed to re-adopt the ASC Procedure Volume measure with modification, with voluntary reporting beginning with the CY 2025 reporting period followed by mandatory reporting beginning with CY 2026 reporting period/CY 2028 payment determination. At the time of this measure's initial adoption in the CY 2012 OPPS/ASC final rule with comment period (76 FR 74509), we finalized that ASCs would report all-patient volume data with respect to six categories: Gastrointestinal, Eye, Nervous System, Musculoskeletal, Skin, and Genitourinary. The first modification of this previously adopted measure that we proposed is that the ASC Procedure Volume measure data collection will cover eight categories: Cardiovascular, Eye, Gastrointestinal, Genitourinary, Musculoskeletal, Nervous System, Respiratory, and Skin. Furthermore, in response to commenter concerns regarding potential difficulty detecting procedural volume differentiation among these broad-based categories (76 FR 74508), the second modification to this measure that we proposed is that, instead of collecting and publicly displaying data surrounding these eight broad categories, we would more granularly collect and publicly display data reported for the top five most frequently performed procedures among ASCs within each category. We refer readers to the Center for Medicare and Medicaid Services Inventory Tool for more information on this measure: *https://cmit.cms.gov/cmit/#/MeasureView?variantId=11740&sectionNumber=1.*

In the CY 2024 OPPS/ASC proposed rule (88 FR 49813), we also proposed that ASCs submit these data to CMS during the time period of January 1 through May 15 in the year prior to the affected payment determination year. For example, for the CY 2028 payment determination, the data submission period would be January 1, 2027, to May 15, 2027, covering the performance period of January 1, 2026, to December 31, 2026. We refer readers to section XV.D.1.c of this final rule with comment period for a more detailed discussion of the requirements for data submitted via a CMS online web-based tool. We previously codified our existing policies regarding data collection and submission under the ASCQR Program at § 416.310.

(b) Review by the Measure Applications Partnership (MAP)

The MAP conditionally supported the ASC Procedure Volume measure for rulemaking, pending testing indicating that the measure is reliable and valid, and endorsement by a CBE.[580] Additionally, the MAP noted that electronic reporting of procedure volumes based on code lists should not be overly burdensome to ASCs, and the public reporting of specific procedure volumes may be useful to patients.

The MAP members expressed differing views on the value of volume data to patients. Specifically, the MAP members representing patients stated the measure would be useful to patients as they decide where to seek care, as one data point along with others (for example, advice from providers). However, other MAP members expressed concern about the value of volume data for informing patient decisions without other context and encouraged the use of outcome measures instead.[581]

As discussed above, we reiterate that various studies have found that there is a well-established positive correlation between the volume of procedures performed at a facility and the clinical outcomes resulting from that procedure. For instance, a recent systematic review highlighted by the MAP found a significant volume-outcome relationship in the vast majority (87 percent) of the 403 studies analyzed.[582] The MAP noted a similar review focused on outpatient surgeries that similarly found a significant volume-outcome relationship across eight studies.[583]

The MAP stated that this measure addresses a national trend in which surgeries are moving from hospital inpatient settings to ASCs, and that public reporting of this measure could help CMS and the public better understand differences in the quality of care provided at facilities.[584] The MAP reported that ASC Procedure Volume measure data from 2015 and 2016 demonstrates variation in performance in the number of procedures performed by facilities in the 25th and 75th percentiles across the condition categories.[585] These findings support our belief, grounded in additional published scientific literature, that volume metrics serve as an indicator of which facilities are experienced with certain outpatient procedures and can assist consumers in making informed decisions about where they receive care.[586] [587]

In addition, the MAP noted the concurrent submission of MUC (Measures Under Consideration) 2022–030: Hospital Outpatient Department Volume Data on Selected Outpatient Surgical Procedures for inclusion in the Hospital Outpatient Quality Reporting (OQR) Program.[588] The MAP highlighted that the specifications of the volume measure proposed for the Hospital OQR Program are aligned with the volume measure we proposed for the ASCQR Program and, therefore, would facilitate comparisons of equivalent procedure volumes across ASCs and hospital outpatient departments (HOPDs), one of the key goals of the Hospital OQR and ASCQR Programs.

(c) Measure Endorsement

As discussed in the previous subsection of this final rule with comment period, the MAP reviewed and conditionally supported the ASC Procedure Volume measure pending testing indicating the measure is reliable and valid, and endorsement by a national CBE as the measure was not submitted for endorsement. We have noted in previous rulemaking (76 FR

[580] Pre-rulemaking MUC lists and map reports. Pre-Rulemaking MUC Lists and MAP Reports | The Measures Management System. (n.d.). Retrieved March 13, 2023, from *https://mmshub.cms.gov/measure-lifecycle/measure-implementation/pre-rulemaking/lists-and-reports.*

[581] Ibid.

[582] Levaillant, M., Marcilly, R., Levaillant, L., Michel, P., Hamel-Broza, J.-F., Vallet, B., & Lamer, A. (2021). Assessing the hospital volume-outcome relationship in surgery: A scoping review. *BMC Medical Research Methodology, 21*(1). *https://doi.org/10.1186/s12874-021-01396-6.*

[583] Stanak, M., & Strohmaier, C. (2020). Minimum volume standards in day surgery: A systematic review. *BMC Health Services Research, 20*(1). *https://doi.org/10.1186/s12913-020-05724-2.*

[584] Medicare Payment Advisory Commission. March 2021 Report to the Congress: Medicare Payment Policy. Available at: *https://www.medpac.gov/document/march-2021-report-to-the-congress-medicare-payment-policy/.*

[585] Pre-rulemaking MUC lists and map reports. The Measures Management System. (n.d.). Retrieved March 13, 2023, from *https://mmshub.cms.gov/measure-lifecycle/measure-implementation/pre-rulemaking/lists-and-reports.*

[586] Ogola, Gerald O. Ph.D., MPH; Crandall, Marie L. MD, MPH; Richter, Kathleen M. MS, MBA, MFA; Shafi, & Shahid MD, MPH. (2018) High-volume hospitals are associated with lower mortality among high-risk emergency general surgery patients. Journal of Trauma and Acute Care Surgery: September 2018—Volume 85—Issue 3—p 560–565. *https://doi.org/10.1097/TA.0000000000001985.*

[587] Saito, Y., Tateishi, K., Kanda, M., Shiko, Y., Kawasaki, Y., Kobayashi, Y., & Inoue, T. (2022). Volume-outcome relationships for percutaneous coronary intervention in acute myocardial infarction. *Journal of the American Heart Association, 11*(6). *https://doi.org/10.1161/jaha.121.023805.*

[588] Pre-rulemaking MUC lists and map reports. The Measures Management System. (n.d.). Retrieved March 13, 2023, from *https://mmshub.cms.gov/measure-lifecycle/measure-implementation/pre-rulemaking/lists-and-reports.*

74494) the requirement that measures reflect consensus among affected parties can be achieved in other ways aside from endorsement by a national CBE, including through the measure development process, through broad acceptance, use of the measure(s), and through public comment.

We considered the MAP's recommendation and proposed to re-adopt the measure because we did not find any other measures of procedure volume and this measure was previously used in the ASCQR Program, with supporters of its use. Given the support from the MAP and feedback from public comment, as well as the increasing shift from inpatient to outpatient surgical procedures and evidence that volume metrics can promote higher quality healthcare for patients, in the CY 2024 OPPS/ASC proposed rule (88 FR 49811 through 49813), we proposed the re-adoption of this measure, with modification, in the ASCQR Program pending endorsement from a national CBE.

We invited public comment on the proposal.

Comment: Several commenters expressed support for our proposal to re-adopt with modification the ASC Procedure Volume measure beginning with the voluntary CY 2025 reporting period followed by mandatory reporting beginning with the CY 2026 reporting period/CY 2028 payment determination. Some of these commenters expressed that this measure provides valuable insights about quality of care and supports consumer decision-making. Some commenters expressed support for the measure's more granular reporting at the procedure level for the five most frequently occurring procedures in each of the clinical categories.

Response: We thank the commenters for their support. Although we are not re-adopting the ASC Procedure Volume measure at this time, we agree that this measure provides valuable insights into care quality and is supportive of consumer decision-making.

Comment: Many commenters did not support our proposal to re-adopt with modification the ASC Procedure Volume measure. Some of these commenters stated that there is a lack of evidence that surgical volume is an indicator of quality, specifically in the outpatient setting, and a few commenters stated that the measure does not align with CMS' Meaningful Measures 2.0 Framework for this reason. A few commenters cited evidence to support these beliefs, which indicates higher volume for transcatheter aortic valve replacement (TAVR) procedures is not an indicator of superior care quality.[589] [590]

Response: We disagree with these comments regarding whether volume can serve as an indicator of quality along with other quality information. We reiterate that recently published scientific literature supports the position that volume metrics can serve as an indicator of quality, denoting which facilities have experience with certain outpatient procedures, and can assist consumers in making informed decisions about where they receive care. Furthermore, a study found that congestive heart failure (CHF) patients who stayed in hospitals with more experience in managing CHF received higher quality care and experienced better outcomes.[591] Referencing commenter concern of a lack of evidence that surgical volume is an indicator of quality, specifically in the outpatient setting, in the CY 2024 OPPS/ASC proposed rule (88 FR 49812), we cited a study, which found that patients who had total hip arthroplasties performed at high-volume hospitals had lower rates of surgical site infections, complications, and mortality compared to patients at low-volume hospitals.[592] In the CY 2021 OPPS/ASC final rule (85 FR 86146), we announced that THA and TKA procedures were removed from the Inpatient Only Procedures (IPO) list, leading to a shift in THA procedures in ASCs. We believe these studies, linking volume to quality of care, aligns with the Meaningful Measures 2.0 Framework goal to use ''only high-quality measures impacting key quality domains.'' Although we are not re-adopting the ASC Procedure Volume measure at this time for the reasons discussed below, we will continue to assess such evidence to ensure alignment with our goals set forth in the Meaningful Measures 2.0 Framework.

We acknowledge the publication of recent research indicating that when patients were treated in high-volume hospitals versus those with best historical outcomes, there was no significant reduction in observed versus modeled adverse events.[593] [594] We believe these recent studies indicate that hospital variation in care metrics is important, but that it does not discount the conclusions of the studies mentioned above or address instances where facility volume is low. Given the potential association between volume and outcomes, we believe that volume information can be useful to patients and consumers. Although we are not re-adopting the ASC Procedure Volume measure at this time, given that there is a potential association between volume and outcome, we believe this measure provides transparency, including information about volume that may be informative to patients.

Comment: Some commenters did not support our proposal to re-adopt with modification the ASC Procedure Volume measure stating that there is a lack of evidence to support volume as a measure of quality in low-risk procedures. This commenter stated that volume literature focuses on high-risk surgical procedures, which are often not performed at ASCs.

Response: We acknowledge that much of the literature addresses the relationship of volume to outcomes in high-risk surgeries, which are less likely to be performed in ASCs. However, a recent meta-analysis showed that low volume hospitals were associated with higher surgical site infection rates, longer length of stay, higher 90-day complication rates, and higher 1-year mortality rates compared with high volume hospitals following Total Hip Arthroplasty (THA) procedures.[595] THA is considered a lower risk procedure and is often performed in ASCs. We note that while this study takes place in the hospital setting, the volume of THA and Total Knee Arthroplasty (TKA) procedures for Medicare beneficiaries aged 65 years and older have been increasing in ASCs. In the CY 2021 OPPS/ASC final rule with comment period (85 FR 86146), we announced

[589] Nelson AJ, Wegermann ZK, Gallup D. Modeling the association of volume vs composite outcome thresholds with outcomes and access to transcatheter aortic valve implantation in the US. JAMA Cardiol 2023; 8(5): 492–502. Available at: *https://doi.org/10.1001/jamacardio.2023.0477.*

[590] Russo MJ, McCabe JM, Thourani VH, et al. Case Volume and Outcomes After TAVR With Balloon-Expandable Prostheses: Insights From TVT Registry. J Am Coll Cardiol. 2019;73(4):427–440. *https://doi.org/10.1016/j.jacc.2018.11.031.*

[591] Joynt, K.E., Orav, E.J., & Jha, A.K. (2011). The association between hospital volume and processes, outcomes, and costs of care for congestive heart failure. Annals of internal medicine, 154(2), 94–102. *https://doi.org/10.7326/0003-4819-154-2-201101180-00008.*

[592] Mufarrih, S.H., Ghani, M.O.A., Martins, R.S. et al. Effect of hospital volume on outcomes of total hip arthroplasty: a systematic review and metaanalysis. J Orthop Surg Res 14, 468 (2019). *https://doi.org/10.1186/s13018-019-1531-0.*

[593] Nelson AJ, Wegermann ZK, Gallup D, et al. Modeling the Association of Volume vs Composite Outcome Thresholds With Outcomes and Access to Transcatheter Aortic Valve Implantation in the US. JAMA Cardiol. 2023;8(5):492–502. Available at: *https://doi.org/10.1001/jamacardio.2023.0477.*

[594] Russo MJ, McCabe JM, Thourani VH, et al. Case Volume and Outcomes After TAVR With Balloon-Expandable Prostheses: Insights From TVT Registry. J Am Coll Cardiol. 2019;73(4):427–440. *https://doi.org/10.1016/j.jacc.2018.11.031.*

[595] Mufarrih, S.H., Ghani, M.O.A., Martins, R.S. et al. (2019) Effect of hospital volume on outcomes of total hip arthroplasty: a systematic review and meta-analysis. J Orthop Surg Res 14, 468. *https://doi.org/10.1186/s13018-019-1531-0.*

that THA and TKA procedures were removed from the Inpatient Only Procedures (IPO) list and added to the ASC covered procedures list (CPL), leading to a shift in THA procedures in both hospitals and ASCs.

Comment: Some commenters did not support our policy to re-adopt the ASC Procedure Volume measure due to the previous rationale for removing this measure: the availability of other measures that are ''more strongly associated with desired patient outcomes for the particular topic'' (currently Factor 6 in our regulation at § 416.320(c)(2)(vi)) (82 FR 59449).

Response: We acknowledge that, in the CY 2018 OPPS/ASC final rule with comment period (82 FR 59449 and 59450), we stated our belief, based on the then-available literature, that measures on specific procedure types would provide patients with more valuable ASC quality of care information as these types of measures are more strongly associated with desired patient outcomes. Thus, we removed the ASC Facility Volume measure under our second criterion for removal from the program; specifically, that there are other measures available that are more strongly associated with desired patient outcomes for the particular topic (82 FR 59449 and 59450). However, as we noted in the CY 2024 OPPS/ASC proposed rule (88 FR 49811 through 49813) and section XV.B.5.a(1) of this final rule with comment period, more recent studies support the use of volume as a quality-of-care indicator and we continue to believe that this information can be of benefit to Medicare beneficiaries and other consumers, especially when case volume is low.

Also, as we noted in the CY 2024 OPPS/ASC proposed rule (88 FR 49811 through 49813) and section XV.B.5.a(1) of this final rule with comment period, the migration of procedures from the inpatient to the outpatient setting has since placed greater importance on tracking the volume of outpatient procedures. As we noted in the CY 2023 OPPS/ASC final rule, forty-five percent of percutaneous coronary intervention (PCI) procedures shifted from the inpatient to outpatient setting from 2004 to 2014, and more than 70 percent of patients who undergo thoracoscopic surgery can be discharged on the day of surgery itself due to the use of innovative techniques and technologies available in the outpatient setting (87 FR 72128). Given the relatively small number of HCPCS codes utilized by most ASCs, we believe that patients may benefit from the public reporting of facility-level volume measure data that illuminates which procedures are performed across ASCs, provides the ability to track volume changes by facility and procedure category, and can serve as an indicator for patients of which facilities are experienced with certain outpatient procedures. We believe that the increasing importance of volume metrics in the outpatient setting supports our proposal to re-adopt this measure with modification. Although we are not re-adopting the ASC Procedure Volume measure at this time, we recognize the increasing importance of volume in the ASC setting.

Comment: Many commenters did not support our proposal because they stated that they believe the potential administrative burden of the ASC Procedure Volume measure outweighs its potential value.

Response: The MAP noted that electronic reporting of procedure volumes based on code lists should not be overly burdensome to ASCs, and the public reporting of specific procedure volumes may be useful to patients. Furthermore, our estimates of burden indicated that each participating ASC would spend 10 minutes per year to submit the data for this measure to CMS, as noted in the CY 2024 OPPS/ASC proposed rule (88 FR 49875). We believe these collection efforts would not impose undue burden on ASCs.

In addition, this measure would further advance CMS' goal of transitioning to a fully digital quality measurement landscape and promoting interoperability while helping to decrease reporting burden in the long-term. We believe that the value of the measure would outweigh potential reporting burden. Although we are not re-adopting the ASC Procedure Volume measure at this time, we believe these collection efforts would not impose undue burden on ASCs.

Comment: Several commenters did not support our proposal because they believe the ASC Procedure Volume measure would lead to potential misuse through ''perverse incentives'' for providers to perform non-indicated procedures to increase procedural volume.

Response: We disagree that the ASC Procedure Volume measure creates an incentive for providers to perform non-indicated procedures. The ASC Procedure Volume measure tracks the top five procedures performed in the outpatient setting using CPT codes. The procedures posted by volume change yearly; thus, we do not believe the volume measure would lead to potential misuse through ''perverse incentives'' for providers to perform non-indicated procedures to increase procedural volume. Furthermore, when this measure was previously included in the ASCQR Program measure set, we did not identify significant changes in reported volume information that would indicate this measure engendered ''perverse incentives'' for facilities to perform non-indicated procedures simply to increase reported numbers of procedures.

Comment: One commenter did not support our proposal to re-adopt with modification the ASC Procedure Volume measure because they stated that volume data would be confusing to Medicare patients. Commenters noted that such data are limited in value due to lack of context related to clinical appropriateness of the procedure for each specific patient and the risk profile for the volume of patients. Commenters added that the measure does not provide context related to overall procedural outcomes.

Response: We disagree with the commenter's assertion that volume data would be confusing to Medicare patients. As we explained in the CY 2024 OPPS/ASC proposed rule (88 FR 49812), we intended to publish the measure's results to the *data.cms.gov* website, or other CMS website, which is designed to be a consumer-friendly portal for quality information on Medicare providers, if the proposal was adopted in future rulemaking. We interpret commenters' concern about the clinical appropriateness of the procedure for each specific patient to indicate concern that the ASC Procedure Volume measure's calculation may appear to be inflated by medically unnecessary procedures. We disagree with this opinion. We believe the ASC Procedure Volume measure provides fundamental information to patients about the frequency with which procedure is performed in a given facility. We do not believe that this information is harmful for patients, and we believe strongly that equipping patients with as much meaningful information as possible about their care builds a stronger health care system. We also do not agree that the measure lacks risk profile context for ASCs as ASCs typically do not perform procedures in higher risk patients. As we stated in the CY 2024 OPPS/ASC proposed rule (88 FR 49811), volume metrics serve as an indicator of which facilities have experience with certain outpatient procedures, likely leading to higher quality outcomes, and assist consumers in making informed decisions about where they receive care. We do agree that other dimensions of quality are also important to patients' outcomes in the

hospital outpatient department, but we believe that data submitted for the ASC Procedure Volume measure provide transparency into volume as a dimension of quality, which may be informative to patients. The ASC Procedure Volume measure is intended to be one of many metrics for determining care. Although we are not re-adopting the ASC Procedure Volume measure at this time, we continue to believe there is significant evidence linking volume to quality of care, and that volume metrics serve as an indicator of which facilities have experience with certain outpatient procedures and can assist consumers in making informed decisions about where they receive care. Based on comments received, we intend to reassess the measure's methodology and reconsider how the data may be publicly displayed in the most meaningful manner for consumers.

Comment: One commenter raised concern over many services and diagnoses distributed over large groups of procedure or diagnostic codes, so even if a facility regularly performs a service, a volume measure may incorrectly identify it as having little to no experience if no single code exceeds a minimum threshold. Another commenter also stated that CMS already has access to these data through claims.

Response: Responding to commenter concerns over the distribution of services over large groups of procedural codes, our method does group some procedural codes within specific procedure categories to account for services being distributed over groups of procedures.[596] We reiterate that the proposal is not being finalized for CY 2024. We will further consider this concern in future rulemaking.

We acknowledge that we can determine facility volumes for procedures performed using Medicare FFS claims. However, as we note in section XV.B.5.a(1) of this final rule with comment period, the specifications for the ASC Procedure Volume measure include reporting data for non-Medicare patients. Relying solely on the use of Medicare FFS claims data to simplify reporting would limit the measure to only this payer, which will not fully account for the volume of procedures performed at a given ASC.

Comment: One commenter expressed confusion related to the number of procedure categories, as they have varied since the measure's initial implementation.

Response: The categories chosen for the proposed ASC Facility Volume measure were informed and updated through CY 2022 ASC Claims with Surgical CPT codes. Since this measure's initial adoption, the number of categories varied annually depending on updated code data. This measure collected data ranging from six to eight procedural categories while incorporated in the ASCQR Program. During this measure's initial adoption in the ASCQR Program in CY 2012, there were six finalized categories (76 FR 74509). During the measure's time in the ASCQR Program, there were predominately seven or eight categories annually. To collect the most meaningful data for this measure, we proposed to collect the top five procedures within each chosen category. We reiterate that these top five procedures would be assessed and updated annually as needed to ensure data collection of most accurate and frequently performed procedures. We will continue to examine these data on an ongoing basis and will consider adjusting the measure specifications as needed.

Comment: One commenter noted the importance of lower-volume sites in providing services to underserved populations, such as Black, Hispanic, and rural patients. One commenter noted that, because ASCs are specialized facilities, there would be a lot of ''0'' data entries for procedure categories that are not applicable.

Response: We recognize that lower-volume sites provide services to patients, including historically underserved populations. We will consider the importance of lower volume sites for historically underserved populations if we re-propose this measure in the future.

We acknowledge commenter's concerns over the data completeness of the ASC Procedure Volume measure. The categories and the top five procedures in each category would be assessed and updated annually as needed to ensure data collection of the most frequently performed procedures. We will continue to examine these data on an ongoing basis and adjust the measure specifications as needed.

Comment: Many commenters provided recommendations in response to our proposal to re-adopt with modification the ASC Procedure Volume measure. A few commenters recommended adopting this measure as voluntary. One commenter recommended that CMS develop a volume measure focusing on procedures transitioning from the inpatient to the outpatient setting to replace this measure. Another commenter recommended the development of complementary measures of patient outcomes to pair with the ASC Procedure Volume measure to provide a complete picture of quality in the care setting. One commenter recommended not limiting the reporting to the 5 most frequently occurring procedures per clinical category. One commenter recommended only confidential-level feedback rather than publicly reporting these data and tying it to payment. Another commenter recommended that the top 5 frequently performed procedure categories are specific to each ASC, rather than national trends, to provide a more accurate picture of the specific facility's procedure volume. Additionally, another commenter suggested that CMS instead focus on outcome measures.

Response: We thank commenters for providing these recommendations for this measure. We agree that refining measure specifications to benefit both patients and providers is important. We will consider these recommendations in future rulemaking. We would like to clarify that the ASCQR Program is a pay-for-reporting program and not a value-based payment program.

Comment: One commenter requested clarification on whether the top 5 most frequently performed procedures are based on national data or if they are specific to each ASC.

Response: The top five most frequently performed procedures are based on national data. We will continue to refine the best approach for determining most frequently performed procedures.

After consideration of the public comments we received, we are not finalizing our proposal to re-adopt with modification the ASC Procedure Volume measure beginning with the voluntary CY 2025 reporting period followed by mandatory reporting beginning with the CY 2026 reporting period/CY 2028 payment determination. We are not finalizing this measure at this time, as we would like to conduct analysis that includes FFS and Medicare Advantage data when evaluating categories and most frequently performed procedures. Based on comments received, we intend to reassess the measure's methodology and reconsider how the data may be publicly displayed.

[596] ASC Specifications Manual version 1.0b. Available at: *https://qualitynet.cms.gov/asc/specifications-manuals#tab6.*

We continue to believe there is significant evidence linking volume to quality of care, and that volume metrics serve as an indicator of which facilities have experience with certain outpatient procedures and assist consumers in making informed decisions about where they receive care. We also refer readers to the discussion of a similar proposal for the same measure as used in the Hospital OQR Program in section XIV.B.3.a of this final rule with comment period.

b. Adoption of the Risk Standardized Patient-Reported Outcome-Based Performance Measure (PRO–PM) Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA) in the ASC Setting (THA/TKA PRO–PM) Beginning With Voluntary CYs 2025 and 2026 Reporting Periods Followed by Mandatory Reporting Beginning With the CY 2027 Reporting Period/CY 2030 Payment Determination

(1) Background

In the FY 2023 IPPS/LTCH PPS final rule with comment period (87 FR 49246 through 49257), we adopted the THA/TKA PRO–PM in the Hospital Inpatient Quality Reporting (IQR) Program beginning with voluntary reporting periods in CYs 2025 and 2026,[597] followed by mandatory reporting for eligible elective procedures occurring July 1, 2024, through June 30, 2025, for the FY 2028 payment determination. In the CY 2024 OPPS/ASC proposed rule (88 FR 49813 through 49818), we proposed the adoption of the THA/TKA PRO–PM into the ASCQR Program using the same specifications as finalized for the hospital-level measure adopted into the Hospital IQR Program (87 FR 49246 through 49257) with modifications to include procedures performed in the ASC setting.

Approximately six million adults aged 65 or older suffer from osteoarthritis in the United States.[598] In 2013, there were approximately 568,000 hospitalizations billed to Medicare for osteoarthritis.[599] Hip and knee osteoarthritis is one of the leading causes of disability among non-institutionalized adults,[600] [601] and roughly 80 percent of patients with osteoarthritis have some limitation in mobility.[602] [603] Elective THA and TKA are most commonly performed for degenerative joint disease or osteoarthritis, which affects more than 30 million Americans.[604] THA and TKA offer the potential for significant improvement in quality of life by decreasing pain and improving function in a majority of patients, without resulting in a high risk of complications or death.[605] [606] [607] However, not all patients experience benefit from these procedures.[608] Many patients note that their pre-operative expectations for functional improvement have not been met.[609] [610] [611] [612] In addition, clinical practice variation has been well documented in the United States,[613] [614] [615] [616] [617] readmission and complication rates vary across hospitals,[618] [619] and international experience documents wide hospital-level variation in patient-reported outcome measure results following THA and TKA.[620]

Due to the absence of recently conducted, large scale and uniformly collected patient-reported outcome (PRO) data available from patients undergoing elective primary THA/TKA, we established an incentivized,

[597] In the CY 2024 OPPS/ASC proposed rule (88 FR 49813 and 49814), we stated these reporting periods as FY. The IQR voluntary reporting periods for the THA/TKA PRO–PM are October 23, 2022, through June 30, 2023, for 2025 voluntary reporting and April 2, 2023, through June 30, 2024, for 2026 voluntary reporting.

[598] Arthritis Foundation (2018). Arthritis By the Numbers Book of Trusted Facts and Figures. Accessed March 8, 2019. Available at: *https://www.arthritis.org/getmedia/e1256607-fa87-4593-aa8a-8db4f291072a/2019-abtn-final-march-2019.pdf.*

[599] Torio CM & Moore BJ (2016). National inpatient hospital costs: the most expensive conditions by payer, 2013. HCUP statistical brief #204. Healthcare Cost and Utilization Project (HCUP) Statistical Briefs. Rockville, MD, Agency for Healthcare Research and Quality. Available at: *https://www.ncbi.nlm.nih.gov/books/NBK368492/.*

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[603] Theis KA, Murphy LB, Baker NA, & Hootman JM (2019). When you can't walk a mile: Walking limitation prevalence and associations among middle-aged and older US adults with Arthritis: A cross-sectional, population-based study. *ACR Open Rheumatol,* 1(6), 350–358. *https://www.doi.org/10.1002/acr2.11046.*

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[605] Rissanen P, Aro S, Slatis P, et al. (1995). Health and quality of life before and after hip or knee arthroplasty. *The Journal of arthroplasty,* 10(2), 169–175. *https://www.doi.org/10.1016/s0883-5403(05)80123-8.*

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[607] Sayah SM, Karunaratne S, Beckenkamp PR, et al. (2021). Clinical Course of Pain and Function Following Total Knee Arthroplasty: A Systematic Review and Meta-Regression. *J Arthroplasty,* 36(12), 3993–4002.e37. *https://www.doi.org/10.1016/j.arth.2021.06.019.*

[608] National Joint Registry. National Joint Registry for England and Wales 9th Annual Report 2012. Available at: *https://www.hqip.org.uk/wp-content/uploads/2018/02/national-joint-registry-9th-annual-report-2012.pdf.*

[609] Suda AJ, Seeger JB, Bitsch RG, et al. (2010). Are patients' expectations of hip and knee arthroplasty fulfilled? A prospective study of 130 patients. *Orthopedics,* 33(2), 76–80. *https://www.doi.org/10.3928/01477447-20100104-07.*

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[611] Harris IA, Harris AM, Naylor JM, et al. (2013). Discordance between patient and surgeon satisfaction after total joint arthroplasty. *The Journal of arthroplasty,* 28(5), 722–727. *https://www.doi.org/10.1016/j.arth.2012.07.044.*

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[613] Roos EM (2003). Effectiveness and practice variation of rehabilitation after joint replacement. *Current opinion in rheumatology,* 15(2),160–162. *https://doi.org/10.1097/00002281-200303000-00014.*

[614] Anderson FA, Huang W, Friedman RJ, et al. (2012). Prevention of venous thromboembolism after hip or knee arthroplasty: findings from a 2008 survey of US orthopedic surgeons. *The Journal of arthroplasty,* 27(5), 659–666 e655. *https://doi.org/10.1016/j.arth.2011.09.001.*

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[617] Siebens HC, Sharkey P, Aronow HU, et al. (2016). Variation in Rehabilitation Treatment Patterns for Hip Fracture Treated With Arthroplasty. *PM&R,* 8(3), 191–207. *https://doi.org/10.1016/j.pmrj.2015.07.005.*

[618] Suter LG, Grady JN, Lin Z, et al. 2013 Measure Updates and Specifications: Elective Primary Total Hip Arthroplasty (THA) And/OR Total Knee Arthroplasty (TKA) All-Cause Unplanned 30-Day Risk-Standardized Readmission Measure (Version 2.0). March 2013. Available at: *http://qualitynet.org/.*

[619] Suter LG, Parzynski CS, Grady JN, et al. 2013 Measures Update and Specifications: Elective Primary Total Hip Arthroplasty (THA) AND/OR Total Knee Arthroplasty (TKA) Risk-Standardized Complication Measure (Version 2.0). March 2013. Available at: *http://qualitynet.org/.*

[620] Rolfson O. (2010). Patient-reported Outcome Measures and Health-economic Aspects of Total Hip Arthroplasty: A study of the Swedish Hip Arthroplasty Register. Accessed July 20, 2013. Available at: *https://gupea.ub.gu.se/bitstream/handle/2077/23722/gupea_2077_23722_1.pdf?sequence=1.*

voluntary PRO data collection opportunity within the Comprehensive Care for Joint Replacement (CJR) model to support measure development.[621] Elective THA/TKAs are important, effective procedures performed on a broad population, and the patient outcomes for these procedures (such as pain, mobility, and quality of life) can be measured in a scientifically sound way,[622] [623] are influenced by a range of improvements in care,[624] and demonstrate hospital-level variation even after patient case mix adjustment.[625] [626] Further, THA/TKA procedures are specifically intended to improve function and reduce pain, making PROs a meaningful outcome metric to assess.[627]

[621] Centers for Medicare & Medicaid Services. Comprehensive Care for Joint Replacement Model. Available at: *https://innovation.cms.gov/innovation-models/cjr.*

[622] Liebs TR, Herzberg W, Ruther W, et al. (2016). Quality-adjusted life years gained by hip and knee replacement surgery and its aftercare. *Archives of physical medicine and rehabilitation,* 97(5), 691–700. *https://doi.org/10.1016/j.apmr.2015.12.021.*

[623] White D & Master H (2016). Patient Reported Measures of Physical Function in Knee Osteoarthritis. *Rheum Dis Clin North Am,* 42(2), 239–252. *https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4853650/.*

[624] Kim K, Anoushiravani A, Chen K, et al. (2019). Perioperative Orthopedic Surgical Home: Optimizing Total Joint Arthroplasty Candidates and Preventing Readmission. *Journal of Arthroplasty,* 34(7), S91–S96. *https://doi.org/10.1016/j.arth.2019.01.020.*

[625] Bozic KJ, Grosso LM, Lin Z, et al. (2014). Variation in hospital-level risk-standardized complication rates following elective primary total hip and knee arthroplasty. *The Journal of Bone and Joint Surgery,* 96(8), 640–647. *https://www.doi.org/10.2106/JBJS.L.01639.*

[626] Makela KT, Peltola M, Sund R, et al. (2011). Regional and hospital variance in performance of total hip and knee replacements: A national population-based study. *Annals of medicine,* 43(sup1), S31–S38. *https://doi.org/10.3109/07853890.2011.586362.*

[627] Liebs T, Herzberg W, Gluth J, et al. (2013). Using the patient's perspective to develop function short forms specific to total hip and knee replacement based on WOMAC function items. The *Bone & Joint Journal,* 95(B), 239–243. *https://www.doi.org/10.1302/0301-620X.95B2.28383.*

In the CY 2021 OPPS/ASC final rule with comment period (85 FR 86146), we announced that THA and TKA procedures were removed from the IPO list and added to the ASC covered procedures list (CPL). As a result, the volume of THA and TKA procedures for Medicare beneficiaries aged 65 years and older have been increasing in outpatient settings, including ASCs.

We analyzed Part B Medicare FFS claims data for the number of ASC facility claims with THA/TKA procedures during CYs 2020, 2021, and 2022 (Table 138). Though we acknowledge that currently the total number of ASCs performing these procedures, and the number of procedures being performed in ASCs, is relatively low and there is wide variation in number of procedures performed in those ASCs, the number of procedures performed in the ASC setting has steadily grown.

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TABLE 138: DISTRIBUTION OF TOTAL HIP ARTHROPLASTY (THA) AND TOTAL KNEE ARTHROPLASTY (TKA) CLAIMS PER ASC CY 2020-2021

CY	CPT	CPT Description	# ASCs with THA/TKA Claims	Median # of Claims	Mean # of Claims	Std Dev	Min	Max
2020	27130	ARTHRP ACETBLR/PROX FEM PROSTC AGRFT/ALGRFT	8	1	1.38	0.74	1	3
2020	27447	ARTHRP KNE CONDYLE&PLATU MEDIAL&LAT COMPARTMENTS	568	8	19.20	32.87	1	296
2020	27130, 27447	All THA/TKA	569	8	19.18	32.90	1	296
2021	27130	ARTHRP ACETBLR/PROX FEM PROSTC AGRFT/ALGRFT	550	7	16.80	28.94	1	351
2021	27447	ARTHRP KNE CONDYLE&PLATU MEDIAL&LAT COMPARTMENTS	749	12	28.20	46.57	1	509
2021	27130, 27447	All THA/TKA	782	16	38.83	69.01	1	860
2022	27130	ARTHRP ACETBLR/PROX FEM PROSTC AGRFT/ALGRFT	646	10	21.45	33.80	1	354
2022	27447	ARTHRP KNE CONDYLE&PLATU MEDIAL&LAT COMPARTMENTS	854	16	33.78	53.85	1	594
2022	27130, 27447	All THA/TKA	881	22	48.47	80.81	1	948

Data source: CMS analysis, Medicare Part B claims January 1, 2020 - December 31, 2022, with a CPT code of 27130 or 27447.

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In the CY 2022 OPPS/ASC proposed rule (86 FR 42276 and 42277), we requested comment on the potential future adoption of the THA/TKA PRO–PM into the ASCQR Program. We refer readers to the CY 2022 OPPS/ASC final rule with comment period (86 FR 63896 through 63898) for a complete summary of feedback from interested parties.

Many commenters supported inclusion of the THA/TKA PRO–PM in the ASCQR Program as procedures move from inpatient to outpatient settings. Commenters noted it was important to monitor quality outcomes and publicly report results. Additionally, commenters stated that the measure is aligned with patient values, being presented in a manner that is easy to understand.

Other commenters did not support expansion of the measure to the ASCQR Program, and expressed concern with data collection burden, patient survey fatigue, and reporting thresholds. In response, we stated that while we recognize that PRO–PMs require providers to integrate data collection into clinical workflows, this integration provides opportunity for PROs to inform clinical decision-making and benefits

patients by engaging them in discussions about potential outcomes. Furthermore, we did not expect this measure to contribute to survey fatigue as the PRO instruments used to calculate pre- and post-operative scores for this THA/TKA PRO–PM were carefully selected, with extensive interested party input, to be low burden for patients. (88 FR 49816) [628] [629]

In the CY 2024 OPPS/ASC proposed rule (88 FR 49816), we proposed to adopt the THA/TKA PRO–PM into the ASCQR Program beginning with two voluntary reporting periods, followed by mandatory reporting. The first voluntary reporting period would begin with the CY 2025 reporting period for eligible elective outpatient procedures between January 1, 2025, through December 31, 2025, and the second voluntary reporting period would begin with the CY 2026 reporting period for eligible outpatient procedures between January 1, 2026, through December 31, 2026. Mandatory reporting would begin with the CY 2027 reporting period/CY 2030 payment determination for eligible elective outpatient procedures occurring January 1, 2027, through December 31, 2027, impacting the CY 2030 payment determination and subsequent years. Because the proposed measure required collection of data during the 3-month pre-operative period and the greater than 1-year post-operative period, there would be a delay between when the elective THA/TKA procedures actually occur, when the results would be reported under the ASCQR Program, and when payment determinations occur. Therefore, we proposed a 3-year gap between the reporting period and the payment determination year (for example, CY 2027 reporting period for the CY 2030 payment determination) for the ASCQR Program. We refer readers to section XV.B.5.b.(2)(a) of this final rule with comment period for more information on the reporting requirements.

(2) Overview of Measure

(a) Data Collection, Submission, Reporting and Measure Specifications

This measure reports the facility-level risk-standardized improvement rate (RSIR) in PROs following elective primary THA/TKA for Medicare FFS beneficiaries aged 65 years and older who were enrolled in Medicare FFS Part A and B for the 12 months prior to the date of the procedure and in Medicare FFS Part A and B during the procedure. The measure includes only elective primary outpatient THA/TKA procedures (patients with fractures and revisions are not included) performed at ASCs and does not include any inpatient procedures. The measure excludes patients with staged procedures (multiple elective primary THA or TKA procedures performed on the same patient during distinct encounters) that occur during the measurement period and excludes discontinued procedures (that is, procedures that were started but not completed).[630]

Substantial clinical improvement is measured by achieving a pre-defined improvement in score on one of the two validated joint-specific PRO instruments measuring hip or knee pain and functioning: (1) The Hip dysfunction and Osteoarthritis Outcome Score for Joint Replacement (HOOS, JR) for completion by THA recipients; or (2) the Knee injury and Osteoarthritis Outcome Score for Joint Replacement (KOOS, JR) for completion by TKA recipients. Improvement is measured from the pre-operative assessment (data collected 90 to 0 days before surgery) to the post-operative assessment (data collected 300 to 425 days following surgery). Improvement scores are risk-adjusted to account for differences in patient case-mix. The measure, if adopted into the ASCQR Program as proposed, would account for potential non-response bias in measure scores through inverse probability weighting based on likelihood of response.

We refer readers to the FY 2023 IPPS/LTCH PPS final rule with comment period (87 FR 49246 through 49257) for more information on the development of the hospital-level THA/TKA PRO–PM, including background on the measure and a complete summary of measure specifications, data sources, and measure calculation.

For additional details regarding the measure specifications, we also refer readers to the Hip and Knee Arthroplasty Patient-Reported Outcomes file, available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.*

(i) Data Sources

The THA/TKA PRO–PM uses four sources of data for the calculation of the measure: (1) PRO data; (2) claims data; (3) Medicare enrollment and beneficiary data; and (4) U.S. Census Bureau survey data. As described in section XV.B.5.b.(1) of this final rule with comment period, the measure uses PRO data directly reported by the patient regarding their health, quality of life, or functional status associated with their health care or treatment. This patient reported-data are collected by facilities pre-operatively and post-operatively, and limited patient-level risk factor data are collected with PRO data and identified in claims as detailed in this section of the final rule.[631] The measure includes PRO data collected with the two joint-specific PRO instruments described in this section of the final rule—the HOOS, JR for completion by THA recipients and the KOOS, JR for completion by TKA recipients—from which scores are used to assess substantial clinical improvement. For risk-adjustment by pre-operative mental health score, ASCs would submit one of two additional PRO instruments: (1) the Patient-Reported Outcomes Measurement Information System (PROMIS)-Global Mental Health subscale; or (2) the Veterans RAND 12-Item Health Survey (VR–12) Mental Health subscale. The risk model also includes a one-question patient-reported assessment of health literacy—the Single Item Literacy Screener questionnaire.

Furthermore, the following data would be collected for identification of the measure cohort, for risk-adjustment purposes, and for the statistical approach to potential non-response bias. ASC facility claims data would be used to identify eligible elective primary outpatient THA/TKA procedures for the measure cohort to which submitted PRO data can be matched, and to identify additional variables for risk-adjustment and in the statistical approach to account for response bias, including patient demographics and clinical co-morbidities up to 12 months prior to surgery. The Medicare Enrollment Database (EDB) identifies Medicare FFS enrollment and patient-identified race, and the Master Beneficiary Summary File allows for determination of Medicare and Medicaid dual eligibility

[628] *Pre-rulemaking MUC lists and MAP reports.* The Measures Management System. (n.d.). Retrieved March 13, 2023, from *https://mmshub.cms.gov/measure-lifecycle/measure-implementation/pre-rulemaking/lists-and-reports.*

[629] Centers for Medicare and Medicaid Services Measures Inventory Tool. (n.d.). Retrieved March 28, 2023, from *https://cmit.cms.gov/cmit/#/MeasureView*?variantId=11547&sectionNumber=1.

[630] U.S. Department of Health and Human Services (2021). Hospital Outpatient Prospective Payment System (OPPS): Use of Modifiers –52, –73, and –74 for Reduced or Discontinued Services. Available at: *https://www.hhs.gov/guidance/document/hospital-outpatient-prospective-payment-system-opps-use-modifiers-52-73-and-74-reduced-or.*

[631] Higgins JP, Thomas J, Chandler J, et al. (2019). *Cochrane handbook for systematic reviews of interventions.* John Wiley & Sons. *https://doi.org/10.1002/9781119536604.*

enrollment status. Demographic information from the U.S. Census Bureau's American Community Survey allows for derivation of the Agency for Healthcare Research and Quality (AHRQ) Socioeconomic Status (SES) Index score. Race, dual eligibility, and AHRQ SES Index score are used in the statistical approach to account for potential non-response bias in the outcome calculation. We refer readers to section XV.B.5.b.(2)(iii) of this final rule with comment period for further details regarding the variables required for data collection and submission.

(ii) Measure Calculation

The ASC facility-level THA/TKA PRO–PM result would be calculated by aggregating all patient-level results across the facility. This measure would be calculated and presented as a RSIR, producing a performance measure per facility which accounts for patient case-mix, addresses potential non-response bias, and represents a measure of quality of care following elective primary outpatient THA/TKA. Response rates for PRO data would be calculated as the percentage of elective primary ASC THA or TKA procedures for which complete and matched pre-operative and post-operative PRO data have been submitted divided by the total number of eligible THA or TKA procedures performed at each facility.

(iii) Data Submission and Reporting

In response to feedback received from interested parties in the request for comments (RFCs) on this measure in the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 25591 through 25592) (as summarized in the FY 2022 IPPS/LTCH PPS final rule with comment period (86 FR 45408 through 45414)) and the CY 2022 OPPS/ASC proposed rule (86 FR 42251 and 42252), and as discussed in the Hospital IQR Program in the FY 2023 IPPS/LTCH PPS final rule with comment period (87 FR 49246 through 49257), we proposed in the CY 2024 OPPS/ASC proposed rule (88 FR 49817) to adopt the THA/TKA PRO–PM in the ASCQR Program utilizing flexible data submission approaches.

In the CY 2024 OPPS/ASC proposed rule (88 FR 49817), we proposed that ASCs would submit the following variables collected pre-operatively between 90 and zero days prior to the THA/TKA procedure for each patient: Medicare provider number; Medicare health insurance claim (HIC) number/Medicare beneficiary identifier (MBI); date of birth; date of procedure; date of PRO data collection; procedure type; mode of collection; person completing the survey; facility admission date; patient-reported outcome measure version; PROMIS Global (mental health subscale items) or VR–12 (mental health subscale items); HOOS, JR (for THA patients); KOOS, JR (for TKA patients); Single-Item Health Literacy Screening (SILS2) questionnaire; BMI or weight (kg)/height (cm); chronic (≥90 day) narcotic use; total painful joint count (patient reported in non-operative lower extremity joint); and quantified spinal pain (patient-reported back pain, Oswestry index question.[632] [633])

Under the proposal, ASCs would also submit the following variables collected post-operatively between 300 and 425 days following the THA/TKA procedure for each patient: Medicare provider number; Medicare HIC number/MBI; date of birth; procedure date; date of PRO data collection; procedure type; mode of collection; person completing the survey; facility admission date; KOOS, JR (TKA patients); and HOOS, JR (THA patients). The data submission period for the THA/TKA PRO–PM would also serve as the review and correction period, and there would be no opportunity to correct the data following the submission deadline.

In the CY 2024 OPPS/ASC proposed rule (88 FR 49817), following the two voluntary reporting periods, we proposed that mandatory reporting of the THA/TKA PRO–PM would begin with the CY 2027 reporting period/CY 2030 payment determination. Under the proposal, for each voluntary and subsequent mandatory reporting period, we would collect data on the THA/TKA PRO–PM in accordance with Health Insurance Portability and Accountability Act of 1996 (HIPAA), Privacy and Security Rules (45 CFR parts 160 and 164, subparts A, C, and E), and other applicable law.

(b) Review by Measure Applications Partnership (MAP)

We included the THA/TKA PRO–PM measure for the ASCQR Program in the publicly available ''2022 Measures Under Consideration List.'' (MUC2022–026).[634] The MAP Coordinating Committee supported the measure, as referenced in the MAP's 2022–2023 Final Recommendations report to HHS and CMS.[635]

The MAP members noted that, while a similar version of this measure has been adopted for use in the Hospital IQR Program, a measure that assesses PROs among THA/TKA patients in ASCs for the ASCQR Program does not currently exist. The MAP highlighted the key strategy for the ASCQR Program is to ensure that procedures done in any type of facility have equivalent quality. As such, the MAP members agreed that quality measures regarding procedures in hospital settings should be incorporated into the ASCQR Program, to the extent feasible and appropriate, so that consumers can compare quality of a specific procedure across different facility types, including ASCs.[636]

In addition, the MAP members stated that the goal of the THA/TKA PRO–PM is to capture the full spectrum of care to incentivize collaboration and shared responsibility for improving patient health and reducing the burden of their disease. They agreed that this measure aligns with the goal of patient-centered approaches to health care quality improvement and addresses the high priority areas of patient and family engagement, communication, and care coordination for the ASCQR Program.[637]

(c) Measure Endorsement

The CBE endorsed the hospital-level version of the THA/TKA PRO–PM (CBE #3559) in November 2020.[638] We note that the ASCQR Program version of the THA/TKA PRO–PM currently uses the same specifications as the CBE endorsed hospital-level THA/TKA PRO–PM with modifications that allow for the capture of procedures performed in for the ASC setting. We intend to seek CBE endorsement for the ASCQR Program's version of the THA/TKA PRO–PM in a future measure endorsement cycle.

We have noted in previous rulemaking (76 FR 74494) the requirement that measures reflect consensus among affected parties can be achieved in other ways aside from CBE endorsement, including through the measure development process, through broad acceptance, use of the measure(s), and through public comment. In the CY 2024 OPPS/ASC proposed rule (88 FR 49818), we proposed this measure without CBE-endorsement based upon strong MAP and public support

[632] Fairbank JC & Pynsent PB (2000). The Oswestry Disability Index. *Spine.* 25(22), 2940–52 *https://journals.lww.com/spinejournal/Abstract/2000/11150/The_Oswestry_Disability_Index.17.aspx.*

[633] The Oswestry Disability Index is in the public domain and available for all hospitals to use.

[634] 2022 Measures Under Consideration List. Available at *https://mmshub.cms.gov/sites/default/files/2022-MUC-List.xlsx.*

[635] MAP MUC Preliminary Recommendations 2022–2023. Available at *https://mmshub.cms.gov/sites/default/files/2022-2023-MAP-Final-Recommendations-508.xlsx.*

[636] Ibid.

[637] Ibid.

[638] Centers for Medicaid & Medicare Services. Hospital-Level, Risk-Standardized Improvement Rate in Patient-Reported Outcomes Following Elective Primary Total Hip and/or Total Knee Arthroplasty (THA/TKA). Available at: *https://cmit.cms.gov/cmit/#/FamilyView?familyId=1618.*

combined with the importance of the measure for Medicare beneficiaries. In addition, there are two existing, CBE-endorsed versions of this measure, one at the clinician-group level (CBE #3639) and one for the hospital-level (CBE #3559). We expect that the measure will perform similarly in the ASC setting, and we intend on submitting the measure for CBE endorsement following data collection during voluntary reporting.

We refer readers to section XV.D.1.d of this final rule with comment period for a discussion on the THA/TKA PRO–PM form, manner, and timing submission requirements.

We invited public comment on the proposal.

Comment: Some commenters supported the adoption of the THA/TKA PRO–PM in the ASCQR Program, noting that the measure will support patients in their choice of a provider and allow comparisons of the quality of care among ASCs.

Response: We thank commenters for their support of the THA/TKA PRO–PM for the ASCQR Program.

Comment: One commenter strongly supported the adoption of the THA/TKA PRO–PM in the ASCQR Program; however, the commenter recommended a shorter timeframe to track patient-reported outcomes following THA/TKA procedures to better identify patients recovering faster, provide a more meaningful guide of the procedure's success, and help to differentiate performance among various implant systems and rehab protocols. The commenter also recommended posting post-operative functional improvements on Medicare's website once sufficient data has been collected so that patients can act as informed consumers of care. The commenter encouraged development of other THA/TKA claims-based outcome measures with a shorter-term post-operative time frame such as one-year mortality and revision rates.

Response: We thank the commenter for their support and recommendations and agree with the importance of measuring patient-reported outcomes for elective primary THA and TKA procedures, particularly to measure functional improvement following the applicable surgical procedure.

We appreciate the commenter's recommendation for a shorter timeframe to track patient-reported outcomes following THA/TKA procedures; however, a longer timeframe has been adopted for capture of full recovery from both THA and TKA and alignment with the typically scheduled one-year post-surgery appointments so that the collection of the post-operative data would not require an additional appointment. Clinical experts strongly advocated for the 300–425-day post-operative data collection window to better align with clinical practice and increase PRO data collection.

We also appreciate the commenter's suggestions to develop other claims-based joint arthroplasty measures and publicly post post-operative functional improvements.

Comment: Several commenters expressed concern about the burden for ASCs associated with the THA/TKA PRO–PM if it is finalized for adoption into the ASCQR Program. Commenters stated that the financial, resource, and labor costs required to collect, track, and submit data for this measure would burden facilities and lead to reporting penalties, which small, rural, and medically underserved facilities cannot afford. One commenter noted that EHRs are not integrated with patient portals in a manner that allow facilities to collect patient-reported information and that many facilities exist in areas where patient portal use is unreliable, requiring infrastructure investments and adding manual burden to extrapolate data. This commenter urged CMS to move the measure from facilities to providers or consider making it optional. One commenter noted that burden to ASCs could detract from the ability to dedicate necessary resources to patient care and safety.

Response: We acknowledge that collecting patient-reported outcome measures (PROM) data may involve more burden and initial implementation resources compared to some other types of quality measures, and that some facilities may lack the necessary infrastructure to collect data on this measure. However, we believe the benefit of collecting direct functional improvement information from the patients outweighs the burden. We believe that measuring patient-reported outcomes is an important aspect of patient-centered healthcare and continue to emphasize, as highlighted in our Meaningful Measures 2.0 Framework, that the patient voice should be prioritized across healthcare systems and providers.[639] While PRO–PMs require providers to integrate data collection into clinical workflows, this integration provides an important opportunity for patient-reported outcomes to inform clinical decision-making and benefit patients by engaging them in discussions about potential outcomes. To allow more time for initial implementation, we are extending the voluntary reporting period by an additional year and delaying implementation of mandatory reporting by one year. We believe that the additional year of voluntary reporting and delaying mandatory reporting will allow more time for ASCs to integrate data collection into their clinical workflows, allow time for CMS to monitor implementation progress with regards to data collection burden, as well as time for rulemaking should any improvements for mandatory reporting need to be made. Additionally, to provide more flexibility, we are not requiring ASCs to collect data in a standardized way. ASCs may use a variety of data collection, storage, and submission approaches, and we encourage ASCs to use processes best suited to them. We will monitor data collection burden during the voluntary reporting period and carefully consider public comments to advance patient-centered measurement with as little burden as possible to both providers and patients.

Additionally, implementation of this measure in the ASC setting has been recommended by interested parties, as summarized in the FY 2023 IPPS/LTCH PPS final rule with comment period (87 FR 49254), and supported by interested parties, as summarized in the CY 2022 OPPS/ASC final rule with comment period (86 FR 63897).

We thank commenters for their feedback on moving this measure to other programs and settings. We also agree that there is value in measurement at the clinician-level; however, this measure is designed as a facility-level measure and helps to capture the quality of care provided during a patient's stay in the ASC setting. Any proposal to implement the measure in other CMS programs would be announced through future rulemaking.

Comment: We received mixed comments with respect to the proposed mandatory reporting timelines. One commenter suggested CMS reconsider the proposed timeline for the THA/TKA PRO–PM measure, possibly delaying the timeline by an additional year, and reconsidering the number of risk variables required for the proposed measure. However, another commenter recommended to move up mandatory reporting, to begin sooner than we proposed. A few commenters noted that the proposal to begin voluntary reporting in CY 2025 does not consider the beginning of mandatory reporting for the Outpatient and Ambulatory Surgery Consumer Assessment of Healthcare Providers and Systems (OAS

[639] Centers for Medicare & Medicaid Services. Meaningful Measures Framework. Available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/CMS-Quality-Strategy.*

CAHPS) survey and therefore, requested delaying the voluntary reporting for the ASCQR Program's THA/TKA PRO–PM to allow the preparatory work required for reporting of the THA/TKA PRO–PM measure. One commenter noted that the extensive data collection required by the measure would rarely be used to guide patient care decisions and suggested that CMS consider an incremental approach to the number of data elements used for the proposed measure or reconsider the number of risk variables required to allow ASCs to implement the survey instruments, required for data collection, in a way that would distribute the burden over a longer period of time.

Response: We have considered the commenters' recommendation regarding voluntary and mandatory reporting timelines for this measure and, as discussed below, we are finalizing the THA/TKA PRO–PM for the ASCQR Program with modification to extend the voluntary reporting period by an additional year, for a total of three years, and, in turn, delay implementation of the mandatory reporting period by one year. We are finalizing the phased implementation approach for adoption and implementation of this measure into the ASCQR Program, with voluntary reporting periods in CY 2025, CY 2026, and CY 2027 followed by mandatory reporting beginning with the CY 2028 reporting period for the CY 2031 payment determination. We believe this implementation approach balances the need to allow ASCs sufficient time to make the necessary enhancements to their clinical workflow to successfully report this measure with the need to make this information public for patient use. We will carefully consider feedback received during voluntary reporting to inform improvements that may be made for mandatory reporting. We also refer readers to section IX.X.10.k. of this final rule with comment period, where we discuss in more detail the form, manner, and timing of reporting the THA/TKA PRO–PM.

Comment: One commenter did not support the proposed adoption of the THA/TKA PRO–PM into the ASCQR Program and expressed concerns regarding the measure specifications, supporting materials guidelines, and volume of data collection. The commenter noted that the supporting guidelines do not make it clear that patients undergoing THA and TKA procedures must be enrolled in Medicare Parts A and B for at least 12 months prior to the procedures and on the day of the procedure in order to be included in the measure calculation. The commenter also noted that the post-operative PRO collection timeframe does not align with that of the American Joint Replacement Registry which is 270–425 days and that one of the measure exclusions criteria includes patients who die within 300 days of their procedure, which does not align with the postoperative data collection period of 300 to 425 days. In addition, the commenter stated that the Veterans Rand (VR)-12 questionnaire is not readily available and suggests CMS provide the questionnaire if this is an option for patient mental health data collection. The commenter also suggested clearer guidelines on how data elements are defined, specifically noting that the Use of Chronic Narcotics data element is not sufficiently defined leaving it open to interpretation. In addition, the commenter suggested that the Total Painful Joint Count data element is not a total painful joint count, but rather an assessment of whether the patient has pain in the non-operative hip or knee and requires rewording to avoid confusion and to reflect the data to be collected. A few commenters expressed concern over the volume of data ASCs would be required to collect and submit to report this measure. A commenter noted the limited availability of PRO data collection modalities, and stated that, under Federal regulation, ASCs may only act as the site for outpatient surgery and may not provide pre-operative services or post-operative follow-up care after patient discharge, thus limiting the options for PRO data collection or requiring significant additional resources to get patient data from other providers and/or their contractors. The commenter further noted that, given the lack of alignment between the proposed ASC THA/TKA PRO–PM and other THA/TKA related quality measures clinicians can report on, reliance on other providers for PRO data collection may not be appropriate.

Response: We acknowledge the commenter's concerns with the ASC THA/TKA PRO–PM measure specifications and supporting materials guidelines. We note that the Data Collection, Submission, Reporting and Measure Specifications section in this rule and in the methodology report, available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology,* clearly state that the THA/TKA PRO–PM reports the facility-level risk-standardized improvement rate (RSIR) in PROs following elective primary THA/TKA for Medicare FFS beneficiaries aged 65 years and older who were enrolled in Medicare FFS Part A and B for the 12 months prior to the date of the procedure and in Medicare FFS Part B during the procedure.

In developing the THA/TKA PRO–PM, the measure developer reviewed registry data capture to inform the post-operative assessment window (initially 270 to 365 days) for capture of full recovery from both THA and TKA and alignment with the typically scheduled one-year post-surgery appointments, so that the collection of the post-operative data collection would not require an additional appointment. Following several years of PRO data collection through the CJR Model, clinical experts expressed concern that the initial 365-day upper limit missed patients who were scheduled or rescheduled for this one-year follow-up beyond 365 days, and they strongly advocated for shifting the post-operative data collection window to better align with clinical practice and increase PRO data collection. For additional details we refer readers to the Patient-Reported Outcomes (PROs) Following Elective Primary Total Hip and/or Total Knee Arthroplasty: Hospital-Level Performance Measure—Measure Methodology Report, available in Hip and Knee Arthroplasty Patient-Reported Outcomes folder at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology*.

The PRO instruments and PROMs such as the Veterans Rand 12-Item Health Survey (VR–12) PROM and the Patient-Reported Outcomes Measurement Information Systems (PROMIS)-Global were carefully considered, with extensive interested party input, including clinicians, to be low burden. ASCs can use either of the two PROMs (VR–12 or PROMIS-Global) to assess general aspects of health and well-being following elective primary THA/TKA. PROMs are available in both free and cost versions.

We thank the commenter on the feedback to provide clearer guidelines regarding reporting the ''Use of Chronic Narcotics'' and labelling of ''Total Painful Joint Count'' data elements. We will conduct further review of the guidance materials.

While we acknowledge the large volume of data required to calculate and risk-adjust measure scores for the proposed ASC THA/TKA PRO–PM, we highlight that the measure as proposed notes registries as an acceptable form of data collection for the measure (88 FR 49813 through 49818) ASCs can utilize registries to reduce data collection

burden. In addition, this measure allows ASCs to use a variety of data collection, storage, and submission approaches to ensure flexibility and reduce burden, and we encourage ASCs to use processes best suited to their care setting and patient populations. We note that while we are not requiring ASCs to collect data in a standardized way, we are standardizing the specific data elements that need to be collected and reported. Further, we believe that clinicians, providers, and facilities should determine practices that avoid duplication across care settings. We will evaluate data collection burden associated with the THA/TKA PRO–PM to inform future changes to measure specifications or reporting processes improvements.

With respect to the concern raised about ASCs' limited PRO data collection opportunities and modalities, we highlight that collecting outcome data after the procedure does not amount to providing post-operative services or care. ASCs will be obtaining data that reflect patients' outcomes after a service that was provided by the ASC. The longer post-operative window for this measure reflects the time course of recovery and benefits the ASCs by providing sufficient recovery time to be reflected in the PRO responses.

Comment: A few commenters expressed concerns about the data submission requirements and reporting thresholds. One commenter did not support the proposed adoption of the THA/TKA PRO–PM into the ASCQR Program because, for data submissions occurring after May 15, 2026, ASCs would be required to submit both pre-operative data for THA/TKAs performed the prior year and post-operative data for THA/TKAs performed two years prior. The commenter suggested that having a single data submission deadline for pre-operative and post-operative measure data for THA/TKA procedures performed in a single calendar year would be less burdensome and more efficient. A few commenters expressed concern regarding the requirement to submit complete and matching pre-operative and post-operative PRO data for at least 45 percent of their eligible elective primary THA/TKA procedures. The commenter noted that while the 45 percent threshold proposed for this measure in the ASCQR Program is slightly less than the 50 percent threshold set for the Hospital IQR and proposed in the Hospital OQR Programs, it is still too high. The commenter cited difficulty with meeting the reporting threshold and also noted that ASCs are currently not collecting on all the PRO measures and would need additional time to prepare to meet this requirement. One commenter noted that data completeness requirement should not fall solely on the ASCs, and neither should the facility be financially penalized for it. The commenter noted that, because ASCs do not know in advance which patients would respond completely or would respond at all, ASCs will have to collect pre-operative data on all their THA/TKA patients. The commenter suggested that CMS select a more reasonable data completeness standard supported by results from the 2019 OAS CAHPS mode experiment [640] and redefine the reporting threshold to include both complete and incomplete responses, since it reflects the facility's attempt to meet requirements for the measure.

Response: We acknowledge commenters' concerns regarding submission of both pre-operative data for the second voluntary reporting period and post-operative data for the first voluntary period by the same data submission. We decided to stagger data submission to reduce burden for ASCs holding onto their pre-operative data for two years, ensure alignment between the pre-operative and post-operative data, and potentially reduce gaming. We will monitor and evaluate the proposed approach during the voluntary reporting period.

Given that THA and TKA procedures were removed from the Inpatient Only Procedures (IPO) list and added to the ASC covered procedures list (CPL), we expect that the volume of THA and TKA procedures will continue to increase in ASCs, and that significant numbers of Medicare beneficiaries will potentially undergo these procedures in the outpatient setting in future years, including ASCs. We selected the 45 percent reporting threshold after considering numerous factors and the experience of CJR Model participants. The proposed reporting threshold for adoption of the measure into the ASCQR Program is based on average response rates for both pre-operative and post-operative surveys collected by participating hospitals in the CJR Model. We note that the proposed reporting threshold for the THA/TKA PRO–PM is lower than that currently used in the CJR Model (45 percent versus 85 percent). Additionally, ASCs are not held to reporting thresholds until mandatory reporting; therefore, we believe ASCs will have time to develop their data collection and reporting processes.[641]

Regarding data completeness requirements, we acknowledge that ASCs would not know in advance which patients would respond completely or would respond at all; however, the original measure in the Hospital IQR Program, and specified for the ASCQR Program, was developed with extensive input from patients, who indicated strong support for a PRO–PM following elective primary THA and TKA. However, we will continue to consider the appropriate pre-operative and post-operative matched survey response rate, data completeness, and reporting thresholds. We will carefully consider feedback received during voluntary reporting to inform improvements that may be made for mandatory reporting.

Comment: One commenter did not support the proposed adoption of the THA/TKA PRO–PM into the ASCQR Program because ASCs will be required to collect and submit incomplete or no patient PRO data to adjust for nonresponse bias in the measure methodology. The commenter noted that since the measure methodology report stated that nonresponse bias weighting did not have a significant impact on the measure outcome, ASCs should not be required to devote resources to submit these PRO responses. A few commenters expressed concern that CMS has underestimated the cost burden to collect PRO data given that ASCs may not have access to an Electronic Health Record (EHR) system, and those that do use EHR technology will spend more than 20 minutes a year to collect PRO data.

Response: We thank the commenter for their concerns about incomplete and missing PRO data. While encouraged, we do not require ASCs to submit incomplete data as that is left to the ASCs discretion. Submitting data (complete or not) during voluntary reporting offers several advantages. These include gaining familiarity with the data submission process, receiving feedback on the cases that were submitted, and potential inclusion in the measure through non-response weights. While we acknowledge the challenge of colleting PRO data, we note that submitting incomplete data should not add additional burden to the ASC. Furthermore, although we agree that during measure development, inverse probability weighting (IPW) for nonresponse bias did not have a substantial impact, we anticipate that

[640] *https://oascahps.org/General-Information/Mode-Experiment.*

[641] *https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9485540/.*

this may be a concern as more ASCs participate in reporting. Therefore, we retained this widely accepted statistical approach in the final measure methodology. The adjustment itself will be done during measure calculation and adds no additional computational burden to the ASC.[642]

We also acknowledge commenters' concerns with the burden to collect PRO data given that some ASCs may have limited or no access to EHR systems. We acknowledge that the Title XIII of the American Recovery and Reinvestment Act of 2009 (ARRA) (Pub. L. 111–5, February 17, 2009), which sets forth the Health Information Technology for Economic and Clinical Health (HITECH) Act, did not offer ASCs financial incentives for EHR adoption like it did for hospitals, thus did not facilitate the proliferation of adoption and utilization of EHRs in ASCs. However, we clarify that this measure, as proposed, provides flexibility for the manner in which ASCs collect, store, and submit data. The modes of PRO data collection could include completion of the pre-operative surveys using electronic devices (such as an iPad or tablet), pen and paper, mail, telephone, or through a patient portal. Post-operative PRO data collection modes are similar to pre-operative modes. We encourage ASCs to use processes best suited to them. We also note that qualified data collection registries are an acceptable form of data collection for the measure and can be utilized to reduce data collection burden for ASCs. This data submission approach is consistent with interested party input received by the measure developer during measure development and comments as summarized in the FY 2022 IPPS/LTCH PPS final rule with comment period (86 FR 45411 through 45414), which recommended that CMS provide multiple options for data submission mechanisms to ensure flexibility.

Comment: Many commenters expressed concern over the technological, operational, resource and financial burden to obtain post-operative data 300 to 425 days. A few commenters expressed concern that ASCs would not have the benefit of collecting post-operative PRO data during a follow-up visit, which would be expected to negatively impact data completeness and overall response rates.

Response: We acknowledge that while PROMs and PRO–PMs may involve more burden and initial implementation resources compared to some other types of quality measures, we believe the benefit of collecting direct functional improvement information from the patients outweighs the burden. We are carefully considering public comments and are seeking to advance patient-centered measurement with as little burden as possible to both providers and patients.

We will review these recommendations to inform ongoing measure evaluation.

After considering the comments received, we are finalizing adoption of the THA/TKA PRO–PM into the ASCQR Program. However, in response to concerns raised by commenters, we are extending the voluntary reporting period by an additional year and delaying implementation of mandatory reporting by one year, such that voluntary reporting would begin with the CY 2025 reporting period and continue through the CY 2027 reporting period followed by mandatory reporting beginning with the CY 2028 reporting period for CY 2031 payment determination. We believe that the additional year of voluntary reporting would allow time for CMS to monitor implementation progress with regards to data collection burden and response rates, as well as time for rulemaking should any improvements for mandatory reporting need to be made.

6. ASCQR Program Quality Measure Set

a. Summary of Finalized ASCQR Program Quality Measure Set for the CY 2024 Reporting Period/CY 2026 Payment Determination

We refer readers to the CY 2023 OPPS/ASC final rule with comment period (87 FR 72120 and 72121) for the previously finalized ASCQR Program measure set for the CY 2024 reporting period/CY 2026 payment determination.

Table 139 below summarizes the finalized ASCQR Program measures for the CY 2024 reporting period/CY 2026 payment determination.

[642] *https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4257477/pdf/nihms578341.pdf.*

TABLE 139: FINALIZED ASCQR PROGRAM MEASURE SET FOR THE CY 2024 REPORTING PERIOD/CY 2026 PAYMENT DETERMINATION

ASC #	CBE #	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 Visual Function (Previously referred to as 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-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
ASC-20	None	COVID–19 Vaccination Coverage Among Health Care Personnel**

† CBE endorsement was removed.

* In the CY 2023 OPPS/ASC final rule with comment period (87 FR 72118 through 72120), we finalized to keep data collection and submission voluntary for this measure for the CY 2025 reporting period and subsequent years. In this final rule, we are finalizing our proposal to standardize the surveys offered to patients pre- and post-surgery beginning with the CY 2024 reporting period/CY 2026 payment determination.

** In this final rule, we are finalizing our proposal to modify the Endoscopy/Polyp Surveillance: Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients and COVID–19 Vaccination Coverage Among HCP measures that begin with the CY 2024 reporting period/CY 2026 payment determination.

b. Summary of Finalized ASCQR Program Quality Measure Set for the CY 2025 Reporting Period/CY 2027 Payment Determination and Subsequent Years

Table 140 summarizes the finalized ASCQR Program measures for the CY 2025 reporting period/CY 2027 payment determination.

TABLE 140: FINALIZED ASCQR PROGRAM MEASURE SET FOR THE CY 2025 REPORTING PERIOD/CY 2027 PAYMENT DETERMINATION

ASC #	CBE #	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-7	None	ASC Procedure Volume (Previously referred to as ASC Facility Volume on Selected ASC Surgical Procedures)**
ASC-9	0658	Endoscopy/Polyp Surveillance: Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients
ASC-11	1536†	Cataracts Visual Function (Previously referred to as 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	The Outpatient and Ambulatory Surgery Consumer Assessment of Healthcare Providers and Systems (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
ASC-20	None	COVID–19 Vaccination Coverage Among Health Care Personnel
ASC-21	3636	Risk-Standardized Patient-Reported Outcome-Based Performance Measure (PRO–PM) Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA) in the ASC Setting (THA/TKA PRO–PM)***

† CBE endorsement was removed.
* In the CY 2023 OPPS/ASC final rule with comment period (87 FR 72118 through 72120), we finalized to keep data collection and submission voluntary for this measure for the CY 2025 reporting period and subsequent years.
** In this final rule, we are not finalizing our proposal to re-adopt the ASC Procedure Volume measure as a voluntary measure beginning with the CY 2025 reporting period followed by mandatory reporting beginning with the CY 2026 reporting period/CY 2028 payment determination.
*** In this final rule, we are finalizing our proposal to adopt Risk-Standardized Patient-Reported Outcome-Based Performance Measure (PRO–PM) Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA) in the ASC Setting (THA/TKA PRO–PM) as a voluntary measure beginning with the CY 2025 reporting period followed by mandatory reporting beginning with the CY 2028 reporting period/CY 2031 payment determination.

7. Maintenance of Technical Specifications for Quality Measures

We maintain technical specifications for previously adopted ASCQR Program measures. These specifications are updated as we modify the ASCQR Program measure-set. The manuals that contain specifications for the previously adopted measures can be found on the CMS website (currently at: *https://qualitynet.cms.gov/asc/specifications-manuals*).[643] Our policy on maintenance of technical specifications for the ASCQR Program are codified in our regulations at § 416.325. In the CY 2024 OPPS/ASC proposed rule (88 FR 49819), we proposed to amend our measure maintenance regulation at § 416.325(c) to replace references to ''QualityNet'' with ''CMS-designated information system'' or ''CMS website,'' and to make other conforming technical edits, to accommodate recent and future systems requirements and mitigate confusion for program participants.

We invited public comment on the proposal.

We received no comments on the proposal. We are finalizing our proposal as proposed.

[643] Qualitynet Home. (n.d.). Retrieved March 21, 2023, from *https://qualitynet.cms.gov/asc/specifications-manuals.*

8. Public Reporting of ASCQR Program Data

We refer readers to the CYs 2012, 2016, 2017, and 2018 OPPS/ASC final rules (76 FR 74514 through 74515; 80 FR 70531 through 70533; 81 FR 79819 and 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 in our regulations at § 416.315 (80 FR 70533).

We did not propose any changes to these policies in the CY 2024 OPPS/ASC proposed rule.

C. Administrative Requirements

1. Requirements Regarding Data Submission

We refer readers to § 416.310(c)(1)(i) for our current policies regarding submission of data via our online data submission tool, including security official and system registration requirements. In the CY 2024 OPPS/ASC proposed rule (88 FR 49820), we proposed to amend our collection and submission regulation at § 416.310(c)(1)(i) to replace references to ''QualityNet'' with ''CMS-designated information system'' or ''CMS website,'' and to make other conforming technical edits, to accommodate recent and future systems requirements and mitigate confusion for program participants.

We invited public comment on the proposal.

We received no comments on the proposal. We are finalizing our proposal as proposed.

2. Requirements Regarding Program Participation

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 beginning with the CY 2014 payment determination. In the CY 2016 OPPS/ASC final rule with comment period (80 FR 70533 and 70534), we codified these requirements regarding participation status for the ASCQR Program in our regulations at § 416.305. In the CY 2024 OPPS/ASC proposed rule (88 FR 49820), we proposed to amend our withdrawal regulation at § 416.305(b)(1) to replace references to ''QualityNet'' with ''CMS-designated information system'' or ''CMS website,'' and to make other conforming technical edits, to accommodate recent and future systems requirements and mitigate confusion for program participants.

We invited public comment on the proposal.

We received no comments on the proposal. We are finalizing our proposal as proposed.

D. Form, Manner, and Timing of Data Submitted for the ASCQR Program

Previously finalized quality measures and information collections discussed in this section were approved by the Office of Management and Budget (OMB) under control number 0938–1270 (expiration date August 31, 2025). An updated PRA package reflecting the updated information collection requirements related to the proposals set forth in this section of the final rule with comment period will be submitted for approval under the same OMB control number.

1. Data Collection and Submission

a. Background

We previously codified our existing policies regarding data collection and submission under the ASCQR Program in our regulations at § 416.310.

b. Requirements for Claims-Based Measures

(1) 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 beginning with the CY 2012 reporting period/CY 2014 payment determination. 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 in our regulations at § 416.310(a)(1) and (2). 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.

We did not propose any changes to these policies in the CY 2024 OPPS/ASC proposed rule.

(2) 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 our regulations at §§ 416.310(a)(3) and 416.305(c) for our policies about minimum threshold, minimum case volume, and data completeness for claims-based measures using QDCs. We also refer readers to section XVI.D.1.b of the CY 2022 OPPS/ASC final rule with comment period (86 FR 63904 and 63905), where we finalized that our policies for minimum threshold, minimum case volume, and data completeness requirements apply to any future claims-based-measures using QDCs adopted in the ASCQR Program.

We did not propose any changes to these policies in the CY 2024 OPPS/ASC proposed rule.

(3) 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 in our regulations at § 416.310(b). We note that these requirements for non-QDC, claims-based measures apply to the following previously adopted measures:

- Facility 7-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy; and
- Facility-Level 7-Day Hospital Visits after General Surgery Procedures Performed at Ambulatory Surgical Centers (CBE #3357).

We did not propose any changes to these policies in the CY 2024 OPPS/ASC proposed rule.

c. 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 our regulations at § 416.310(c)(1) for our requirements regarding data submitted via a CMS online data submission tool. We are currently using the HQR System (formerly referred to as the QualityNet Secure Portal) [644] to host our CMS online data submission tool, available by securely logging in at: *https://hqr.cms.gov/hqrng/login.* 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

[644] The HQR System was previously referred to as the QualityNet Secure Portal.

corresponding changes at § 416.310(c)(1)(i).

The following previously finalized measures require data to be submitted via a CMS online data submission tool beginning with the CY 2019 reporting period/CY 2021 payment determination:

- Endoscopy/Polyp Surveillance: Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients;
- Cataracts Visual Function measure (Previously referred to as Cataracts: Improvement in Patients' Visual Function within 90 Days Following Cataract Surgery);
- Normothermia Outcome; and
- Unplanned Anterior Vitrectomy.

In the CY 2022 OPPS/ASC final rule with comment period (86 FR 63883 through 63885), we finalized our proposal to require and resume data collection beginning with the CY 2023 reporting period/CY 2025 payment determination for the following four measures:

- Patient Burn;
- Patient Fall;
- Wrong Site, Wrong Side, Wrong Patient, Wrong Procedure, Wrong Implant; and
- All-Cause Hospital Transfer/Admission.

Measure data for these measures must be submitted via the HQR System.

Other than the proposal to amend § 416.310(c)(1)(i) and (d)(1) discussed in sections XV.C.1 and XV.D.1.h., respectively, of this final rule with comment period, we did not propose any changes to these policies.

(a) Data Submission and Reporting Requirements for the ASC Procedure Volume Measure

As discussed in section XV.B.5.a of this final rule with comment period, we are not finalizing our proposal to re-adopt the ASC Procedure Volume measure (with modification), with voluntary reporting beginning with the CY 2025 reporting period followed by mandatory reporting beginning with CY 2026 reporting period/CY 2028 payment determination. We also proposed that ASCs would submit these data to CMS through the HQR System during the time period of January 1 to May 15 in the year prior to the affected payment determination year. For example, for the CY 2025 reporting period, the data submission period would be January 1, 2026 to May 15, 2026, covering the performance period of January 1, 2025 to December 31, 2025.

Under this requirement, we proposed that we would collect and publicly display data surrounding the top five most frequently performed procedures among ASCs in each of the following eight categories: Cardiovascular, Eye, Gastrointestinal, Genitourinary, Musculoskeletal, Nervous System, Respiratory, and Skin.[645] We proposed that we would assess and update the top five procedures in each category annually as needed. ASCs would submit aggregate-level data through the CMS web-based tool (currently the HQR system). Data received through the HQR system website will then be publicly displayed on the *data.cms.gov* website, or other CMS website, following our 30-day preview period of submitted data.

We refer readers to our regulation at § 416.315 for our codified policies regarding public reporting of data under the ASCQR Program, as well as our existing policies regarding data collection and submission under the ASCQR Program in our regulations at § 416.310.

We invited public comment on the proposal.

We did not receive public comments on the form, manner, and timing for the ASC Procedure Volume measure. However, as previously discussed, we are not finalizing our proposal to re-adopt with modification the ASC Facility Volume Data on Selected ASC Surgical measure beginning with the voluntary CY 2025 reporting period followed by mandatory reporting beginning with the CY 2026 reporting period/CY 2028 payment determination.

(b) Data Submission and Reporting Requirements for the Cataracts Visual Function Measure

In section XV.B.4.b of this final rule with comment period, we finalized our proposal to modify the Cataracts Visual Function measure by standardizing acceptable survey instruments, beginning with the CY 2024 reporting period, which will limit the allowable survey instruments to those listed below:

- The National Eye Institute Visual Function Questionnaire-25 (NEI VFQ–25)
- The Visual Functioning Patient Questionnaire (VF–14)
- The Visual Functioning Index Patient Questionnaire (VF–8R)

ASCs will submit these data to CMS during the time period of January 1 to May 15 in the year prior to the affected payment determination year. For example, for the CY 2024 reporting period, the data submission period would be January 1, 2025, to May 15, 2025, covering the performance period of January 1, 2024, to December 31, 2024. Specifically, for data collection, ASCs will submit aggregate-level data through the HQR System. We previously codified our existing policies regarding data collection and submission under the ASCQR Program in our regulations at § 416.310.

We invited public comment on the proposal.

We refer readers to section XV.B.4.b of this final rule with comment period regarding our discussion of the Cataracts Visual Function measure, including summaries of the comments we received on our proposal and our responses thereto. We did not receive public comments on the form, manner, and timing for the Cataracts Visual Function measure; as such, we are finalizing our proposal to begin collection of the modified Cataracts Visual Function measure beginning with the voluntary CY 2024 reporting period and subsequent years.

(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 and 75140) and the CY 2015 OPPS/ASC final rule with comment period (79 FR 66985 and 66986) for our requirements regarding data submitted via a non-CMS online data submission tool (specifically, the CDC's National Health Safety Network [NHSN]). 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 in our regulations at § 416.310(c)(2). While we did not finalize any changes to those policies in the CY 2022 OPPS/ASC final rule with comment period (86 FR 63875 through 63883), we did finalize policies specific to the COVID–19 Vaccination Coverage Among HCP measure, for which data will be submitted via the CDC NHSN.

In section XV.B.4.a of this final rule with comment period, we discuss the modification of the COVID–19 Vaccination Coverage Among HCP measure beginning with the CY 2024 reporting period/CY 2026 payment determination. The requirements for measure data submitted via the CDC NHSN website would remain as previously finalized.

We did not propose any changes to these policies in the CY 2024 OPPS/ASC proposed rule.

[645] Ambulatory Surgical Center Specifications Manuals. Available at: *https://qualitynet.cms.gov/asc/specifications-manuals#tab6.*

d. Data Submission and Reporting Requirements for Patient-Reported Outcome-Based Performance Measures (PRO–PMs)

In section XV.B.5.b of this final rule with comment period, we finalized our proposal to adopt the THA/TKA PRO–PM into the ASCQR Program measure set. In this section of the final rule, we are finalizing our proposal of the reporting and submission requirements for PRO–PM measures as a new type of measure to the ASCQR Program.

(1) Submission of PRO–PM Data

(a) Data Submission Generally

We believe that ASCs should have the choice of selecting from multiple submission approaches, in line with input received by the measure developer during measure development and comments as summarized in the FY 2022 IPPS/LTCH PPS final rule with comment period (86 FR 45411 through 45414), which recommended that we provide multiple options for data submission mechanisms to ensure flexibility.

In section XV.B.5.b of the CY 2024 OPPS/ASC proposed rule (88 FR 49813 through 49818), we proposed to adopt the THA/TKA PRO–PM into the ASCQR Program beginning with voluntary CYs 2025 and 2026 reporting periods and mandatory reporting period beginning with the CY 2027/CY 2030 payment determination. We proposed that both ASCs and vendors would use the HQR System for data submission for the THA/TKA PRO–PM, which would enable us to incorporate this new requirement into the infrastructure we have developed and use to collect other quality data. We would provide ASCs with additional detailed information and instructions for submitting data using the HQR System through CMS' existing websites, and through outreach, or both.

We invited public comment on the proposals.

We did not receive any comments on the proposal and therefore, are finalizing the proposal as proposed.

We also refer readers to section XV.B.5.b of this final rule with comment period regarding our discussion of the Adoption of the Risk Standardized Patient-Reported Outcome-Based Performance Measure (PRO–PM) Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA) in the ASC Setting (THA/TKA PRO–PM), including summaries of the comments we received on our proposal and our responses thereto. After considering commenters' recommendations regarding voluntary and mandatory reporting timelines received in section XV.B.5.b of this final rule with comment period, we are extending the voluntary reporting period by an additional year and delaying implementation of mandatory reporting by one year. We believe that the additional year of voluntary reporting would allow time for CMS to monitor implementation progress with regards to data collection burden and response rates, as well as time for rulemaking should any improvements for mandatory reporting need to be made. We are finalizing our proposal to begin voluntary reporting with the CY 2025 reporting period and continue through the CY 2027 reporting period followed by mandatory reporting beginning with the CY 2028 reporting period for CY 2031 payment determination.

(2) Data Submission Reporting Requirements

(a) Data Submission Requirements for Measures Submitted via a Web-Based Tool

We refer readers to the QualityNet website available at: *https://qualitynet.cms.gov* for a discussion of the requirements for measure data submitted via the HQR System (formerly referred to as the QualityNet Secure Portal) for the CY 2017 payment determination and subsequent years. The HQR System is safeguarded in accordance with the HIPAA Privacy and Security Rules to protect submitted patient information. See 45 CFR parts 160 and 164, subparts A, C, and E, for more information regarding the HIPAA Privacy and Security Rules.

(b) Voluntary Reporting Requirements for the Proposed THA/TKA PRO–PM

In the CY 2024 OPPS/ASC proposed rule (88 FR 49821), for ASCs participating in voluntary reporting for the THA/TKA PRO–PM, we proposed that ASCs submit pre-operative PRO data, as well as matching post-operative PRO data, for at least 45 percent of their eligible elective primary THA/TKA procedures.

For the THA/TKA PRO–PM, we proposed that the first voluntary reporting period for the CY 2025 reporting period would include pre-operative PRO data collection from 90 to 0 days before the procedure (for eligible elective THA/TKA procedures performed from January 1, 2025, through December 31, 2025) and post-operative PRO data collection from 300 to 425 days after the procedure. Therefore, during this first voluntary reporting period for CY 2025, ASCs would submit pre-operative data by May 15, 2026, and post-operative data by May 15, 2027, and we intend to provide ASCs with their results in confidential feedback reports in CY 2028. 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 non-workday for Federal employees by statute or executive order would be extended to the first day thereafter. After the initial submission of pre-operative data for the first voluntary period, ASCs would submit both pre-operative and post-operative data by the same day, but for different time periods. For example, ASCs would need to submit: (1) post-operative data for the first voluntary reporting period (for procedures performed between January 1, 2025, and December 31, 2025); and (2) pre-operative data for the second voluntary reporting (for procedures performed between January 1, 2026, and December 31, 2026) of the THA/TKA PRO–PM by May 15, 2027.

For the THA/TKA PRO–PM, we proposed that the second voluntary reporting period for the CY 2026 reporting period would include pre-operative PRO data collection from 90 to 0 days before the procedure (for eligible elective THA/TKA procedures performed from January 1, 2026, through December 31, 2026) and post-operative PRO data collection from 300 to 425 days after the procedure. ASCs would submit pre-operative data by May 15, 2027, and post-operative data by May 15, 2028, and we intend to provide ASCs with their results in confidential feedback reports in CY 2029. ASCs that voluntarily submit data for this measure would receive confidential feedback reports that detail submission results from the reporting period. Results of voluntary reporting would not be made publicly available. If feasible, we would calculate and provide each participating ASC with their RSIR as part of the confidential feedback reports. This would provide each ASC with an indication of their performance relative to the other facilities that participate in the voluntary reporting period.

While we did not propose to publicly report the data we receive during the voluntary reporting periods for the THA/TKA PRO–PM facility-level RSIR, we proposed to publicly report which ASCs choose to participate in voluntary reporting and/or the percent of pre-operative data submitted by participating ASCs for the first voluntary reporting period, and their percent of pre-operative and post-operative matched PRO data submitted for subsequent voluntary reporting

periods. For example, if out of 100 eligible procedures a facility submits 45 pre-operative cases that match to post-operative cases, then we would report that facilities submitted 45 percent of matched pre-operative and post-operative PRO surveys during voluntary reporting.

We refer readers to Table 141 for an overview of the proposed performance period, pre- and post-operative data collection timeframes, and data submission deadlines during the voluntary reporting periods for THA/TKA PRO–PM.

TABLE 141: PROPOSED PRE-OPERATIVE AND POST-OPERATIVE PERIODS FOR THA/TKA PRO-PM VOLUNTARY REPORTING

Reporting Cycle	Performance Period	Pre-Procedure Data Collection (0 to 90 days before the procedure)	Pre-Procedure Data Submission Date	Post-Procedure Data Collection (300 to 425 days after the procedure)	Post-Procedure Data Submission	Confidential Reporting
Voluntary Reporting CY 2025	January 1, 2025-December 31, 2025	October 3, 2024-December 31, 2025	May 15, 2026	October 28, 2025-March 1, 2027	May 15, 2027*	CY 2028**
Voluntary Reporting CY 2026	January 1, 2026-December 31, 2026	October 3, 2025-December 31, 2026	May 15, 2027*	October 28, 2026-February 29, 2028	May 15, 2028	CY 2029**

*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 non-workday for Federal employees by statute or executive order would be extended to the first day thereafter.

**Public reporting of information on facility participation in the voluntary reporting periods would occur in CY 2028 for the CYs 2025 and 2026 reporting periods.

We refer readers to section XV.B.5.b of this final rule with comment period regarding our discussion of the Adoption of the Risk Standardized Patient-Reported Outcome-Based Performance Measure (PRO–PM) Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA) in the ASC Setting (THA/TKA PRO–PM), including summaries of the comments we received on our proposal and our responses thereto. After considering commenters' recommendations regarding voluntary and mandatory reporting timelines received in section XV.B.5.b of this final rule with comment period, we are extending the voluntary reporting period by an additional year and delaying implementation of mandatory reporting by one year. We believe that the additional year of voluntary reporting would allow time for CMS to monitor implementation progress with regards to data collection burden and response rates, as well as time for rulemaking should any improvements for mandatory reporting need to be made.

We are finalizing our proposal to begin voluntary reporting with the CY 2025 reporting period and continue through the CY 2027 reporting period followed by mandatory reporting beginning with the CY 2028 reporting period for CY 2031 payment determination and refer readers to Table 142 for an overview of the finalized performance period, pre- and post-operative data collection timeframes, and data submission deadlines during the voluntary reporting periods for THA/TKA PRO–PM.

TABLE 142: FINALIZED PRE-OPERATIVE AND POST-OPERATIVE PERIODS FOR THA/TKA PRO–PM VOLUNTARY REPORTING

Reporting Cycle	**THA/TKA Procedures Performed**	**Pre-Procedure Data Collection (0 to 90 days before the procedure)**	**Pre-Procedure Data Submission Date ***	**Post-Procedure Data Collection (300 to 425 days after the procedure)**	**Post-Procedure Data Submission ***	Preview/ Public Reporting**
Voluntary Reporting CY 2025	January 1, 2025-December 31, 2025	October 3, 2024-December 31, 2025	May 15, 2026	October 28, 2025-March 1, 2027	May 15, 2027*	CY 2028
Voluntary Reporting CY 2026	January 1, 2026-December 31, 2026	October 3, 2025-December 31, 2026	May 15, 2027	October 28, 2026-February 29, 2028	May 15, 2028	CY 2029
Voluntary Reporting CY 2027	January 1, 2027-December 31, 2027	October 3, 2026-December 31, 2027	May 15, 2028	October 28, 2027-February 28, 2029	May 15, 2029	CY 2030

*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 non-workday for Federal employees by statute or Executive Order would be extended to the first day thereafter.

**Public reporting of information on facility participation in the voluntary reporting periods would occur in CY 2028 for the CY 2025 reporting period, CY 2029 for the CY 2026 reporting period, and CY 2030 for the CY 2027 reporting period.

(c) Mandatory Reporting

Following the two voluntary reporting periods, we proposed that mandatory reporting of the THA/TKA PRO–PM would begin with reporting PRO data for eligible elective THA/TKA procedures from January 1, 2027, through December 31, 2027 (the CY 2027 performance period), impacting the CY 2030 payment determination. This initial mandatory reporting would include pre-operative PRO data collection from 90 days preceding the applicable performance period and from 300 to 425 days after the performance period. For example, pre-operative data from October 3, 2026, through December 31, 2027 (for eligible elective primary THA/TKA procedures from January 1, 2027, through December 31, 2027) and post-operative PRO data collection from October 28, 2027, to February 28, 2029. Pre-operative data submission would occur by May 15, 2028, and post-operative data submission in May 15, 2029.

In the CY 2024 OPPS/ASC proposed rule, we noted that we intend to provide ASCs with their results in CY 2030 before publicly reporting results on the Compare tool hosted by HHS, currently available at *https://www.medicare.gov/care-compare,* or its successor website. We would provide confidential feedback reports during the voluntary period which would include the RSIR as well as other results that support understanding of their performance prior to public reporting. For this first mandatory reporting period, facilities that fail to meet the reporting requirements would receive a reduction of their ASC annual fee schedule update in the CY 2030 payment determination. ASCs would be required to submit 45 percent of eligible, complete pre-operative data with matching eligible, complete post-operative data as a minimum amount of data for mandatory reporting in the ASCQR Program.

We refer readers to Table 143 for an overview of the proposed performance period, pre- and post-operative data collection timeframes, and data submission deadlines during the first mandatory reporting period.

TABLE 143: PROPOSED PRE-OPERATIVE AND POST-OPERATIVE PERIODS FOR THA/TKA PRO-PM FOR MANDATORY REPORTING

Reporting Cycle	Performance Period	Pre-Procedure Data Collection (0 to 90 days before the procedure)	Pre-Procedure Data Submission Date	Post-Procedure Data Collection (300 to 425 days after the procedure)	Post-Procedure Data Submission	Confidential Reporting
Mandatory Reporting CY 2027	January 1, 2027-December 31, 2027	October 3, 2026-December 31, 2027	May 15, 2028	October 28, 2027-February 28, 2029	May 15, 2029	CY 2030*

*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 non-workday for Federal employees by statute or executive order would be extended to the first day thereafter.

*Public reporting of information on facility results in the mandatory reporting period would occur in CY 2030 for CY 2027 reporting period/CY 2030 payment determination.

We refer readers to section XV.B.5.b of this final rule with comment period regarding our discussion of the Adoption of the Risk Standardized Patient-Reported Outcome-Based Performance Measure (PRO–PM) Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA) in the ASC Setting (THA/TKA PRO–PM), including summaries of the comments we received on our proposal and our responses thereto.

We invited comment on these proposals.

After considering commenter's recommendation regarding voluntary and mandatory reporting timelines received in section XV.B.5.b of this final rule with comment period, we are extending the voluntary reporting period by an additional year and delaying implementation of mandatory reporting by one year. We believe that the additional year of voluntary reporting would allow time for CMS to monitor implementation progress with regards to data collection burden and response rates, as well as time for rulemaking should any improvements for mandatory reporting need to be made. We are finalizing our proposal to begin voluntary reporting with the CY 2025 reporting period and continue through the CY 2027 reporting period followed by mandatory reporting beginning with the CY 2028 reporting period for CY 2031 payment determination.

Following the voluntary reporting periods, we are finalizing that mandatory reporting of the THA/TKA PRO–PM would begin with reporting PRO data for eligible elective THA/TKA procedures from January 1, 2028, through December 31, 2028 (the CY 2028 performance period), impacting the CY 2031 payment determination. This initial mandatory reporting would include pre-operative PRO data collection from 90 days preceding the applicable performance period and from 300 to 425 days after the performance period. For example, pre-operative data from October 3, 2027, through December 31, 2028 (for eligible elective primary THA/TKA procedures from January 1, 2028, through December 31, 2028) and post-operative PRO data collection from October 27, 2028, to March 1, 2030. Pre-operative data submission would occur by May 15, 2029, and post-operative data submission would occur by May 15, 2030.

We refer readers to Table 144 for an overview of the finalized performance period, pre- and post-operative data collection timeframes, and data submission deadlines during the mandatory reporting periods for THA/TKA PRO–PM.

TABLE 144: FINALIZED PRE-OPERATIVE AND POST-OPERATIVE PERIODS FOR THA/TKA PRO–PM FOR MANDATORY REPORTING

Reporting Cycle	THA/TKA Procedures Performed	Pre-Procedure Data Collection (0 to 90 days before the procedure)	Pre-Procedure Data Submission Date *	Post-Procedure Data Collection (300 to 425 days after the procedure)	Post-Procedure Data Submission *	Preview and Public Reporting
Mandatory Reporting CY 2028	January 1, 2028- December 31, 2028	October 3, 2027- December 31, 2028	May 15, 2029	October 27, 2028- March 1, 2030	May 15, 2030	2031**

*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 non-workday for Federal employees by statute or Executive order would be extended to the first day thereafter.

**Public reporting of information on facility results in the Mandatory Reporting periods would occur in CY 2031 for CY 2028 reporting period/CY2031 payment determination.

e. ASCQR Program Data Submission Deadlines

We refer readers to the CY 2021 OPPS/ASC final rule (85 FR 86191) for a detailed discussion of our data submission deadlines policy, which we codified in our regulations at § 416.310(f).

We did not propose any changes to this policy in the CY 2024 OPPS/ASC proposed rule.

f. Review and Corrections Period for Measure Data Submitted to the ASCQR Program

Review and Corrections Period for Data Submitted via a CMS Online Data Submission Tool

We refer readers to the CY 2021 OPPS/ASC final rule (85 FR 86191 and 86192) for a detailed discussion of our review and corrections period policy, which we codified in our regulations at § 416.310(c)(1)(iii).

We did not propose any changes to this policy in the CY 2024 OPPS/ASC proposed rule.

g. ASCQR Program Reconsideration Procedures

We refer readers to the CY 2016 OPPS/ASC final rule (82 FR 59475) (and the previous rulemakings cited therein) and § 416.330 for the ASCQR Program's reconsideration policy.

We did not propose any changes to this policy in the CY 2024 OPPS/ASC proposed rule.

h. Extraordinary Circumstances Exception (ECE) Process

We refer readers to the CY 2018 OPPS/ASC final rule (82 FR 59474 through 59475) (and the previous rulemakings cited therein) and § 416.310(d) for the ASCQR Program's extraordinary circumstance exceptions (ECE) request policy. In the CY 2024 OPPS/ASC proposed rule (88 FR 49824), we proposed to amend our exception policy codified at § 416.310(d)(1) to replace references to ''QualityNet'' with ''CMS-designated information system'' or ''CMS website'', and to make other conforming technical edits, to accommodate recent and future systems requirements and mitigate confusion for program participants.

We invited public comment on the proposal.

We received no comments on the proposal. We are finalizing our proposal as proposed.

E. Payment Reduction for ASCs That Fail To Meet the ASCQR Program Requirements

1. Statutory Background

We refer readers to the CY 2012 OPPS/ASC final rule with comment period (76 FR 74492 and 74493) 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 2024, the ASC conversion factor is equal to the conversion factor calculated for the previous year updated by the productivity-adjusted hospital market basket update factor. The productivity adjustment is set forth in section 1833(i)(2)(D)(v) of the Act. The productivity-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 in certain payment rates under the ASC payment system 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 and 68500), in order to implement the requirement to reduce the annual update for ASCs that fail to meet the ASCQR Program requirements, we finalized the following policies: (1) to calculate a full update conversion factor and an ASCQR Program reduced update

conversion factor; (2) to calculate 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; and (3) 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 productivity 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, are 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 and 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 have noted our belief 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 the CY 2013 OPPS/ASC 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 2023 OPPS/ASC final rules with comment period, we did not make any other changes to these policies. We proposed the continuation of these policies for the CY 2024 reporting period.

We did not receive any public comments on our proposal. We are finalizing the continuation of these policies for CY 2024.

XVI. Requirements for the Rural Emergency Hospital Quality Reporting (REHQR) Program

A. Background

1. Overview

The Rural Emergency Hospital Quality Reporting (REHQR) Program's overarching goals are to improve the quality of care provided to Medicare beneficiaries, facilitate public transparency, ensure accountability, and safeguard the accessibility of hospitals in rural settings. We refer readers to section XVI of the CY 2023 Hospital Outpatient Prospective Payment System (OPPS)/Medicare Ambulatory Surgical Center Payment System (ASC) final rule (87 FR 72136 through 72150) for an overview of the REHQR Program.

2. Statutory and Regulatory History of Quality Reporting for REHs

Congress established Rural Emergency Hospitals (REHs) as a new Medicare provider type in the Consolidated Appropriations Act (CAA), 2021. Section 125 of Division CC of the CAA, 2021 added section 1861(kkk) to the Social Security Act (the Act). This section defines an REH as a facility that was, as of December 27, 2020: (1) a critical access hospital (CAH); or (2)(i) a subsection (d) hospital with not more than 50 beds located in a county (or equivalent unit of local government) in a rural area,[646] or (ii) a subsection (d) hospital with not more than 50 beds that was treated as being in a rural area.[647] [648] Among other requirements, an REH must apply for enrollment in the Medicare program, provide emergency department (ED) services and observation care, and not provide any acute care inpatient services (other than post-hospital extended care services furnished in a distinct part unit licensed as a skilled nursing facility).[649] [650] At the election of the REH, it can also provide certain services furnished on an outpatient basis.[651]

[646] As defined in section 1886(d)(2)(D) of the Act.

[647] Pursuant to section 1886(d)(8)(E) of the Act.

[648] As set out under section 1861(kkk)(3) of the Act.

[649] 42 CFR part 485, subpart E (§§ 485.500 through 485.546).

[650] Qualification requirements for REHs are set out under section 1861(kkk)(2) of the Act.

[651] *See* section 1861(kkk)(1)(A)(ii) of the Act.

3. Codification of the Statutory Authority of the REHQR Program

In the CY 2024 OPPS/ASC proposed rule (88 FR 49825 and 49826), we proposed to codify the statutory authority for the REHQR Program at 42 CFR 419.95 by adding paragraph (a), ''Statutory authority.'' Section 1861(kkk)(7)(A) of the Act authorizes the Secretary to implement a quality reporting program requiring REHs to submit data on measures in accordance with the Secretary's requirements in section 1861(kkk)(7). Section 1861(kkk)(7)(B)(ii) requires REHs to submit quality measure data to the Secretary ''in a form and manner, and at a time, specified by the Secretary.'' The Act does not require the Secretary to provide incentives for submitting this data under the REHQR Program, nor does it require the Secretary to impose penalties for failing to comply with this requirement under the REHQR Program.

We invited public comment on the proposal. We did not receive any comments on the proposal and are finalizing our proposal to codify the statutory authority of the REHQR Program at § 419.95(a).

B. REHQR Program Quality Measures

1. Considerations in the Selection of REHQR Program Quality Measures

As we stated in the CY 2023 OPPS/ASC final rule, we seek to adopt a concise set of important, impactful, reliable, accurate, and clinically relevant measures for REHs that would inform consumer decision-making regarding care and drive further quality improvement efforts in the REH setting (87 FR 72137). As we considered potential measures for the REHQR Program, we prioritized measures that had undergone previous consensus-based entity (CBE) [652] review for the hospital outpatient department (HOPD) setting that reflect important areas of service for REHs while adhering to the CMS National Quality Strategy goals,[653] Strategic Plan,[654] Meaningful Measures 2.0 initiatives,[655] and the Department of Health and Human Services' (HHS) Strategic Plan.[656] When identifying potential measures for the REHQR Program, we focused on the considerations of service and patient volume, care accountability and quality, rurality and care setting relevance, and health equity.

We note that under section 1861(kkk)(7)(C)(i) of the Act, unless the exception of subclause (ii) applies, a measure selected for the REHQR Program must have been endorsed by the entity with a contract under section 1890(a) of the Act, also known as the CBE. The CBE is a voluntary, consensus-based, standard-setting organization with a diverse representation of consumer, purchaser, provider, academic, clinical, and other health care stakeholder organizations. The CBE was established to standardize healthcare quality measurement and reporting through its consensus development processes. In general, we prefer to adopt measures that have been endorsed by the CBE identified by the Secretary; however, due to lack of an endorsed measure for a given setting, procedure, or other aspect of care, the requirement that measures reflect consensus among affected parties can be achieved in other ways, including input from the measure development process, through broad acceptance, use of the measure(s) in other programs, and through public comment. More specifically, section 1861(kkk)(7)(C)(ii) provides an exception to CBE-endorsement, which is that, in the case of a specified area or medical topic determined appropriate by the Secretary for which a measure has not been endorsed by the entity with a contract under section 1890(a) of the Act, the Secretary may specify a measure that is not endorsed as long as due consideration is given to measures that have been endorsed or adopted by a consensus organization identified by the Secretary.

In the CY 2024 OPPS/ASC proposed rule (88 FR 49826), we proposed to adopt four measures for the REHQR Program measure set—(1) Abdomen Computed Tomography (CT)—Use of Contrast Material; (2) Median Time from Emergency Department (ED) Arrival to ED Departure for Discharged ED Patients; (3) Facility 7-Day Risk-Standardized Hospital Visit Rate After Outpatient Colonoscopy; and (4) Risk-Standardized Hospital Visits Within 7 Days After Hospital Outpatient Surgery—which are measures currently adopted in the Hospital Outpatient Quality Reporting (OQR) Program. We recognize REHs will be smaller hospitals that will likely have limited resources compared with larger hospitals in metropolitan areas.[657] As discussed in the CY 2024 OPPS/ASC proposed rule, for the REHQR Program, we intend to seek balance between the costs associated with reporting data and the benefits of ensuring safety and quality of care through measurement and public reporting. Because REHs will consist of hospitals formerly operating as either CAHs or subsection (d) hospitals, we assessed whether these facilities have successfully reported the REHQR Program measures within the context of the Hospital OQR Program with sufficient volume to meet CMS case number thresholds for data to be publicly reported, though we note that CAHs report data voluntarily. More specifically, we considered reporting rates and measure performance for CAHs and subsection (d) hospitals that are eligible to convert to REHs and also analyzed data for other subsection (d) hospitals that are not eligible for conversion to permit comparisons of these providers' ability to report these data in sufficient numbers to permit public reporting and to view comparative performance. Table 145 includes the results of this analysis.

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[652] In previous years, we referred to the consensus-based entity by corporate name. We have updated this language to refer to the consensus-based entity more generally.

[653] CMS (2023). What is the CMS National Quality Strategy? Available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Value-Based-Programs/CMS-Quality-Strategy*. Last accessed April 13, 2023.

[654] CMS (2023). CMS Strategic Plan. Available at: *https://www.cms.gov/cms-strategic-plan*. Last accessed March 10, 2023.

[655] CMS (2022), Meaningful Measures 2.0: Moving from Measures Reduction to Modernization. Available at *https://www.cms.gov/medicare/meaningful-measures-framework/meaningful-measures-20-moving-measure-reduction-modernization*. Last accessed April 13, 2023.

[656] HHS (2022). Strategic Plan FY 2022–2026. Available at *https://www.hhs.gov/about/strategic-plan/2022-2026/index.html*. Last accessed March 10, 2023.

[657] American Hospital Association, Rural Report. (February 2019) 2019 Challenges Facing Rural Communities and the Roadmap to Ensure Local Access to High-quality, *Affordable Care 3*. Available at *https://www.aha.org/system/files/2019-02/rural-report-2019.pdf*. Last accessed February 28, 2023.

TABLE 145: REPORTING RESULTS AND MEASURE PERFORMANCE FOR HOSPITALS PUBLICLY REPORTING REHQR PROGRAM MEASURES

Abdomen Computed Tomography (CT) - Use of Contrast Material*					
Statistic	**Critical Access Hospitals**	**Subsection (d) hospitals with ≤ 50 beds Rural Only**	**Subsection (d) hospitals with ≤ 50 beds Urban Only**	**Subsection (d) hospitals with 51 -100 beds**	**Subsection (d) hospitals with >100 beds**
Total Number of Hospitals	1,361	200	300	556	2,197
Number Reporting (% of Total)	1,060 (77.9%)	151 (75.5%)	146 (48.7%)	500 (89.9%)	2,060 (93.8%)
Mean (CT studies)	6.3	7.5	7.4	6.4	6.0
10th Percentile	1.7	2.4	0.6	1.7	1.4
25th Percentile	2.9	4.2	2.2	3.2	3
Median	5	6.5	4.7	5.35	5.1
75th Percentile	7.8	10.1	8.1	8.15	7.9
90th Percentile	12.1	14	12.7	11.7	11

*Ratio of CT abdomen studies that are performed both with and without contrast of all CT abdomen studies performed. Lower scores indicate better performance.

Median Time from Emergency Department (ED) Arrival to ED Departure for Discharged ED Patients – Overall Rate*					
Statistic	**Critical Access Hospitals**	**Subsection (d) hospitals with ≤ 50 beds Rural Only**	**Subsection (d) hospitals with ≤ 50 beds Urban Only**	**Subsection (d) hospitals with 51 -100 beds**	**Subsection (d) hospitals with >100 beds**
Total Number of Hospitals	1,361	200	300	556	2,197
Number Reporting (% of Total)	1,126 (82.7%)	163 (81.5%)	173 (57.7%)	507 (91.2%)	2 ,081 (94.7%)
Mean (minutes)	125.9	130.0	142.5	156.7	193.6
10th Percentile	91	99	97	111	138
25th Percentile	106	109	113	130	160
Median	123	130	137	153	188
75th Percentile	142	148	169	179	219
90th Percentile	164	159	197	204	254

*Rate is time in minutes from ED arrival to ED departure for patients discharged from the ED. Lower values indicate better performance. This measure is stratified by four category types of patients.

Median Time from Emergency Department (ED) Arrival to ED Departure for Discharged ED Patients - Reported Measure, Excluding Psychiatric/Mental Health and Transfer Patients*					
Statistic	**Critical Access Hospitals**	**Subsection (d) hospitals with ≤ 50 beds Rural Only**	**Subsection (d) hospitals with ≤ 50 beds Urban Only**	**Subsection (d) hospitals with 51 -100 beds**	**Subsection (d) hospitals with >100 beds**
Total Number of Hospitals	1,361	200	300	556	2,197
Number Reporting (% of Total)	1,124 (82.6%)	163 (81.5%)	173 (57.7%)	507 (91.2%)	2,078 (94.6%)
Mean (minutes)	118.5	122.6	137.0	150.6	188.0
10th Percentile	86	94	92	106	133
25th Percentile	100	104	110	125	155
Median	116	122	132	148	183
75th Percentile	134	140	159	172	214
90th Percentile	153	153	191	199	248

*Rate is time in minutes from ED arrival to ED departure for patients discharged from the ED. Lower values indicate better performance. This measure is stratified by four category types of patients.

Median Time from ED Arrival to ED Departure for Discharged ED Patients - Psychiatric/Mental Health Patients*					
Statistic	**Critical Access Hospitals**	**Subsection (d) hospitals with ≤ 50 beds Rural Only**	**Subsection (d) hospitals with ≤ 50 beds Urban Only**	**Subsection (d) hospitals with 51 -100 beds**	**Subsection (d) hospitals with >100 beds**
Total Number of Hospitals	1,361	200	300	556	2,197
Number Reporting (% of Total)	703 (51.7%)	128 (64.0%)	87 (29.0%)	419 (75.4%)	1,869 (85.1%)
Mean (minutes)	213.1	208.6	265.9	267.8	340.9
10th Percentile	118	119	120	142	174
25th Percentile	148	143.5	169	181	226
Median	190	187.5	230	232	294
75th Percentile	243	237	312	315	395
90th Percentile	333	330	444	406	552

*Rate is time in minutes from ED arrival to ED departure for patients discharged from the ED. Lower values indicate better performance. This measure is stratified by four category types of patients.

Median Time from ED Arrival to ED Departure for Discharged ED Patients - Transfer Patients*					
Statistic	**Critical Access Hospitals**	**Subsection (d) hospitals with ≤ 50 beds Rural Only**	**Subsection (d) hospitals with ≤ 50 beds Urban Only**	**Subsection (d) hospitals with 51 -100 beds**	**Subsection (d) hospitals with >100 beds**
Total Number of Hospitals	1,361	200	300	556	2,197
Number Reporting (% of Total Eligible)	934 (68.6%)	145 (72.5%)	119 (39.7%)	384 (69.1%)	681 (31.0%)
Mean (minutes)	259.4	300.6	321.7	315.2	366.3
10th Percentile	162	186	201	210	236
25th Percentile	194	214	249	247	276
Median	242	256	300	299.5	341
75th Percentile	301	311	376	360.5	422
90th Percentile	385	387	486	439	519

*Rate is time in minutes from ED arrival to ED departure for patients discharged from the ED. Lower values indicate better performance. This measure is stratified by four category types of patients.

Risk-Standardized Hospital Visits Within 7 Days After Hospital Outpatient Surgery* Excluding Eye Surgery and Routine Colonoscopy					
Statistic	**Critical Access Hospitals**	**Subsection (d) hospitals with ≤ 50 beds Rural Only**	**Subsection (d) hospitals with ≤ 50 beds Urban Only**	**Subsection (d) hospitals with 51 -100 beds**	**Subsection (d) hospitals with >100 beds**
Total Number of Hospitals	1,361	200	300	556	2,197
Number Reporting (% of Total)	182 (13.4%)	78 (39.0%)	184 (61.3%)	403 (72.5%)	1,939 (88.3%)
Mean (ratio of predicted to expected visits)	1.006	1.024	0.988	1.016	1.010
10th Percentile	0.9	0.9	0.8	0.9	0.8
25th Percentile	0.9	1	0.9	0.9	0.9
Median	1	1	1	1	1
75th Percentile	1	1.1	1.1	1.1	1.1
90th Percentile	1.1	1.2	1.2	1.2	1.2

*Ratio of "predicted" unplanned hospital visits to the number of "expected" unplanned hospital visits. Lower scores indicate better performance.

Facility 7-Day Risk-Standardized Hospital Visit Rate After Outpatient Colonoscopy Rate*					
Statistic	**Critical Access Hospitals**	**Subsection (d) hospitals with ≤ 50 beds Rural Only**	**Subsection (d) hospitals with ≤ 50 beds Urban Only**	**Subsection (d) hospitals with 51 -100 beds**	**Subsection (d) hospitals with >100 beds**
Total Number of Hospitals	1,361	200	300	556	2,197
Number Reporting (% of Total)	609 (44.7%)	131 (65.5%)	131 (43.7%)	465 (83.6%)	1,945 (88.5%)
Mean (visits)	14.3	14.4	14.3	14.3	14.2
10th Percentile	13.6	13.4	13.2	13	12.7
25th Percentile	13.8	13.8	13.7	13.6	13.4
Median	14.2	14.2	14.2	14.2	14.1
75th Percentile	14.6	15	14.8	14.9	14.9
90th Percentile	15.1	15.6	15.6	15.7	15.7

*Rate is the number of unplanned hospital visits after colonoscopy (per 1,000 colonoscopies). Lower scores indicate better performance.

Data sources: Program Resource System (PRS) accessed January 10, 2023, Care Compare data updated each January 2018-2023, and CMS Providers of Services File (PSF) - Hospital & Non-Hospital Facilities Q3 2022.
Includes all data submitted for all CAHs and subsection (d) hospitals open as of December 27, 2020.
Hospitals are considered eligible to report in Care Compare if they have a Medicare accept date prior to the latest measure end date and are open as of the PRS accessed date. March 31, 2022, is the measure end date for Hospital OQR Program measures for public reporting in the January 2023 Care Compare refresh.
Hospitals are considered reporting Hospital OQR Program measures if they have a score published on Care Compare. Requirements for publication include that aggregated case numbers reported be greater than or equal to 10. The published data value must not be "Not Available".
Rural/urban location is identified by the CMS PSF - Hospital & Non-Hospital Facilities Q3 2022. Rural/urban location is based on Core Based Statistical Area (CBSA), which indicates whether the county is defined as urban or rural to limit the analysis to areas currently viewed as rural.
Hospital bed size is the number of total Medicare certified beds listed in PRS.

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Based on our analysis of these data, current to the January 2023 refresh of Care Compare, we note that a relatively high percentage of the hospitals eligible to convert to REH status have reported aggregated measure data that meet the requirements for disclosure per CMS privacy policy[658] for the measures we proposed for the REHQR Program. For example, in comparing solely the averages for the Abdomen Computed Tomography (CT)—Use of Contrast Material measure, a significant majority of CAHs (77.9 percent) and rural subsection (d) hospitals with 50 or fewer beds (75.5 percent) have data publicly reported. In addition, for the Facility 7-Day Risk-Standardized Hospital Visit Rate After Outpatient Colonoscopy measure, rural subsection (d) hospitals with 50 or fewer beds were more often able to have data publicly reported than urban subsection (d) hospitals with 50 or fewer beds (65.5 percent versus 43.7 percent), which indicates that this measure could be useful for small rural hospitals that convert to REHs. For this latter measure, while the mean values are similar across categories of hospitals, the results show that there are outlier hospitals with higher levels of hospital events following outpatient colonoscopies than expected, which provides potentially valuable information when discerning individual hospital performance.

While it is not possible to identify the exact group of hospitals that will choose to convert to REH status, our analysis indicates that the services targeted by the REHQR measures are relevant for hospitals that may participate in the REHQR Program as these hospitals are currently providing the services assessed by the selected measures with case volumes sufficient to meet thresholds to allow public reporting of the collected data.[659]

2. Retention of Measures Previously Adopted Into the REHQR Program

a. Background

For purposes of our quality reporting programs, we retain measures from previously adopted measure sets for subsequent years unless otherwise specified; for example, see the Hospital OQR (42 CFR 419.46(i)(1)) and Ambulatory Surgical Center Quality Reporting (ASCQR) Programs (§ 416.320(a)). As this approach establishes regularity and predictability for participating providers and suppliers, we seek to align the REHQR Program with this policy.

[658] CMS Policy for Privacy Act Implementation & Breach Notification, July 23, 2007, Document Number: CMS–CIO–POL–PRIV01–01, p 4. Statistical, aggregate or summarized information created as a result of analysis conducted using identifiable CMS data obtained under CMS-approved projects/studies may only be disclosed if the data are not individual-specific and the data are aggregated to a level where no data cells contain 10 or fewer individuals.

[659] CMS does not report measures publicly unless measures are the result of an analysis of more than 10 cases. See CMS Policy for Privacy Act Implementation & Breach Notification, July 23, 2007, Document Number: CMS–CIO–POL–PRIV01–01, p 4.

b. Adoption and Codification of a Measure Retention Policy for the REHQR Program

In the CY 2024 OPPS/ASC proposed rule (88 FR 49831), we proposed that, once adopted into the REHQR Program measure set, each measure would be retained for use, except when they are removed, suspended, or replaced under our policies for measure removal, suspension, or replacement, discussed below in sections XVI.B.3.a and XVI.B.3.b of this final rule with comment period. We also proposed to codify this policy at § 419.95 by adding paragraph (e), ''Retention and removal of quality measures under the REHQR Program.'' In paragraph (e)(1), we proposed that quality measures would be adopted into the REHQR Program measure set until such time that such measures are removed, suspended, or replaced, as set forth at paragraphs (e)(2) and (3) of the section.

We invited public comment on these proposals.

Comment: One commenter expressed broad support of CMS' proposals to support REHQRs' efforts to collect data, report quality measures, and improve performance, including CMS' proposal to adopt a measure retention policy for the REHQR Program, in alignment with the Hospital OQR and ASCQR Programs.

Response: We thank the commenter for their support.

After consideration of the public comments we received, we are finalizing adoption of the measure retention policy as proposed for the REHQR Program and to codify this policy at § 419.95(e)(1).

3. Removal of Quality Measures From the REHQR Program Measure Set

a. Adoption and Codification of an Immediate Removal Policy for Adopted REHQR Program Measures

When there is reason to believe that the continued collection of a measure as currently specified raises potential patient safety concerns, we believe it would be appropriate for us to take immediate action to remove the measure from the REHQR Program outside of rulemaking. Therefore, in the CY 2024 OPPS/ASC proposed rule (88 FR 49831), we proposed to adopt an immediate measure removal policy that would allow us to promptly remove such a measure and notify REHs and the public of the decision to remove the measure through standard hospital communication channels, including, but not limited to, REHQR Program-specific listservs and REHQR Program guidance currently housed on a CMS website (such as QualityNet). We also proposed to confirm the removal of the measure in the next appropriate rulemaking, typically an OPPS rulemaking cycle. We note that the Hospital OQR Program previously finalized a similar policy (74 FR 60634 through 60635).

We proposed to codify this policy at § 419.95 by adding paragraph (e)(2), ''Immediate measure removal.'' In paragraph (e)(2), we proposed that in cases where CMS believes that the continued use of a quality measure as specified raises patient safety concerns, CMS would immediately remove the measure from the REHQR Program, promptly notify REHs and the public of the removal of the measure and the reasons for its removal, and confirm the removal of the measure in the next appropriate rulemaking.

We invited public comment on these proposals.

Comment: One commenter did not support our proposal to adopt a policy to immediately remove a measure in cases where CMS believes that the continued use of the measure as specified raises patient safety concerns. The commenter stated that this policy would enable CMS to remove REHQR Program measures without going through the rulemaking process, which the commenter believed would thus strip consumers of their voice in this decision-making, diminish transparency, and send the wrong message about the importance of quality and safety at REHs. The commenter also felt that the circumstances triggering immediate removal of a measure under the proposed measure removal policy (''the continued collection of a measure as currently specified raises potential patient safety concerns'') should be held to public scrutiny through rulemaking.

Response: We believe that we should take immediate action to discontinue the use of quality measures when clinical evidence suggests that continued collection of the data may result in harm to patients. Under such circumstances, we may not be able to wait until the annual rulemaking cycle or until we have had the opportunity to obtain input from the public to remove the measure because of the necessity to not encourage potentially harmful practices which may result from the continued collection of the measure. However, we agree with the commenter that seeking public input on the removal of the measure increases the public's voice in decision-making and increases transparency. Therefore, we are finalizing a policy in which we would suspend the measure's use until the removal can be accomplished through the standard rulemaking process.

After consideration of the public comment we received regarding reducing consumer voice in decision-making and diminishing transparency, we are finalizing a modified version of the proposed immediate measure removal policy. When the collection of the measure as currently specified raises potential patient safety concerns, instead of immediately removing the measure, we will suspend the measure's use until the removal can be proposed and finalized through rulemaking. We will notify REHs and the public of the decision to suspend the measure through standard hospital communication channels, including, but not limited to, REHQR Program-specific listservs and REHQR Program guidance currently housed on a CMS website (such as QualityNet). We will then address any such suspension and propose any permanent action regarding such suspended measure in the next appropriate rulemaking cycle. We are codifying this policy at § 419.95(e)(2).

b. Adoption and Codification of a Measure Removal Factors Policy

The Hospital OQR and ASCQR Programs use similar sets of factors for determining whether to remove measures. For more detail on the measure removal factors in those programs, we refer readers to §§ 419.46(i)(3)(i) and 416.320(c)(2), respectively. Generally, we prefer to use similar removal factors across the quality reporting programs for consistency and alignment. Therefore, in the CY 2024 OPPS/ASC proposed rule (88 FR 49831), we proposed to adopt a similar set of removal factors for the REHQR Program.

Specifically, we proposed to adopt the following eight factors to determine conditions for measure removal from the REHQR Program:

- Factor 1. Measure performance among REHs is so high and unvarying that meaningful distinctions and improvements in performance can no longer be made (''topped-out'' measures).
- Factor 2. Performance or improvement on a measure does not result in better patient outcomes.
- Factor 3. A measure does not align with current clinical guidelines or practice.
- Factor 4. The availability of a more broadly applicable (across settings, populations, or conditions) measure for the topic.
- Factor 5. The availability of a measure that is more proximal in time to desired patient outcomes for the particular topic.

- Factor 6. The availability of a measure that is more strongly associated with desired patient outcomes for the particular topic.
- Factor 7. Collection or public reporting of a measure leads to negative unintended consequences other than patient harm.
- Factor 8. The costs associated with a measure outweigh the benefit of its continued use in the program.

In addition, for Measure Removal Factor 1, we proposed that a measure for the REHQR Program would be deemed topped-out by determining: (1) when the difference between the 75th and 90th percentiles for an REH's measure is within two times the standard error of all measure data reported for all REHs, and (2) when the measure's truncated coefficient of variation (TCOV) is less than or equal to 0.1.

We proposed to codify these policies at § 419.95 by adding paragraph (e)(3), ''Measure removal, suspension, or replacement through the rulemaking process.'' In paragraph (e)(3), we proposed that unless a measure raises specific safety concerns as set forth in paragraph (e)(2) of the section, we would use rulemaking to remove, suspend, or replace quality measures in the REHQR Program. We also proposed to adopt the eight removal factors discussed previously by codifying them at paragraph (e)(3)(i), in alignment with other quality reporting programs (74 FR 60634 and 60635, 77 FR 68472, and 83 FR 59082). Additionally, we proposed to adopt the criteria to determine topped-out measures discussed previously at paragraph (e)(3)(ii). Similar to the Hospital OQR Program (79 FR 66941 and 66942), we proposed to assess the benefits of removing a measure from the REHQR Program on a case-by-case basis at paragraph (e)(3)(iii). An REHQR Program measure would not be removed solely based on meeting any specific factor.

We invited public comment on these proposals.

Comment: One commenter did not support CMS' proposal to adopt measure removal factors to consider when determining whether to remove REHQR Program measures. The commenter specifically did not agree with the ''topped-out criteria'' under Measure Removal Factor 1 because some measures included in CMS quality reporting programs quantify ''never events.'' The commenter stated that comparing performance between the 75th and 90th percentiles does not adequately consider variation between higher and lower performing hospitals in these cases. The commenter further stated that many of CMS' quality measures only include patients covered by Medicare FFS and exclude the large population of Medicare Advantage beneficiaries, which makes the determination of whether a measure is topped out incomplete and inaccurate.

Response: We thank the commenter for this feedback. We acknowledge that our topped-out policy does not lend itself well to measures of rare adverse events also known as ''never events.'' We do consider these types of measures important, especially with regard to patient safety measures. As discussed in the CY 2024 OPPS/ASC proposed rule (88 FR 49831), the benefits of removing a measure from the REHQR Program would be assessed on a case-by-case basis. Under this case-by-case approach, a measure would not be removed solely on the basis of meeting any specific factor (88 FR 49831).

We also agree that across our quality programs, many measures currently are specified for only Medicare FFS beneficiary information. As recommended by the commenter, we seek to include Medicare Advantage as well as other payer information in our measures.

However, we believe that for many measures, when performance is so high and unvarying that meaningful distinctions and improvements in performance can no longer be made, the measures would not provide useful information to Medicare beneficiaries or the public about the quality of care. For this reason, we believe that topped-out status is an important consideration when assessing whether to remove a measure from the REHQR Program.

Comment: One commenter recommended that CMS consider an additional measure removal factor based on whether a substantial number of REHs have reported aggregated measure data in sufficient numbers to permit public reporting. The commenter stated that if most REHs do not have a sufficient number of cases for a specific measure, such a measure should be removed from the REHQR Program because it would not be providing meaningful insight regarding REH quality performance. Another commenter requested that CMS adopt a new Factor 1 that explicitly states that CMS' measure removal policy is centered on the best interests of Medicare beneficiaries and the public. This commenter also requested that CMS provide more details on the costs and benefits of a measure that we would consider under Factor 8, noting that there is a cost to beneficiaries of not having access to insights as a result of a measure removal.

Response: We thank the commenters for their recommendations and appreciate the articulation of these important considerations in relation to measure removal under the REHQR Program. We believe that the concerns raised by the commenters are addressed by other REHQR Program policies and other measure removal factors. For example, with regard to the concern regarding low volume, as discussed in the CY 2024 OPPS/ASC proposed rule (88 FR 49830), CMS does not report measures publicly unless it achieves sufficient case volumes to allow for public reporting of the collected data. We further note that, as discussed in the CY 2024 OPPS/ASC proposed rule (88 FR 49827 through 49830), many CAHs and small, rural subsection (d) hospitals—hospitals which are eligible to convert to REH status—had sufficient measure data to be publicly reported on the Care Compare website for the four measures we are finalizing in section XVI.D of this final rule with comment period.

We also do not believe that an additional measure removal factor explicitly stating that CMS' measure removal policy is centered on the best interests of beneficiaries and the public is necessary because we do consider the benefits of retaining a measure to patients, beneficiaries, and the public as part of our consideration under Factor 8: The costs associated with a measure outweigh the benefit of its continued use in the program. We agree with the commenter that access to information regarding the quality of care provided at a specific REH is a benefit to retaining a measure and that loss of this information is a cost. When we determine that a measure's costs outweigh the benefits of retaining that measure, we provide additional details on the costs and benefits that we have considered in our proposal to remove that measure through rulemaking. Moreover, as discussed in the CY 2024 OPPS/ASC proposed rule (88 FR 49831), similarly to the Hospital OQR Program, our assessment would be made on a case-by-case basis, and a measure would not be removed solely on the basis of meeting any single factor.

After consideration of the public comments we received, we are finalizing our proposal to adopt the measure removal factors and related policies as proposed and to codify these policies at § 419.95(e)(3).

4. Modifications to Previously Adopted Measures

a. Background

It is important for measures adopted for the REHQR Program to remain up-to-date. We believe the way to achieve this is to have in place a sub-regulatory process to incorporate non-substantive updates to measure specifications to facilitate the incorporation of scientific advances and updates to measure specifications in as timely a manner as possible.

b. Adoption and Codification of a Sub-Regulatory Measure Modification Policy

In the CY 2024 OPPS/ASC proposed rule (88 FR 49831 and 49832), we proposed a policy under which we would use a sub-regulatory process to make non-substantive updates to measures adopted for the REHQR Program. Examples of non-substantive changes to measures might include updated diagnoses or procedure codes. With respect to what constitutes substantive versus non-substantive changes, we expect to make this determination on a case-by-case basis.

We proposed that when there is an update to an REHQR Program measure that we believe does not substantially change the nature of the measure, we would use a sub-regulatory process to incorporate those updates to the measure specifications that we apply to the program. We stated that we would develop a specifications manual that will provide the complete and current technical specifications and abstraction information for quality measures used in the REHQR Program. We would revise the specifications manual to clearly identify any updates and would provide sufficient lead time for REHs to implement the revisions where changes to the data collection systems would be necessary. We would also provide notification of the measure specification updates on a CMS website (such as the QualityNet website). We noted that this policy for the REHQR Program aligns with the policies under the Hospital OQR Program (73 FR 68766 and 68767) and ASCQR Program (§ 416.325) that allow measures to be refined through a sub-regulatory process.

We proposed to codify this policy at § 419.95(d), ''Technical specifications and measure maintenance under the REHQR Program.'' In paragraph (d)(2), we proposed that REHQR Program specifications would be updated based on whether the change is considered substantive or non-substantive, as determined by CMS. In paragraph (d)(2)(ii), we proposed that if CMS determines that a change to a measure previously adopted in the REHQR Program is non-substantive, CMS would use a sub-regulatory process to revise the specifications manual as discussed previously.

Changes that we determine to be substantive would be those in which the changes are so significant that the measure is no longer the same measure. In paragraph (d)(2)(i), we proposed that we would use rulemaking to adopt substantive updates to measures previously adopted under the REHQR Program. We believe that this adequately balances the need to incorporate updates to the REHQR Program measures in the most expeditious manner possible to maintain relevancy, reliability, and accuracy of data collection while also preserving the public's ability to comment on updates that significantly change a measure.

We invited public comment on these proposals.

Comment: One commenter expressed broad support of CMS' proposals to support REHQR Program efforts to collect data, report quality measures, and improve performance, including CMS' proposals to adopt policies related to modification of previously adopted measures under the REHQR Program, in alignment with the Hospital OQR and ASCQR Programs.

Response: We thank the commenter for their support.

Comment: One commenter expressed concern with the use of a sub-regulatory process in certain circumstances, including within the context of a new program where transparency and the opportunity to comment on proposals is so essential.

Response: We appreciate the commenter's feedback and agree that transparency and opportunity to comment on proposals is essential, particularly within the context of a new program. We note that as discussed in the CY 2024 OPPS/ASC proposed rule (88 FR 49831 and 49832), we would use the sub-regulatory process to make non-substantive updates to measures previously adopted into the REHQR Program. We also noted that non-substantive changes to measures might include updated diagnoses or procedure codes. In contrast, changes that we determine to be substantive would be those in which the changes are so significant that the measure is no longer the same measure, and we proposed that we would utilize rulemaking to adopt substantive updates to measures previously adopted by the REHQR Program. We also note that we use the sub-regulatory process to address urgent issues, such as patient safety, as discussed later in section XVI.B.3.a, as well as in other quality reporting programs (for example, §§ 412.140(g)(2), 412.164(c)(3)(iii), 412.24(d)(3)(iii), 416.320(b), and 419.46(i)(2), 84 FR 42382 fn. 318, and 84 FR 42404 fn. 328). We believe this policy adequately balances the need to incorporate updates to REHQR Program measures in the most expeditious manner possible to maintain relevancy, reliability, and accuracy of data collection while also preserving the public's ability to comment on updates that significantly change a measure.

After consideration of the public comments we received, we are finalizing our proposals related to a sub-regulatory measure modification policy and to codify this policy at § 419.95(d)(2).

c. Development and Maintenance of Technical Specifications for Quality Measures

We intend to maintain technical specifications for adopted REHQR Program measures. We note that the measures proposed for the REHQR Program have been previously adopted by the Hospital OQR Program. To simplify and streamline participation in the REHQR Program, in the CY 2024 OPPS/ASC proposed rule (88 FR 49832), we proposed to adopt a policy for maintaining the measure specifications of REHQR Program measures that aligns with the Hospital OQR Program's policy (83 FR 59104 and 59105).

We proposed that, whenever we modify the REHQR Program measures and measure sets, we would also update the specifications manual for the REHQR Program. The manuals containing specifications for previously adopted measures can be found on the QualityNet website at: *https://qualitynet.cms.gov/outpatient/specifications-manuals.* At paragraph (d)(1) of § 419.95, we proposed to update the specifications manual for REHQR Program measures at least every 12 months beginning with CY 2024.

We invited public comment on the proposal.

We did not receive any comments specific to the proposal and therefore are finalizing our proposal related to the development and maintenance of technical specifications for quality measures and to codify this policy at § 419.95(d)(1) as proposed. We also refer readers to section XVI.B.2 of this final rule with comment period where we summarize the broad support we received for our proposals related to modifications to previously adopted measures.

5. New Measures for the REHQR Program Measure Set

In the CY 2024 OPPS/ASC proposed rule (88 FR 49832 through 49839), we proposed to adopt four measures into the REHQR Program measure set beginning CY 2024: (1) Abdomen Computed Tomography (CT)—Use of Contrast Material measure; (2) Median Time from ED Arrival to ED Departure for Discharged ED Patients measure; (3) Facility 7-Day Risk-Standardized Hospital Visit Rate After Outpatient Colonoscopy measure; and (4) Risk-Standardized Hospital Visits Within 7 Days After Hospital Outpatient Surgery measure. Three of these measures would be calculated from Medicare Fee-For-Service (FFS) claims and enrollment information. The fourth is a chart-abstracted measure. We noted that many hospitals that are eligible to convert to REH status would already have established resources and experience with submitting these four measures as part of the Hospital OQR Program as previously discussed.

We received comments about the initial measure set for the REHQR Program and CMS' future approach to developing the REHQR Program measure set.

Comment: Several commenters supported the initial REHQR Program measure set. One commenter expressed support for analyzing measures that REH-eligible facilities have reported on to ensure that REHs will be able to successfully participate in this program. Another commenter stated that these measures adequately balance quality reporting burden with ensuring safety and quality of care.

Response: We thank commenters for their support. We agree that it is important to analyze measures that REH-eligible facilities have reported on to ensure successful participation. As demonstrated in Table 146, most of the 16 hospitals that have successfully converted to REH status thus far reported data for the four REHQR Program measures in sufficient case volumes for these data to be public reported and some hospitals reported data for each of the measures being finalized in this rulemaking.[660] We also agree with the need to balance reporting burden with quality of care and safety. Three of the four measures in the initial set for the REHQR Program are based fully on claims, thus not requiring additional data collection burden while representing patient safety and adverse outcome measures. The fourth measure is chart-abstracted, but it is a measure that hospitals that are eligible to convert to REH status are likely to have experience with as it is a long-standing measure under the Hospital OQR Program.

Comment: Several commenters recommended adding measures to the REHQR Program measure set slowly to account for the newness of the program and the lack of certainty regarding what services REHs will provide.

Response: We agree that measures should be added slowly to the REHQR Program measure set to account for newness of the program and uncertainty regarding what services REHs will provide. However, we believe that the measures selected for the initial measure set reflect services that REHs will continue to provide at levels that will enable at least some REHs to publicly report data. We will take commenters' feedback into consideration when deciding how and when to introduce additional measures into the REHQR Program.

Comment: One commenter expressed concern that the REHQR Program measure set as outlined in this rule does not provide the public with sufficient information on the quality of care provided in REHs. The commenter also recommended identifying measure gaps to expand the measure set. The commenter stated that CMS could readily fill two measurement gaps they had identified by implementing two existing measures related to avoidable morbidity and mortality as well four ED measures used in the Hospital OQR Program. These measures are: (1) Severe Sepsis and Septic Shock: Management Bundle measure (SEP–1); (2) Door to Diagnostic Evaluation by a Qualified Medical Professional (OP–20); (3) Fibrinolytic Therapy Received Within 30 Minutes of ED arrival (OP–2); (4) Median Time to Transfer to Another Facility for Acute Coronary Intervention-Reporting Rate (OP–3); (5) Median Time from ED Arrival to ED Departure for Discharged ED Patients (OP–18); and (6) Left Without Being Seen (OP–22).

Response: Regarding the commenter's concern regarding measurement gaps, we acknowledge that the initial REHQR Program with the four measures outlined in this rule serves as a starter set for initial program implementation, while also being sensitive to provider burden. We also believe that the selected measures reflect a core area of REH services (ED services) plus selected outpatient services (imaging and surgical) that sufficiently account for small case volume, and note that the set allows most hospitals that have converted to REH status thus far to have had some data publicly reported. Although the number of facilities converting to REH status is in flux and the services provided may shift, Table R–B2 depicts performance data for REHs that publicly reported data for the four measures we are finalizing in this rule, among the 16 hospitals that have converted to REH status based on data from the Medicare Provider Enrollment, Chain, and Ownership System (PECOS) as of October 13, 2023. As further discussed in section XVI.B.5, these four measures are: (1) Abdomen Computed Tomography (CT)—Use of Contrast Material measure; (2) Median Time from ED Arrival to ED Departure for Discharged ED Patients measure; (3) Facility 7-Day Risk-Standardized Hospital Visit Rate After Outpatient Colonoscopy measure; and (4) Risk-Standardized Hospital Visits Within 7 Days After Hospital Outpatient Surgery measure.

[660] The data provided in Table 146, discussed in section XVI.B.5 below are from the Medicare Provider Enrollment, Chain, and Ownership System (PECOS) as of October 13, 2023.

TABLE R-B2 Care Compare Data on Hospitals that have Converted to REH status for the Four Measures Being Adopted in the REHQR Program in the CY 2024 OPPS/ASC Final Rule

Measure	Number of REHs Reporting	Mean	Median	Minimum	Maximum
Abdomen Computed Tomography (CT) - Use of Contrast Material*	11	8.6	9.6	4.2	13.6
Median Time from Emergency Department (ED) Arrival to ED Departure for Discharged ED Patients - Overall Rate**	14	113.1	109.5	68	178
Median Time from Emergency Department (ED) Arrival to ED Departure for Discharged ED Patients - Reported Measure, Excluding Psychiatric/Mental Health and Transfer Patients**	14	107.2	103	70	155
Median Time from Emergency Department (ED) Arrival to ED Departure for Discharged ED Patients - Psychiatric/Mental Health Patients**	11	228.9	155	114	548
Median Time from Emergency Department (ED) Arrival to ED Departure for Discharged ED Patients - Transfer Patients**	9	276.9	284	194	390
Facility 7-Day Risk-Standardized Hospital Visit Rate After Outpatient Colonoscopy Rate***	5	14.7	14.7	13.6	15.7
Risk-Standardized Hospital Visits Within 7 Days After Hospital Outpatient Surgery**** Excluding Eye Surgery and Routine Colonoscopy	2	1.1	1.05	0.9	1.2

* Ratio of CT abdomen studies that are performed both with and without contrast of all CT abdomen studies performed. Lower scores indicate better performance.

** Rate is time in minutes from ED arrival to ED departure for patients discharged from the ED. Lower values indicate better performance. This measure is stratified by four category types of patients.

*** Rate is the number of unplanned hospital visits after colonoscopy (per 1,000 colonoscopies). Lower scores indicate better performance.

**** Ratio of "predicted" unplanned hospital visits to the number of "expected" unplanned hospital visits. Lower scores indicate better performance.

Source: Data from Medicare Provider Enrollment, Chain, and Ownership System (PECOS) as of October 13, 2023.

We also appreciate the commenter's suggested measures for the REHQR Program measure set and will take this feedback into consideration. We note that one of the ED measures suggested by the commenter, the Median Time from ED Arrival to ED Departure for Discharged ED Patients measure, was proposed for the REHQR Program in the CY 2024 OPPS/ASC proposed rule (88 FR 49834 and 49835) and is being finalized for adoption for the REHQR Program measure set in this final rule, as discussed in section XVI.B.5.b of this final rule with comment period.

Comment: One commenter stated that REHs are likely to be small facilities with limited staff and recommended limiting the use of chart-abstracted measures and creating accommodations to minimize the burden of reporting these measures.

Response: As discussed below in section XVI. B.5.b of this final rule with comment period, we are finalizing one chart-abstracted measure, the Median Time for Discharged ED Patients measure. While we understand that reporting this measure is associated with some burden, as discussed in section XXIV.D of this final rule with comment period, we believe that hospitals that convert to REH status

from being a subsection (d) hospital or CAH will have experience with this measure and likely have existing processes in place to collect and submit data for this measure. In addition, as ED services are statutorily mandated to be provided by REHs, we believe this measure is especially suited for the program. We will, however, take the commenter's feedback into consideration as we continue to evaluate all elements of the REHQR Program.

a. Adoption of the Abdomen Computed Tomography (CT)—Use of Contrast Material Measure Beginning With the CY 2024 Reporting Period

(1) Background

A CT study performed with and without contrast increases the radiation dose to patients,[661] exposing them to the potential harmful side effects of the contrast material itself[662] and it is often unnecessary.[663] In the past, reports showed deviations from clinically appropriate American College of Radiology contrast practices for abdominal/pelvic CTs nationally.[664] A 2020 study using CMS Care Compare data determined that hospitals are now conducting fewer duplicate abdomen CTs (that is, less often performing CTs twice, once with and once without contrast). These improvements are more pronounced among hospitals that formerly conducted the most duplicate abdomen CTs. The reduction in duplicate abdomen CTs observed in the 2020 study may indicate that the Abdomen Computed Tomography (CT)—Use of Contrast Material (Abdomen CT) measure has been effective in identifying performance gaps among some hospitals. Thus, collecting data on this measure may have been effective in reducing duplicate abdomen CTs and lowering related patient risks.[665] However, the same 2020 study found that duplicate abdomen CTs continue to occur.

As discussed in the CY 2024 OPPS/ASC proposed rule (88 FR 49832 through 49834), we believe that the Abdomen CT measure is relevant for REH quality reporting. Although analysis of Care Compare data indicate the practice of duplicate scans continues among hospitals both large and small, and in both rural and urban settings, rural hospitals during the study period accounted for nearly half of those cases.[666] We note that this measure is also part of the Hospital OQR Program's measure set (adopted in the CY 2009 OPPS/ASC final rule (73 FR 68766)).

(2) Measure Overview

This measure provides the percentage of CT abdomen and abdominopelvic studies performed with and without contrast out of all CT abdomen studies performed (those without contrast, those with contrast, and those with both).

Section 1890A(a)(2) of the Act outlines the pre-rulemaking process established under section 1890A of the Act, which requires the Secretary to make available to the public by December 1 of each year a list of quality and efficiency measures under consideration. The Abdomen CT measure was on the 2022 Measures Under Consideration (MUC) list,[667] and the Measure Applications Partnership (MAP) Hospital Workgroup provided conditional support for this measure to be included in rulemaking for the REHQR Program. The MAP provides an annual review of the MUC list, and presents CMS with its recommendations in its Final Recommendations.[668] In its February 1, 2023 Final Recommendations, the MAP noted that the measure addresses a critical priority of patient safety in rural hospitals for the REHQR Program.[669] In the Final Recommendations, the MAP noted that the Health Equity Advisory Group expressed the importance of the measure and its potential to advance health equity, and the Rural Health Advisory Group discussed the measure in detail and cited no concerns with regard to rural health. The MAP conditionally supported the measure for rulemaking, pending testing indicating the measure is reliable and valid, and receiving CBE endorsement.[670]

Although section 1861(kkk)(7)(C)(i) of the Act requires that measures specified by the Secretary for use in the REHQR Program be endorsed by the entity with a contract under section 1890(a) of the Act, section 1861(kkk)(7)(C)(ii) of the Act states that in the case of a specified area or medical topic determined appropriate by the Secretary for which a feasible and practical measure has not been endorsed by the entity with a contract under section 1890(a) of the Act, the Secretary may specify a measure that is not so endorsed as long as due consideration is given to measures that have been endorsed or adopted by a consensus organization identified by the Secretary. The Abdomen CT measure is not CBE endorsed and we were unable to identify any other CBE-endorsed measures on this topic; therefore, we believe the exception in section 1861(kkk)(7)(C)(ii) of the Act applies for this measure. Also, we believe the measure has received sufficient support from consensus organizations, given the conditional support for the measure by the MAP Hospital Workgroup,[671] favorable comments received by the Health Equity Advisory Group,[672] and lack of objection by the Rural Health Advisory Group.[673]

We proposed to adopt the Abdomen CT measure into the REHQR Program measure set beginning with the CY 2024 reporting period. By addressing the critical priority area of patient safety in rural hospitals, collecting data on this measure seeks to ensure that CT abdomen imaging in rural communities adheres to evidence-based clinical guidelines. Inclusion of this measure aligns with the CMS National Quality Strategy goals of embedding quality into

[661] Sahbaee, P, et al. (2017). The Effect of Contrast Material on Radiation Dose at CT: Part II. A Systematic Evaluation across 58 Patient Models. Radiology, 283(3), 749–757. *https://doi.org/10.1148/radiol.2017152852.*

[662] An, J, et al. (2019). Differences in Adverse Reactions Among Iodinated Contrast Media: Analysis of the KAERS Database. The Journal of Allergy and Clinical Immunology: In Practice, 7(7), 2205–2211. *https://www.sciencedirect.com/science/article/abs/pii/S2213219819302570.*

[663] Hwang, IK, Lee, YS, Kim, J, Lee, YJ, Park, JH, Hwang (2015). Do we really need additional contrast-enhanced abdominal computed tomography for differential diagnosis in triage of middle-aged subjects with suspected biliary pain. *Medicine,* 94(7):e546. doi: 10.1097/MD.0000000000000546.

[664] Broder JS, Hamedani AG, Liu SW, Emerman CL (2013). Emergency department contrast practices for abdominal/pelvic computed tomography—a national survey and comparison with the American College of Radiology Appropriateness Criteria(®). *J Emerg Med,* 44(2): 423–433. Available at: *https://doi.org/10.1016/j.jemermed.2012.08.027.* Last accessed February 28, 2023.

[665] Davis, M, McKiernan, C, Lama, S, Parzynski, C, Bruetman, C, & Venkatesh, A (July 2020). Trends in publicly reported quality measures of hospital imaging efficiency, 2011–2018. *American Journal of Roentology* 215: 153–158. Available at *https://www.ajronline.org/doi/pdf/10.2214/AJR.19.21993.* Last accessed April 3, 2023.

[666] Ibid.

[667] Centers for Medicare & Medicaid Services (CMS). 2022 Measures Under Consideration Spreadsheet. Available at: *https://mmshub.cms.gov/measure-lifecycle/measure-implementation/pre-rulemaking/lists-and-reports.* Last accessed March 13, 2023.

[668] Interested parties convened by the consensus-based entity will provide input and recommendations on the Measures under Consideration (MUC) list as part of the pre-rulemaking process required by section 1890A of the Act. We refer readers to *https://p4qm.org/PRMR-MSR* for more information.

[669] Centers for Medicare & Medicaid Services (CMS). *2022–2023 MAP Final Recommendations.* Available at: *https://mmshub.cms.gov/measure-lifecycle/measure-implementation/pre-rulemaking/lists-and-reports.* Last accessed April 13, 2023.

[670] Ibid.

[671] CMS, 2022 Measures Under Consideration Spreadsheet.

[672] CMS, 2022–2023 MAP Final Recommendations.

[673] Ibid.

the care journey, as well as the goal of promoting safety,[674] and is aligned with the priorities we identified for our Meaningful Measures 2.0 initiative, including using only high-value quality measures that impact key quality domains and aligning measures across our programs.[675]

(3) Data Sources

This measure addresses excessive radiation exposure from improper outpatient imaging procedures in Medicare beneficiaries. It would be calculated using Medicare FFS final action claims and enrollment data for hospital services paid through the OPPS for abdomen CT studies performed in the REH setting. Data from the hospital outpatient file is used to determine beneficiary inclusion (for example, in the case of REHs, a CT abdomen study performed at an REH) and exclusion (that is, diagnoses of adrenal mass, hematuria, infections of the kidney, jaundice, liver lesion (mass or neoplasm), malignant neoplasm of the bladder, malignant neoplasm of the pancreas, diseases of the urinary system, pancreatic disorders, non-traumatic aortic disease, and unspecified disorders of the kidney or ureter).[676]

(4) Measure Calculation

This measure calculates the percentage of CT abdomen and abdominopelvic studies that are performed with and without contrast out of all CT abdomen studies performed (those with contrast, those without contrast, and those with both). The measure would be calculated based on a 12-month window of claims data. From this patient cohort, the numerator contains patients who had a combined CT abdomen study (that is, a CT abdomen study without contrast followed by a CT abdomen study with contrast, documented using the CT Abdomen With and Without Contrast CPT code). For this measure, lower scores indicate less usage of CT scanning as scans with and without contrast are typically not medically necessary, which means a high-performing hospital reports a value nearer to zero, whereas facilities that may be performing too many combined CT abdomen studies score closer to 100 percent.[677]

(5) Cohort

This measure would apply to Medicare beneficiaries enrolled in original, Medicare FFS who underwent an abdomen or abdominopelvic CT study with or without contrast performed at an REH. This measure does not include Medicare managed care beneficiaries, non-Medicare patients, or beneficiaries who were admitted to the hospital as inpatients. A beneficiary can be included in the measure's initial patient population multiple times because each abdomen or abdominopelvic CT (without contrast, with contrast, or both with and without contrast) performed at an REH during the data collection period is counted once in the measure's denominator.

This claims-based imaging measure is not risk-adjusted; instead, Medicare FFS beneficiaries who have a clinical diagnosis of one or more conditions for which imaging with and without contrast is considered appropriate are excluded from the measure.[678] Thus, this measure does not include beneficiaries with the following conditions: adrenal mass, hematuria, infections of the kidney, jaundice, liver lesion (mass or neoplasm), malignant neoplasm of the bladder, malignant neoplasm of the pancreas, diseases of the urinary system, pancreatic disorders, non-traumatic aortic disease, and unspecified disorders of the kidney or ureter.[679]

We invited public comment on the proposal.

Comment: Several commenters supported adoption of the Abdomen CT—Use of Contrast Material measure.

Response: We thank commenters for their support.

Comment: Some commenters expressed concern regarding measure specifications for the Abdomen CT measure, including that it uses denominator exclusions as opposed to risk-adjustment and that it does not account for clinical reasons that providers may perform duplicate abdomen CTs.

Response: We recognize that using risk-adjustment as opposed to denominator exclusions would also account for the possibility that patients with some conditions are more likely to receive clinically appropriate duplicate abdominal CT scans. However, we believe that reporting the measure with the same specifications as adopted in the Hospital OQR Program, which underwent an extensive development process prior to implementation in the Hospital OQR Program, including soliciting broad interested party input and which many REH-eligible hospitals have historically reported on, will ensure alignment and comparability across programs, and preserve provider and consumer measure familiarity.

Comment: Several commenters expressed concern that this measure has not been endorsed by the CBE for this setting and that it is insufficiently tested to show that there is a performance gap and that the measure is valid and reliable. One of these commenters, however, also observed that rural hospitals do appear to be outliers on the Abdomen CT measure and therefore the measure may be appropriate for the REHQR Program if adequately tested.

Response: Under section 1861(kkk)(7)(C)(i) of the Act, a measure selected for use in the REHQR Program must have been endorsed or adopted by the entity with a contract under section 1890(a) of the Act, also known as the CBE. However, section 1861(kkk)(7)(C)(ii) states that in the case of a specified area or medical topic determined appropriate by the Secretary for which a feasible and practical measure has not been endorsed by the CBE, the Secretary may specify a measure that is not so endorsed as long as due consideration is given to measures that have been endorsed or adopted by a consensus organization identified by the Secretary. Further, while we prefer to adopt CBE-endorsed measures, it may not be feasible or practicable, such as when a CBE-endorsed measure does not exist. We reviewed measures endorsed by consensus organizations and were unable to identify any other measures on this topic endorsed or adopted by a consensus organization, and therefore, we believe the exception in section 1861(kkk)(7)(C)(ii) of the Act applies.

As we noted in the CY 2024 OPPS/ASC proposed rule (88 FR 49833), this measure has been used in Hospital OQR Program for many years involving many

[674] CMS (2023). What is the CMS National Quality Strategy? Available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Value-Based-Programs/CMS-Quality-Strategy.* Last accessed April 13, 2023.

[675] CMS (2022), Meaningful Measures 2.0: Moving from Measures Reduction to Modernization. Available at *https://www.cms.gov/medicare/meaningful-measures-framework/meaningful-measures-20-moving-measure-reduction-modernization.* Last accessed April 13, 2023.

[676] YNHHSC/CORE and The Lewin Group, 2021. *Abdomen Computed Tomography (CT)—Use of Contrast Material (OP–10): 2021 Annual Reevaluation Report.* Available at: *https://qualitynet.cms.gov/files/607ee75eaba8620022335d7e?filename=OP=10_2021_ReevalReport.pdf.* Last accessed March 13, 2023.

[677] Ibid.

[678] American College of Radiology. ACR Appropriateness Criteria. Available at: *https://www.acr.org/Clinical-Resources/ACR-Appropriateness-Criteria.* Last accessed April 4, 2023.

[679] Centers for Medicare & Medicaid Services Measures Inventory Tool (CMIT). Abdomen Computed Tomography (CT)—Use of Contrast Material. Available at *https://cmit.cms.gov/cmit/#/MeasureView?variantId=1842&sectionNumber=1.* Last accessed April 3, 2023.

participating facilities, some of which are eligible to convert to REHs. Through both the MAP and rulemaking processes regarding this measure, we believe it has received sufficient support from consensus organizations. We also believe that, because facilities eligible to convert to REH status have been reporting this measure under the Hospital OQR Program, these facilities are meaningfully similar to HOPDs and therefore the testing that was completed for the HOPD setting is applicable to this setting.

In addition, we note that this measure underwent an extensive development process prior to adoption in the Hospital OQR Program which included a development process involving testing for reliability and validity. We believe that, because facilities eligible to convert to REH status have been reporting this measure under the Hospital OQR Program, these facilities are meaningfully similar to HOPDs and therefore the testing is applicable to this setting.

In response to commenters' concerns regarding demonstrating a performance gap, we refer readers to the CY 2024 OPPS/ASC proposed rule (88 FR 49832) where we noted that a 2020 study using CMS Care Compare data found that duplicate abdomen CTs continue to occur. Although the study found that the practice of duplicate scans continues with some hospitals large and small in both rural and urban settings, rural hospitals during the study period accounted for nearly half of those cases.[680]

Comment: One commenter expressed concern that duplicate abdominal CT with and without contrast is already performed at a very low frequency and therefore this measure would not provide useful data.

Response: While we acknowledge that identifiable adverse events related to conducting CT with and without contrast are rare, we believe this measure is important, impactful, and clinically relevant, and can help compare between care settings. Conducting duplicate CT scans both with and without contrast increases the radiation dose to patients, and the potential harmful side effects associated with increased exposure to radiation are well-documented and understood. We also note that duplicative procedures represent deviations from clinically appropriate American College of Radiology contrast practices for abdominal/pelvic CTs.

In addition, as depicted in Table R–B1 in section XVI.B.1 of this final rule with comment period, a significant majority of CAHs (77.9 percent) and rural subsection (d) hospitals with 50 or fewer beds (75.5 percent) reported on this measure in sufficient numbers to be publicly reported. Furthermore, the use of this measure in the Hospital OQR Program has been correlated with reductions in the frequency of duplicate abdominal CTs (that is, the use of this measure encourages providers to reduce the frequency of performing CTs twice, once with and once without contrast), indicating that the use of this measure has been effective in improving the safety of clinical and diagnostic medicine.[681] Moreover, as we noted in the CY 2024 OPPS/ASC proposed rule (88 FR 49832), studies have found that facilities with outlier values on this measure (that is, facilities that perform an unusually large number of duplicate abdominal CT scans) are overrepresented in rural settings.[682]

Comment: One commenter recommended that CMS evaluate how to appropriately publicly report this measure so that the public understands the measure results.

Response: We agree that providing information to help the public understand a measure's importance is necessary when publicly reporting a measure. We note that in publicly reporting this measure for the Hospital OQR Program, we include information stating that lower percentages are better and have information on Care Compare explaining the risks of ''double scans.'' We believe that this public reporting of information enables public understanding of the measure results. We intend to provide such explanatory information when publicly reporting this measure for the REHQR Program, consistent with our current approach in the Hospital OQR Program.

After consideration of the public comments we received, we are finalizing our proposal to adopt the Abdomen Computed Tomography (CT)—Use of Contrast Material Measure, beginning with the CY 2024 reporting period as proposed.

b. Adoption of the Median Time From Emergency Department (ED) Arrival to ED Departure for Discharged ED Patients Measure Beginning With the CY 2024 Reporting Period

(1) Background

Care provided in the ED will be a focus of REH services and we seek measures that assess the quality of care in this setting. Improving ED throughput times is important for alleviating overcrowding and reducing wait times.[683] Crowding has led to a number of potentially avoidable problems in EDs, including ambulance diversion, prolonged patient waiting times, and potentially poor patient outcomes due to delays, such as in the administration of medication.[684]

As discussed in the CY 2024 OPPS/ASC proposed rule (88 FR 49834), the Median Time from Emergency Department (ED) Arrival to ED Departure for Discharged ED Patients (the Median Time for Discharged ED Patients measure) was adopted for reporting in the Hospital OQR Program beginning with the CY 2013 payment determination (75 FR 72086).

(2) Measure Overview

The Median Time for Discharged ED Patients measure is a chart-abstracted measure that evaluates the time between the arrival to and departure from the ED, also known as ED throughput time. As described in the measure specifications and Measure Information Form (MIF),[685] [686] measure data are stratified for four separate calculations: (1) the Overall Rate is calculated as the overall rate; (2) the Reported Measure calculates data for all patients excluding psychiatric/mental health patients and transfer patients; (3) Psychiatric/Mental Health calculates data for psychiatric/mental health patients; and (4) Transfers calculates data for transfer patients.

Although section 1861(kkk)(7)(c)(i) of the Act requires that measures specified by the Secretary for use in CMS hospital

[680] Davis, M, McKiernan, C, Lama, S, Parzynski, C, Bruetman, C, & Venkatesh, A (July 2020). Trends in publicly reported quality measures of hospital imaging efficiency, 2011–2018. *American Journal of Roentology* 215: 153–158. Available at *https://www.ajronline.org/doi/pdf/10.2214/AJR.19.21993*. Last accessed October 17, 2023.

[681] Davis, M, McKiernan, C, Lama, S, Parzynski, C, Bruetman, C, & Venkatesh, A (July 2020). Trends in publicly reported quality measures of hospital imaging efficiency, 2011–2018. American Journal of Roentology 215: 153–158. Available at *https://www.ajronline.org/doi/pdf/10.2214/AJR.19.21993*. Last accessed Sept. 3, 2023.

[682] Ibid.

[683] Smalley, CM, Simon, EL, Meldon, SW, et al. (2020). The impact of hospital boarding on the emergency department waiting room. *JACEP Open*,1(5):1052–1059. doi: 10.1002/emp2.12100.

[684] Kelen GD, Wolfe R, D-Onofrio G, Mills AM, Diercks D, Stern SA, Wadman MC, Sokolove PE. Emergency Department Crowding: The Canary in the Health Care System. *NEJM Catalyst.* 2021; 5(2). *https://catalyst.nejm.org/doi/full/10.1056/CAT.21.0217.* Last accessed February 28, 2023.

[685] A Measure Information Form provides detail on the rationale for a measure as well as the relevant numerator statements, denominator statements and measure calculations.

[686] Hospital OQR Program ED Throughput Measures Information Form. Available at: *https://qualitynet.cms.gov/files/638e75e376962e0016ad907d?filename=1d_ED_Throughput_set_v16.0a.pdf* (p. 1–26). Last accessed February 28, 2023.

quality programs be endorsed by the entity with a contract under section 1890(a) of the Act, section 1861(kkk)(7)(C)(ii) of the Act states that in the case of a specified area or medical topic determined appropriate by the Secretary for which a feasible and practical measure has not been endorsed by the entity with a contract under section 1890(a) of the Act, the Secretary may specify a measure that is not so endorsed as long as due consideration is given to measures that have been endorsed or adopted by a consensus organization identified by the Secretary. This measure is not CBE-endorsed. We reviewed CBE-endorsed measures and were unable to identify any other CBE-endorsed measures on this topic; therefore, we believe the exception in section 1861(kkk)(7)(C)(ii) of the Act applies for this measure.

The Median Time for Discharged ED Patients measure was included in the 2022 MUC list.[687] In its February 1, 2023 Final Recommendations, the MAP stated their belief that changes in wait times may not directly influence mortality or patient outcomes and had concerns that transfer times may be delayed due to weather and transport safety issues that are out of a facility's control. The Rural Health Advisory Group expressed similar concerns regarding the impact on transport times of issues beyond a facility's control, such as weather, local facility transport modalities, and distance; but also noted that transfer time for trauma patients is especially important. The Health Equity Advisory Group, however, emphasized the importance of the measure and its potential to advance health equity. Ultimately, the MAP did not provide support for this measure for the REHQR Program.[688]

As we stated in the CY 2024 OPPS/ASC proposed rule (88 FR 49834), we recognize the concerns expressed in the MAP Final Recommendation. However, we believe that ED throughput times have significant impact on patients. Prolonged waiting times, especially the door-to-doctor time component, are associated with worse patient experience in patients discharged from the ED.[689] Studies demonstrate that higher patient satisfaction is associated with patient outcomes, including decreased mortality[690] and lower readmission rates.[691]

We acknowledge that transfer times may be delayed due to weather and transport safety issues that are out of a hospitals control. However, we believe that some factors such as building transfer relationships and process improvements can be addressed by hospitals to improve ED throughput times. Further, this information could be useful to Medicare beneficiaries and other interested parties toward assessing care provided and the care environment of a hospital. If we implement this measure, we are supporting CMS National Quality Strategy goals, including embedding quality into the care journey (for example, by addressing quality throughout, subsequently addressing the patient experience); promoting safety (for example, by minimizing associated negative patient outcomes, such as delayed administration of treatment); and increasing alignment (given that this measure is used in other quality programs).[692] Alignment of measures across CMS Federal programs is also an objective of the Meaningful Measures 2.0 initiative.[693]

This measure also promotes the Meaningful Measures goal of driving outcome improvement through public reporting, given that CMS predicts that data for this measure will be reported in sufficient numbers to permit public reporting (see Table R–B1 in section XVI.B.1 of this final rule with comment period). Care Compare data current to January 2023 show that many CAHs and subsection (d) hospitals with fewer than 50 beds reported sufficient data for this measure under the Hospital OQR Program to be publicly reported for all of these strata, indicating that hospitals eligible to convert to REH status would be able to report data for this measure to a level sufficient for public reporting. Discussion of publicly reporting these data can be found in section XVI.B.8.c of this final rule with comment period. Thus, in the CY 2024 OPPS/ASC proposed rule (88 FR 49834 and 49835), we proposed to adopt this measure in the REHQR Program beginning with the CY 2024 reporting period.

(3) Data Sources

The measure would be calculated using chart-abstracted data on a rolling quarterly basis and would be publicly reported in aggregate for one calendar year. Sources of the relevant data may include claims forms, electronic health care data, electronic health records (EHRs), or paper records. Data elements necessary for the calculation of the measure include arrival time, discharge code, Evaluation and Management (E/M) code, ED departure date, ED departure time, ICD–10–CM principal diagnosis code, and outpatient encounter date.

(4) Measure Calculation

The measure calculates the median time (in minutes) from ED arrival to time of departure from the ED for discharged patients. Reducing the time patients remain in the ED can improve access to treatment and increase quality of care.[694] [695] Improvement is noted as a decrease in the median value. The included population is any ED patient who completes an ED discharge process. This process measure is not risk-adjusted or risk-stratified.[696] However, the measure is stratified by certain subgroups of patients, as described in the next section.

(5) Cohort

The Median Time for Discharged ED Patients measure is calculated in stratified subsections for certain types of patients: (1) All Patients Excluding Psychiatric/Mental Health and

[687] Centers for Medicare & Medicaid Services. *2022 Measures Under Consideration Spreadsheet.* Available at: *https://mmshub.cms.gov/measure-lifecycle/measure-implementation/pre-rulemaking/lists-and-reports.* Last accessed March 13, 2023.

[688] Centers for Medicare & Medicaid Services. *2022–2023 MAP Final Recommendations.* Available at: *https://mmshub.cms.gov/measure-lifecycle/measure-implementation/pre-rulemaking/lists-and-reports.* Last accessed March 13, 2023.

[689] Nyce, A, Gandhi, S, Freeze, B, Bosire, J, Ricca, T, Kupersmith, E, Mazzarelli, A, Rachoin, J-S. Association of Emergency Department Waiting Times With Patient Experience in Admitted and Discharged Patients. 2021. J Pat Exp 8:1–7. *https://doi.org/10.1177/23743735211011404.*

[690] Glickman SW, Boulding W, Manary M, Staelin R, Roe MT, Wolosin RJ, et al. Patient satisfaction and its relationship with clinical quality and inpatient mortality in acute myocardial infarction. *Circ Cardiovasc Qual Outcomes.* 2010; 3:188–95. Available at *https://www.ahajournals.org/doi/10.1161/CIRCOUTCOMES.109.900597?url_ver=Z39.88-2003&rfr_id=ori:rid:crossref.org&rfr_dat=cr_pub%20%200pubmed.*

[691] Boulding W, Glickman SW, Manary MP, Schulman KA, Staelin R. Relationship between patient satisfaction with inpatient care and hospital readmission within 30 days. *Am J Manag Care.* 2011;17:41–8. Available at *https://www.ajmc.com/view/ajmc_11jan_boulding_41to48.*

[692] CMS (2023). What is the CMS National Quality Strategy? Available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Value-Based-Programs/CMS-Quality-Strategy.* Last accessed April 13, 2023.

[693] CMS (2022), Meaningful Measures 2.0: Moving from Measures Reduction to Modernization. Available at *https://www.cms.gov/medicare/meaningful-measures-framework/meaningful-measures-20-moving-measure-reduction-modernization.* Last accessed April 13, 2023.

[694] Smalley, CM, Simon, EL, Meldon, SW, et al. (2020). The impact of hospital boarding on the emergency department waiting room. *JACEP Open,*1(5):1052–1059. doi: 10.1002/emp2.12100.

[695] Kelen GD, Wolfe R, D-Onofrio G, Mills AM, Diercks D, Stern SA, Wadman MC, Sokolove PE. Emergency Department Crowding: The Canary in the Health Care System. *NEJM Catalyst.* 2021; 5(2). *https://catalyst.nejm.org/doi/full/10.1056/CAT.21.0217.*

[696] CMIT. Median time from ED Arrival to ED Departure for Discharged ED patients. Available at *https://cmit.cms.gov/cmit/#/MeasureView?variantId=695&sectionNumber=1.* Last accessed April 4, 2023.

Transferred Patients; (2) Psychiatric/Mental Health Patients; (3) Transfer Patients; and (4) All Patients. All strata of the measure exclude patients who expired in the ED, left against medical advice, or whose discharge was not documented or unable to be determined.[697]

We invited public comment on the proposal.

Comment: Several commenters supported adoption of the ED throughput measure. One of these commenters stated that measuring ED throughput would improve patient outcomes. Another commenter stated that this measure will track whether REHs have the capacity and staff to treat their patients appropriately.

Response: We thank commenters for their support.

Comment: Several commenters did not support the ED throughput measure because this measure does not account for factors beyond the REH's control.

Response: We understand the commenters' concern that there are many factors outside of an REH's control that could affect ED throughput; however, we believe that many hospitals face such concerns and that that timely care is a critical aspect of quality of care, directly impacting patient outcomes, particularly for an ED episode of care. Therefore, the public reporting of these data can help patients and their caregivers identify which facilities are performing better than others despite potential challenges, and drive quality improvement efforts. Additionally, we believe that having a consistent ED throughput measure across REHs and HOPDs will allow consumers to compare across programs, especially for vulnerable populations in need of transfer to more appropriate care settings.

Comment: Some commenters did not support this measure because of concerns that REHs will have low patient volumes and that including four strata within the measure may lead to statistically unreliable rates.

Response: We note the commenters' concern applies to all measures and providers, and that CMS does not report measures publicly unless it achieves sufficient case volumes to allow for public reporting of the collected data. We further note that, as discussed in the CY 2024 OPPS/ASC proposed rule (88 FR 49827 through 49829), many CAHs and small, rural subsection (d) hospitals—hospitals which are eligible to convert to REH status—had sufficient measure data to be publicly reported for this measure, including by strata. We acknowledge that having four strata will create lower volumes within each stratum but reiterate that we will only publicly report measure results with sufficient case volumes, both to protect patient privacy and to ensure that data are statistically reliable. As shown in Table 146 in section XVI.B.5, many of the 16 hospitals that have converted to REH status as of October 13, 2023, had data in sufficient volumes to be publishable for all four strata.[698]

Comment: Several commenters expressed the belief that this measure does not represent the quality of care provided by REHs. Some of these commenters observed that measure results are not directly tied to patient outcomes. One commenter stated that the measure does not have appropriate risk-adjustment to reflect quality of care. Another commenter stated that while this measure is appropriate in crowded urban EDs, it is not clinically appropriate in rural EDs.

Response: We appreciate commenters' feedback. Regarding commenters' concerns regarding the significance of this measure within the setting of REHs, we note that per section 1861(kkk)(1), ED services are required REH services and are thus a focus of care provided at REHs. Furthermore, as discussed in the CY 2024 OPPS/ASC proposed rule (88 FR 49834), we believe that ED wait times have significant impact on patients. Prolonged waiting times are associated with worse patient experience in patients discharged from the ED.[699] Studies demonstrate that higher patient satisfaction is associated with improved patient outcomes, including decreased mortality[700] and lower readmission rates.[701] Regarding urban versus rural difference, we note that small rural hospitals including the subset that have converted to REH status tend to have times on par or lower (better performance) than large urban hospitals. We therefore believe ED measures are of paramount importance to the REHQR Program measure set.

We recognize that using risk-adjustment would account for potentially higher ED throughput times for patients who require more extensive ED services. However, as specified, the measure provides metrics for the case mix each hospital experiences, thus providing Medicare beneficiaries and other interested parties valuable information on hospital performance. In addition, the measure is stratified for four separate calculations: (1) the Overall Rate is calculated as the overall rate; (2) the Reported Measure calculates data for all patients excluding psychiatric/mental health patients and transfer patients; (3) Psychiatric/Mental Health calculates data for psychiatric/mental health patients; and (4) Transfers calculates data for transfer patients. This stratification accounts for significant variables affecting ED throughput time.

Comment: One commenter did not support this measure due to the high reporting burden. Another commenter stated that because reporting this measure under the Hospital OQR Program is currently voluntary, only hospitals with sufficient resources report this measure and under-resourced hospitals will be disadvantaged if reporting is required.

Response: We thank the commenter for their feedback. Regarding the comment about the voluntary nature of reporting this measure under the Hospital OQR Program, we wish to clarify that under the Hospital OQR Program, reporting of this measure by subsection (d) hospitals, including small, rural subsection (d) hospitals, is mandatory in order to avoid a payment penalty, whereas data submission and public reporting of this measure are voluntary for CAHs. We also wish to clarify that under the REHQR Program, data submission and public reporting of this measure, as with all REHQR Program measures, would be mandatory. We further note that many subsection (d) hospitals and CAHs established on or before December 27, 2020, that are eligible for REH conversion are currently reporting outpatient quality data under the Hospital OQR Program and have publicly available data (87 FR 72137).

While we understand that reporting this measure is associated with some burden, as discussed in section XXIV.D of this final rule with comment period,

[697] QualityNet. Hospital Outpatient Specifications Manuals. Available at: *https://qualitynet.cms.gov/outpatient/specifications-manuals.* Last accessed April 5, 2023.

[698] The data provided in Table 146, discussed in section XVI.B.5 are from the Medicare Provider Enrollment, Chain, and Ownership System (PECOS) as of October 13, 2023.

[699] Nyce, A, Gandhi, S, Freeze, B, Bosire, J, Ricca, T, Kupersmith, E, Mazzarelli, A, Rachoin, J-S. Association of Emergency Department Waiting Times With Patient Experience in Admitted and Discharged Patients. 2021. J Pat Exp 8:1–7. *https://doi.org/10.1177/23743735211011404.*

[700] Glickman SW, Boulding W, Manary M, Staelin R, Roe MT, Wolosin RJ. et al. Patient satisfaction and its relationship with clinical quality and inpatient mortality in acute myocardial infarction. *Circ Cardiovasc Qual Outcomes.* 2010; 3:188–95. Available at *https://www.ahajournals.org/doi/10.1161/CIRCOUTCOMES.109.900597?url_ver=Z39.88-2003&rfr_id=ori:rid:crossref.org&rfr_dat=cr_pub%20%200pubmed.*

[701] Boulding W, Glickman SW, Manary MP, Schulman KA, Staelin R. Relationship between patient satisfaction with inpatient care and hospital readmission within 30 days. *Am J Manag Care.* 2011;17:41–8. Available at *https://www.ajmc.com/view/ajmc_11jan_boulding_41to48.*

we believe the benefits outweigh the burden, as ED services are statutorily mandated to be provided by REHs; as a focus of care provided at REHs, we believe ED measures are of paramount importance to the REHQR Program measure set. In addition, as depicted in Table R–B1 in section XVI.B.1 of this final rule with comment period, a significant majority of CAHs (82.6 percent) and rural subsection (d) hospitals with 50 or fewer beds (81.5 percent) reported on the reported measure stratum of this measure in sufficient numbers to be publicly reported, indicating the measure is not overly burdensome.

Comment: One commenter did not support this measure because of concerns that this measure may have unintentional consequences such as leading to premature ED discharge for the most vulnerable patients.

Response: We appreciate the commenter's concern; however, we respectfully disagree with the commenter that reporting this measure would incentivize REHs to prematurely discharge patients, particularly their most vulnerable patients, from the ED. Rather, we remain confident that REHs will continue to provide quality care and submit data as part of their commitment to the patient experience and ongoing quality improvement efforts, as evidenced by the fact that many hospitals which are eligible to convert to REH status have been reporting on this measure through the Hospital OQR Program for many years.

Comment: One commenter stated that this measure is unnecessary because REHs cannot exceed an annual average length of stay of 24 hours per patient, which incentivizes reducing ED wait times.

Response: Given the variation in wait times between zero to 24 hours, we believe patients will be interested in knowing the ED throughput times, even if they average less than 24 hours. Moreover, we believe quality reporting is an important for transparency as well as for driving improvement in care separate from any statutory requirement related to an annual mean patient length of stay.

Comment: Several commenters recommended alternative measures that they believe would better reflect the quality of care provided by REHs. One commenter suggested measuring time from ED arrival to being seen by a clinician instead of time from ED arrival to ED departure for discharged patients stratified by patients seen during standard working hours versus nights or weekends. Another commenter recommended the Medicare Beneficiary Quality Improvement Project (MBQIP) Emergency Department Transfer Communication measure. Finally, one commenter noted that CMS cited studies linking patient satisfaction to improved patient outcomes and stated that the ED CAHPS measure [702] would be a better indicator of patient satisfaction.

Response: We thank commenters for their feedback and will take these recommendations into future consideration as we continue to evaluate all elements of the REHQR Program to ensure a relevant and meaningful measure set.

After consideration of the public comments we received, we are finalizing our proposal to adopt the Median Time from ED Arrival to ED Departure for Discharged ED Patients measure, beginning with the CY 2024 reporting period as proposed.

c. Adoption of the Facility 7-Day Risk-Standardized Hospital Visit Rate After Outpatient Colonoscopy Measure Beginning With the CY 2024 Reporting Period

(1) Background

Colonoscopies are one of the most frequently performed procedures in the outpatient setting in the United States,[703] with more than 16 million procedures performed each year.[704] Colonoscopies are associated with a range of well-described and potentially preventable adverse events that can lead to hospital visits, repeat procedures, or surgical intervention for treatment, including colonic perforation, gastrointestinal (GI) bleeding, and abdominal pain.[705] While hospital visits are generally unexpected after an outpatient colonoscopy, the literature indicates that the majority of such visits occurring later than seven days post-procedure are more likely to be unrelated to the procedure,[706] and may be complicated by patient comorbidities and high risk factors.[707]

As noted in Table R–B1 with Hospital OQR Program data current to January 2023, the average rate of reported unplanned hospital visits per 1,000 colonoscopies at CAHs and rural subsection (d) hospitals eligible for REH conversion are 14.3 (1.43 percent) and 14.4 (1.44 percent), respectively. These average rates are in line with those of small, urban subsection (d) hospitals, and larger, rural hospitals subsection (d) with 50 or more beds (that is, with categories of subsection (d) hospitals that are not eligible for REH conversion). Hospitals in these categories that are in the top 10th percentile in terms of numbers of cases (that is, unplanned hospital visits within 7 days of an outpatient colonoscopy) reported, however, do appear to perform differently. In this percentile, hospitals eligible for REH conversion do not perform as well as those that are not eligible for REH conversion. REH-eligible hospitals with these larger caseloads have a higher rate of unplanned hospital visits per 1,000 colonoscopies than non-REH eligible hospitals.

The Facility 7-Day Risk-Standardized Hospital Visit Rate After Outpatient Colonoscopy (the 7-Day Hospital Visit Rate After Outpatient Colonoscopy) measure was adopted for reporting in the Hospital OQR Program, first with a dry run (that is, confidential reports containing measure results were made available for hospitals to review, provide feedback, and become familiar with the measure methodology in advance of public reporting and impact on payment determinations), and then fully implemented beginning with the CY 2018 payment determination (79 FR 66948 through 66955).

(2) Measure Overview

The 7-Day Hospital Visit Rate After Outpatient Colonoscopy measure was on the 2022 MUC list.[708] In its February 1, 2023 Final Recommendations, the MAP considered and supported it for

[702] The Emergency Department Consumer Assessment of Healthcare Providers and Systems (ED CAHPS) is a survey designed to measure patients' opinions of the care they receive in the ED.

[703] Definitive Healthcare. Top 10 Outpatient Procedures at Surgery Centers and Hospitals. Available at: *https://www.definitivehc.com/blog/top-10-outpatient-procedures-at-ascs-and-hospitals#:~:text=Definitive%20Healthcare%20data%20shows%20that,procedures%20at%20ASCs%20by%20volume.* Last accessed March 12, 2023.

[704] I Data Research. An Astounding 16.6 Million Colonoscopies are Performed Annually in The United States. (*https://idataresearch.com/an-astounding-19-million-colonoscopies-are-performed-annually-in-the-united-states/* [sic]). Accessed February 28, 2023.

[705] I. Ranasinghe, C.S. Parzynski, R. Searfoss, et al. *Differences in colonoscopy quality among facilities: development of a post-colonoscopy risk-standardized rate of unplanned hospital visits.* Gastroenterology, 150 (2016), pp. 103–113 Available at: *https://www.gastrojournal.org/action/showPdf?pii=S0016-5085%2815%2901353-0.* Last accessed March 12, 2023.

[706] L.B. Grossberg, A. Vodonos, K. Papamichael, et al. *Predictors of post-colonoscopy emergency department use.* Gastrointest Endosc, 87 (2018), pp. 517–525. Available at: *https://www.sciencedirect.com/science/article/pii/S0016510717322010?viewFullText=true#sec4.* Last accessed March 12, 2023.

[707] Ibid.

[708] Centers for Medicare & Medicaid Services. *2022 Measures Under Consideration Spreadsheet.* Available at: *https://mmshub.cms.gov/measure-lifecycle/measure-implementation/pre-rulemaking/lists-and-reports.* Last accessed March 13, 2023.

rulemaking for the REHQR Program given that a previous version of this measure specified for colonoscopies performed in ambulatory surgical centers (ASCs) and HOPDs received endorsement from the CBE (CBE #2539) in 2014 and 2020, and that this measure is currently in use in the ASCQR and Hospital OQR Programs.[709]

As evidenced in Table R–B1, many CAHs and small, rural subsection (d) hospitals—hospitals which are eligible to convert to REH status—performed a sufficient number of colonoscopies and had sufficient measure data for this measure to be publicly reported on the Care Compare website. Using data current to January 2023 for the Hospital OQR Program, out of those eligible to report data, 65.5 percent (131) of small, rural subsection (d) hospitals and 44.7 percent (609) of CAHs eligible to convert to REHs reported for this measure.

We believe this could be an important measure for those REHs that elect to provide outpatient services and for patients seeking information regarding complications following this procedure. Inclusion of this measure in the REHQR Program would also promote goals of the CMS National Quality Strategy, including embedding quality into the care journey; advancing health equity within and across settings; and increasing alignment of performance metrics, programs, policy, and payment across CMS.[710] Inclusion would also advance goals of the Meaningful Measures 2.0 initiative, including by empowering consumers to make good health care choices by providing public transparency; and by leveraging quality measures to promote health equity and close gaps in care.[711] Therefore, in the CY 2024 OPPS/ASC proposed rule (88 FR 49835 through 49837), we proposed to include the 7-Day Hospital Visit Rate After Outpatient Colonoscopy measure in the REHQR Program beginning with the CY 2024 reporting period.

(3) Data Sources

This outcome measure is calculated using Medicare FFS claims and enrollment data, estimating a facility-level rate of risk-standardized, all-cause, unplanned hospital visits within 7 days of an outpatient colonoscopy among Medicare FFS patients aged 65 years and older.[712] In alignment with the reporting period for this measure as used in the Hospital OQR Program, we proposed the initial reporting period to be a three-year period beginning with patient encounters from January 1, 2024 through December 31, 2026 with annual updates on a rolling basis.[713]

(4) Measure Calculation

The measure defines the outcome as any (one or more) unplanned hospital visits within 7 days of an outpatient colonoscopy procedure.[714] For this measure, a hospital visit includes any ED visit, observation stay, or unplanned inpatient admission to any short-term, acute care facility.[715] [716] The measure score is the ratio of predicted hospital visits (numerator) over the expected hospital visits (denominator) multiplied by the national observed rate. The numerator is the number of predicted (meaning adjusted actual) hospital visits, which is the number of unplanned hospital visits the facility is predicted to have within 7 days of colonoscopy, and it accounts for the observed unplanned hospital visit rate, the number of colonoscopies performed at the facility, and the facility's case mix. The denominator is the number of expected hospital visits, which is the number of unplanned hospital visits the facility is expected to have based on the facility's case mix. It is the sum of all patients' expected probabilities of a hospital visit, given their risk factors and the risk of readmission at an average facility. The national observed rate is the national unadjusted number of patients who had a hospital visit post-colonoscopy among all patients who had a colonoscopy.[717] Additional methodology details and information obtained from public comments for measure development are available at: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html* under ''Hospital Outpatient Colonoscopy.''

We note that the measure calculation is comparable to the Hospital OQR Program version of the measure, as set out in the CY 2015 OPPS/ASC final rule (79 FR 66948 through 66955).

(5) Cohort

The measure denominator includes Medicare FFS patients with paid, final action claims for typical colonoscopies. The denominator excludes patients undergoing concomitant high-risk upper GI endoscopy because this is a more extensive procedure that places these patients at a higher risk for hospital visits than patients undergoing a typical colonoscopy, as well as patients with a history of inflammatory bowel disease (IBD) or diverticulitis in the year preceding the colonoscopy because we likely could not fully characterize and adjust for their pre-procedure risk of needing a post-procedure hospital visit or identify whether these admissions are planned or unplanned. The measure also excludes procedures for patients who lack continuous enrollment in Medicare FFS Parts A and B in the month after the procedure to ensure all patients have complete data available for outcome assessment. For further discussion of the cohort for the 7-Day Hospital Visit Rate After Outpatient Colonoscopy measure, please see ''2022 Measure Updates and Specifications Report: Hospital Outpatient Quality Reporting Program,'' available at: *https://qualitynet.cms.gov/outpatient/measures/surgery/methodology.*

(6) Risk Adjustment

The statistical risk-adjustment model includes 15 clinically relevant risk-adjustment variables that are strongly associated with risk of hospital visits within seven days following colonoscopy. Additional methodology details and information for measure

[709] Centers for Medicare & Medicaid Services. *2022–2023 MAP Final Recommendations.* Available at: *https://mmshub.cms.gov/measure-lifecycle/measure-implementation/pre-rulemaking/lists-and-reports.* Last accessed March 13, 2023.

[710] CMS (2023). What is the CMS National Quality Strategy? Available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Value-Based-Programs/CMS-Quality-Strategy.* Last accessed April 13, 2023.

[711] CMS (2022), Meaningful Measures 2.0: Moving from Measures Reduction to Modernization. Available at *https://www.cms.gov/medicare/meaningful-measures-framework/meaningful-measures-20-moving-measure-reduction-modernization.* Last accessed April 13, 2023.

[712] CMIT. Facility 7-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy. Available at *https://cmit.cms.gov/cmit/#/MeasureView?variantId=1354&sectionNumber=1.* Last accessed February 28, 2023.

[713] CMS, Hospital Outpatient Specifications Manuals—Measure Information Form, 1.6 Outcome Measures, OP–32: Facility 7-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy. Available at *https://qualitynet.cms.gov/files/638e788ffb845c00175c7aaf?filename=1u_OP32MIF_v16.0a.pdf.* Last accessed February 28, 2023.

[714] 2022 Measure Updates and Specifications Report: Hospital Outpatient Quality Reporting Program. available at: *https://qualitynet.cms.gov/outpatient/measures/surgery/methodology.* Last accessed May 2, 2023.

[715] Ibid.

[716] CMS, Frequently Asked Questions. Available at: *https://qualitynet.cms.gov/outpatient/measures/colonoscopy/resources.* Last accessed May 2, 2023.

[717] ''Included colonoscopies'' are outpatient colonoscopy procedures using Healthcare Common Procedure Coding System (HCPCS) codes G0121 and G0105, and Common Procedural Terminology (CPT) codes 45378, 45380, 45385, 45384, 45383, and 45381. This measure also uses a number of exclusion criteria. Additional methodology details and information obtained from public comments for measure development are available at: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html* under ''Hospital Outpatient Colonoscopy.''

development are available at: *https://qualitynet.cms.gov/outpatient/measures/surgery/methodology.*

We invited public comment on the proposal.

Comment: Several commenters supported adoption of the Facility 7-Day Risk-Standardized Hospital Visit Rate After Outpatient Colonoscopy measure. One of these commenters stated that assessing hospital visits within seven days would ensure the visitation rate is proximal to the procedure while promoting a robust enough volume to support valid measurement. Another commenter stated that this measure will help ensure REHs provide services of comparable quality to other settings.

Response: We thank commenters for their support.

Comment: Some commenters stated that if REHs perform a sufficient number of colonoscopies to generate adequate volume to calculate performance, the measure would be appropriate for use in the REHQR Program, and they would not oppose its adoption; however, other commenters did not support adoption of the measure due to their uncertainty as to whether the measure would yield enough volume to be statistically valid or relevant. One commenter stated that CAHs in their state averaged less than 50 colonoscopies on an annual basis during FY 2022. The commenter further stated that the tiered framework approach to measure reporting based on the scope of services provided by an REH, as discussed in section XVI.B.7.c. of this final rule with comment period, would be particularly relevant for this measure.

Response: We note that minimum case numbers for statistical reliability purposes apply for calculation of the measure for public reporting purposes. In addition, as we state in section XVI.B.1 of this final rule with comment period, while it is not possible to identify the exact group of hospitals that will choose to convert to REH status, our analysis indicates that the services targeted by the REHQR measures are relevant for hospitals that may participate in the REHQR Program as these hospitals are currently providing the services assessed by the selected measures, including the Facility 7-day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy measure, some with case volumes sufficient to meet thresholds to allow public reporting of the collected data. This is evidenced by data publicly reported by the initial 16 hospitals that have converted to REH status as of October 13, 2023.[718] We reiterate that we will only publicly report measure results with sufficient case volumes, both to protect patient privacy and to ensure that data are statistically reliable.

After consideration of the public comments we received, we are finalizing our proposal to adopt the Facility 7-day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy measure, beginning with the CY 2024 reporting period, as proposed.

d. Adoption of the Risk-Standardized Hospital Visits Within 7 Days After Hospital Outpatient Surgery Measure Beginning With the CY 2024 Reporting Period

(1) Background

Most surgical procedures in the United States are performed in outpatient settings; there are approximately 23 million such procedures performed annually.[719] Same-day surgery offers significant patient benefits as compared with inpatient surgery, including shorter waiting times, avoidance of hospitalizations, and rapid return home.[720] Furthermore, as same-day surgery costs are significantly less than an equivalent inpatient surgery, there is a significant cost saving opportunity to the health system.[721] With the ongoing shift towards outpatient surgery, assessing the quality of surgical care provided by hospitals has become increasingly important. Patients undergoing same-day surgery may require subsequent unplanned hospital visits for a broad range of reasons. While most outpatient surgery is safe, there are well-described and potentially preventable adverse events that occur after outpatient surgery, such as uncontrolled pain, urinary retention, infection, bleeding, and venous thromboembolism, which can result in unplanned hospital visits.[722] Similarly, direct admissions after surgery that are primarily caused by non-clinical patient considerations (for example, lack of transport home upon discharge) or facility logistical issues (for example delayed start of surgery) are common causes of unplanned yet preventable hospital admissions following same-day surgery.[723] Hospital utilization following same-day surgery is an important and accepted patient-centered outcome reported in the literature. As evidenced by one study, ''national estimates of hospital visit rates following surgery vary from 0.5 to 9.0 percent based on the type of surgery, outcome measured (admissions alone or admissions and ED visits), and timeframe for measurement after surgery,'' [724] suggesting variation in surgical and discharge care quality. However, providers (hospitals and surgeons) are often unaware of their patients' hospital visits after surgery because patients often present to the ED or to different hospitals.[725] This risk-standardized measure provides the opportunity for providers to improve the quality of care and to lower the rate of preventable adverse events that occur after outpatient surgery.

The Risk-Standardized Hospital Visits Within 7 Days After Hospital Outpatient Surgery (the 7-Day Hospital Visit Rate After Outpatient Surgery) measure was adopted for reporting in the Hospital OQR Program beginning with the CY 2020 payment determination (81 FR 79771).

(2) Measure Overview

The 7-Day Hospital Visit Rate After Outpatient Surgery measure would make unplanned patient hospital visits (ED visits, observation stays, or unplanned inpatient admissions) after surgery more visible to providers and patients through publicly reporting scores. It could also encourage providers to engage in quality improvement activities to reduce these visits by providing feedback to hospitals and providers. This measure meets the National Quality Strategy goals of embedding quality into the care journey

[718] The data provided in Table 146, discussed in section XVI.B.5 are from the Medicare Provider Enrollment, Chain, and Ownership System (PECOS) as of October 13, 2023.

[719] Munnich, EL & Richards, MR (February 2022). Long-run growth of ambulatory surgery centers 1990–2015 and Medicare payment policy. *Health Services Research, 57*(1), 66–71. *https://doi.org/10.1111/1475-6773.13707.*

[720] Banner Health. Outpatient Experience & Benefits. Available at: *https://www.bannerhealth.com/services/outpatient-surgery/experience-benefits.* Last accessed April 4, 2023.

[721] Munnich, EL & Parente, ST (January 2018). Returns to specialization: Evidence from the outpatient surgery market. Journal of health economics, 57, 147–167. *https://doi.org/10.1016/j.jhealeco.2017.11.004.*

[722] Bongiovanni, T, Parzynski, C, Ranasinghe, I, Steinman, MA, & Ross, JS. (July 2021). Unplanned hospital visits after ambulatory surgical care. *PloS one, 16*(7), e0254039. *https://doi.org/10.1371/journal.pone.0254039.*

[723] Ibid.

[724] Ibid.

[725] Williams, BR, Smith, LC, Only, AJ., Parikh, HR, Swiontkowski, MF, & Cunningham, BP (September 2021). Unplanned Emergency and Urgent Care Visits After Outpatient Orthopaedic Surgery. *Journal of the American Academy of Orthopaedic Surgeons. Global research & reviews, 5*(9), e21.00209. *https://doi.org/10.5435/JAAOSGlobal-D-21-00209.*

and promoting safety.[726] We expect that the measure would promote improvement in patient care over time.

The 7-Day Hospital Visit Rate After Outpatient Surgery measure was on the 2022 MUC list.[727] The Rural Health Advisory Group members did not have any rural health concerns about the measure. We believe that the proposed measure reflects consensus among the affected parties as public comment received during the MAP and measure development processes was in agreement with the MAP's conclusions on the measure. The MAP recommended the measure for rulemaking.[728]

We believe it is important to reduce adverse patient outcomes associated with preparation for surgery, the procedure itself, and follow-up care. Therefore, in the CY 2024 OPPS/ASC proposed rule (88 FR 49837 through 49839), we proposed to include the 7-Day Hospital Visit Rate After Outpatient Surgery measure in the REHQR Program beginning with the CY 2024 reporting period.

(3) Data Sources

The 7-Day Hospital Visit Rate After Outpatient Surgery measure is calculated from Part A and Part B Medicare administrative claims data for Medicare FFS beneficiaries with an outpatient same-day surgical procedure excluding eye surgeries and colonoscopies (except colonoscopy with biopsy). Colonoscopies are excluded from this measure as these procedures are examined separately on their own. The exclusion of eye procedures is discussed below. The performance period for the measure is one year (that is, the measure calculation includes eligible outpatient same-day surgeries occurring within a 1-year timeframe),[729] and we proposed the first reporting period in the REHQR Program would begin with the CY 2024 reporting period. We also considered increasing the data collection time-period, to account for low volume, to two or three years.

(4) Measure Calculation

The measure outcome would include unplanned hospital visits within seven days after a surgery performed at an REH that are: (1) an inpatient admission at a separate hospital that can admit patients; or (2) an ED visit or observation stay at the REH or other hospital occurring after discharge. If more than one unplanned hospital visit occurs, only the first hospital visit within the outcome timeframe is counted in the outcome.

The facility-level measure score is a ratio of the predicted to expected number of post-surgical hospital visits among the hospital's patients. The numerator of the ratio is the number of hospital visits predicted for the hospital's patients accounting for its observed rate, the number of surgeries performed at the hospital, the case-mix, and the surgical procedure mix. The denominator of the ratio is the expected number of hospital visits given the hospital's case-mix and surgical procedure mix. A ratio of less than one indicates the hospital's patients have fewer post-surgical visits than expected compared to hospitals with similar surgical procedures and patients; and a ratio of greater than one indicates the hospital's patients were estimated as having more visits than expected.

To ensure the accuracy of the algorithm for attributing claims data and the comprehensive capture of hospital surgeries potentially affected by the CMS 3-day payment window policy,[730] we identify physician claims for same-day surgeries in hospital settings from the Medicare Part B Standard Analytical Files (SAF) with inpatient admissions that occur within three days after these surgeries that lack a corresponding hospital facility claim. Under the 3-day payment window policy, all outpatient diagnostic services furnished to a Medicare beneficiary by a hospital (or an entity wholly owned or operated by the hospital), on the date of a beneficiary's admission or during the three days immediately preceding the date of a beneficiary's inpatient hospital admission, must be included on the Part A bill for the beneficiary's inpatient stay at the hospital. Hospitals must include the following information on the claim for a beneficiary's inpatient stay: (1) the diagnoses; (2) procedures; and (3) charges for all outpatient diagnostic services and admission-related outpatient non-diagnostic services that are furnished to the beneficiary during the 3-day payment window.[731] A surgery identified as affected by this policy would be attributed to the appropriate hospital facility using the facility provider identification from the inpatient claim.[732]

(5) Cohort

The measure includes Medicare FFS patients aged 65 years and older undergoing same-day, outpatient surgery in REHs, excluding eye surgeries and colonoscopies, but including colonoscopy with biopsy. ''Same-day surgeries'' are substantive surgeries and procedures listed on Medicare's list of covered ASC procedures excluding eye surgeries and colonoscopies (except colonoscopy with biopsy).[733] This list was developed for Medicare to identify surgeries that can be safely performed as same-day surgeries and do not typically require an overnight stay. Surgeries on the ASC list of covered procedures do not involve or require major or prolonged invasion of body cavities, extensive blood loss, major blood vessels, or care that is either emergent or life-threatening.

Although Medicare developed this list of surgeries for ASCs, we use it more broadly for this measure for two reasons. First, it aligns with our target cohort of surgeries that have low to moderate risk profile and are safe to be performed as same-day surgeries. By only including surgeries on this list in the measure, we effectively do not include surgeries performed at hospitals that typically require an overnight stay which are more complex, higher risk surgeries. Second, we use this list of surgeries because it is annually reviewed and updated by CMS and includes a transparent public comment submission and review process for

[726] CMS, What is the CMS National Quality Strategy?. Available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Value-Based-Programs/CMS-Quality-Strategy*.

[727] Centers for Medicare & Medicaid Services. *2022 Measures Under Consideration Spreadsheet.* Available at: *https://mmshub.cms.gov/measure-lifecycle/measure-implementation/pre-rulemaking/lists-and-reports.* Last accessed March 13, 2023.

[728] Centers for Medicare & Medicaid Services. *MAP 2016 Considerations for Implementing Measures in Federal Programs—Hospitals.* Available at: *https://www.qualityforum.org/Publications/2016/02/MAP_2016_Considerations_for_Implementing_Measures_in_Federal_Programs_-_Hospitals.aspx.* Last accessed March 13, 2023.

[729] 2022 Measure Updates and Specifications Report (2022), available at *https://qualitynet.cms.gov/outpatient/measures/surgery/methodology.* Last accessed February 28, 2023.

[730] *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Three_Day_Payment_Window.* Accessed May 4, 2023.

[731] Three Day Payment Window Implementation of New Statutory Provision Pertaining to Medicare 3-Day (1-Day) Payment Window Policy—Outpatient Services Treated As Inpatient. Centers for Medicare and Medicaid Services (CMS). Available at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Three_Day_Payment_Window.* Last accessed on March 28, 2023.

[732] For additional methodology details, we refer readers to the documents posted at: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology,* including ''2016 Measure Updates and Specifications Report: Hospital Visits after Hospital Outpatient Surgery Measure (PDF)''. Last accessed March 21, 2023.

[733] YNHHSC/CORE (2016). 2016 Measure Updates and Specifications Report Hospital Outpatient Quality Reporting Program 2022. Available at *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.* Last accessed March 21, 2023.

addition or removal of procedures codes. To view the ASC covered procedures list for 2023, we refer readers to the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ASCPayment/ASC-Regulations-and-Notices.* On that page, readers may select ''CMS–1772–FC'' from the list of regulations. The ASC Addenda are contained in a zipped folder entitled ''Addendum AA, BB, DD1, DD2, and EE.'' Addendum AA includes the relevant list of covered surgeries.

For further discussion of the cohort for this measure, please see ''2022 Measure Updates and Specifications Report: Hospital Outpatient Quality Reporting Program,'' available at *https://qualitynet.cms.gov/outpatient/measures/surgery/methodology.*

As noted previously, the cohort for this measure excludes eye surgeries. Eye surgery is performed in high volume and is generally perceived as being ''low risk.'' However, studies have indicated non-insignificant levels of hospital visits following cataract surgery. One study reported 0.3 percent of patients as having an inpatient admission within seven days following cataract surgery [734] and another study showing a 1.77 percent of patients with ED visits within 30 days following cataract surgery.[735] The measure cohort also excludes procedures for patients who lack continuous enrollment in Medicare FFS Parts A and B in the seven days after the procedure to ensure all patients have complete data available for outcome assessment.

(6) Risk Adjustment

The statistical risk-adjustment model includes 25 clinically relevant risk-adjustment variables that are strongly associated with risk of hospital visits within seven days following outpatient surgery.[736] The measure risk-adjusts for surgical procedure complexity using two variables. First, it adjusts for surgical procedure complexity using the Work Relative Value Units (RVUs).[737] Work RVUs are assigned to each CPT procedure code and approximate procedure complexity by incorporating elements of physician time and effort. Second, it classifies each surgery into an anatomical body system group using the Agency for Healthcare Research and Quality (AHRQ) Clinical Classification System (CCS),[738] to account for organ-specific differences in risk and complications, which are not adequately captured by the Work RVU alone.

We invited public comment on the proposal.

Comment: Several commenters supported the Risk-Standardized Hospital Visits Within 7 Days After Hospital Outpatient Surgery measure. One commenter stated that this measure will ensure REHs provide quality services and provide information for consumers to use when selecting a provider.

Response: We thank commenters for their support

Comment: Several commenters expressed concern that REHs will not have sufficient surgical volumes to allow reporting of the Risk-Standardized Hospital Visits Within 7 Days After Hospital Outpatient Surgery measure. One of these commenters stated that the tiered framework approach to measure reporting based on the scope of services provided by an REH, as discussed in section XVI.B.7.c. of this final rule with comment period, would be particularly relevant for this measure.

Response: We note that the commenters' concern regarding low volumes applies to all measures and providers, and that CMS does not report measures publicly unless it achieves sufficient case volumes to allow for public reporting of the collected data. In addition, as we state in section XVI.B.1 of this final rule with comment period, while it is not possible to identify the exact group of hospitals that will choose to convert to REH status, our analysis indicates that the services targeted by the REHQR measures are relevant for hospitals that may participate in the REHQR Program as these hospitals are currently providing the services assessed by the selected measures with case volumes sufficient to meet thresholds to allow public reporting of the collected data. We reiterate that we will only publicly report measure results with sufficient case volumes, both to protect patient privacy and to ensure that data are statistically reliable. We agree that the tiered framework approach to measure reporting based on the scope of services provided by an REH could be particularly relevant for this measure and refer readers to section XVI.B.7.c. of this final rule with comment period for further discussion.

After consideration of the public comments we received, we are finalizing our proposal to adopt the Risk-Standardized Hospital Visits Within 7 Days After Hospital Outpatient Surgery measure, beginning with the CY 2024 reporting period as proposed.

6. Summary of Finalized REHQR Program Measure Set Beginning With the CY 2024 Reporting Period

Table 147 summarizes the finalized REHQR Program measure set beginning with the CY 2024 reporting period:

[734] Wang, SY, Blachley, TS, Andrews, CA, Avanian, JZ, Lee, PP, & Stein, JD (Feb 22, 2016). Hospitalization after Cataract Surgery in a Nationwide Managed-Care Population. *PLOS ONE* (11:2). *https://doi.org/10.1371/journal.pone.0149819.*

[735] Sahil Aggarwal, Andrew Gross, Alex Snyder, Jay Rathinavelu, Terry Kim, Leon Herndon. Younger Age and Longer Case Times Associated With Emergency Department Visits After Cataract Surgery Published: August 23, 2022 DOI: *https://doi.org/10.1016/j.ajo.2022.08.017.*

[736] Information about the risk-adjustment model and measure methodology are located in the Measure Updates and Specifications Report available on QualityNet at: *https://qualitynet.cms.gov/outpatient/measures/surgery/methodology.*

[737] Coberly, S. (January 12, 2015). The Basics; Relative Value Units (RVUs). *National Health Policy Forum.* Available at: *https://hsrc.himmelfarb.gwu.edu/cgi/viewcontent.cgi?article=1275&context=sphhs_centers_nhpf.* Last accessed February 28, 2023.

[738] HCUP Clinical Classifications Software for Services and Procedures. Healthcare Cost and Utilization Project (HCUP). 2008. Agency for Healthcare Research and Quality. Available at: *https://www.hcup-us.ahrq.gov/toolssoftware/ccs_svcsproc/ccssvcproc.jsp.* Last accessed February 28, 2023.

TABLE 147: Finalized REHQR Program Measure Set Beginning With the CY 2024 Reporting Period

CBE #	Measure Name
None	Abdomen CT (long name: Abdomen Computed Tomography (CT) – Use of Contrast Material)
None	Median Time for ED Discharged Patients (formerly Median Time from ED Arrival to ED Departure for Discharged ED Patients)
2539	7-Day Hospital Visit Rate After Outpatient Colonoscopy (formerly Facility 7-Day Risk-Standardized Hospital Visit Rate After Outpatient Colonoscopy*)
2687	7-Day Hospital Visit Rate After Outpatient Surgery (long name Risk-Standardized Hospital Visits Within 7 Days After Hospital Outpatient Surgery)

*Reporting period for this measure is a three-year period, beginning CYs 2024-2026.

7. REHQR Program Measures and Topics for Future Consideration

a. Electronic Clinical Quality Measures (eCQMs) for Reporting Quality Data Under the REHQR Program

In the CY 2024 OPPS/ASC proposed rule (88 FR 49840 and 49841), we requested comment on the use of electronic clinical quality measures (eCQMs) for reporting quality data under the REHQR Program. eCQMs are measures specified in a standard electronic format that use data electronically extracted from EHRs and/or health information technology systems to measure the quality of health care provided. Through electronic reporting, hospitals have leveraged EHRs to capture, calculate, and electronically submit quality data instead of manually chart-abstracting and submitting to CMS. Adoption of certain eCQMs into the REHQR Program could address high priority areas as stated in our Meaningful Measures Framework, including the transition to digital quality measures and the adoption of high-quality measures that improve patient outcomes and safety.[739]

We acknowledged in the request for comment that technological, monetary, and staffing barriers may present challenges to eCQM adoption and use in some REHs. Although some REH staff may have had experience reporting eCQMs in the Hospital Inpatient Quality Reporting (IQR), Hospital OQR, or Medicare Promoting Interoperability (PI) Programs during the time-period when their REHs were organized as CAHs or subsection (d) hospitals, we acknowledge that challenges will remain. We see evidence of these challenges when analyzing eCQM reporting under the Medicare PI Program for eligible hospitals and CAHs. Tables 148 and 149 compare urban and rural hospital eCQM reporting, as defined by census area, with respect to the Medicare PI Program for the CY 2021 reporting period. Most hospitals of all bed sizes successfully reported eCQMs, but eCQM submission compliance percentages for smaller hospitals and rural hospitals were slightly lower than for larger or urban hospitals.

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[739] CMS. Meaningful Measures Initiative. *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/CMS-Quality-Strategy*. Last accessed April 3, 2023.

TABLE 148: Urban Hospitals that did or did not meet CY 2021 Reporting Period Promoting Interoperability eCQM Submission Requirements or were granted an Extraordinary Circumstances Exception (ECE)/Hardship Exception*

Hospital Type and Location	MET	Percent Met	NOT MET	Percent Not Met	ECE/Hardship	Percent with ECE/Hardship	Total
Rural and Urban Hospitals Eligible to submit eCQMs for CY 2021 Reporting Period	4,123	92.0%	286	6.4%	71	1.6%	4,480
Location							
Urban	3,088	95.1%	98	3.0%	60	1.8%	3,246
Bed Size Urban							
0-50	667	87.0%	81	10.6%	19	2.5%	767
51-100	408	96.5%	6	1.4%	9	2.1%	423
101+	2,013	97.9%	11	0.5%	32	1.6%	2,056
Provider Urban							
CAH	402	85.7%	67	14.3%	0	0.0%	469
IQR-Eligible	2,643	96.8%	26	1.0%	60	2.2%	2,729
Voluntary**	43	89.6%	5	10.4%	0	0.0%	48

*A CAH cannot request an extraordinary circumstances exception (ECE) if it is found to be non-compliant with the requirements of a quality reporting program, but they may be able to request a Hardship Exception through the Medicare PI Program.

**Voluntary hospitals are those not required to participate in the Hospital IQR Program (located in Puerto Rico and other U.S. Territories and Maryland) as well as seven cancer centers or research hospitals that choose to report.

Data source: Hospitals are identified from eCQM data submitted via Hospital Quality Reporting for FY 2023 and PRS accessed May 18, 2022. Hospitals are included if they were eligible to submit eCQM measures for the CY 2021 reporting period.

TABLE 149: Rural Hospitals that did or did not meet CY 2021 Reporting Period Promoting Interoperability eCQM Submission Requirements or were granted an Extraordinary Circumstances Exception (ECE)/Hardship Exception*

Hospital Type and Location	MET	Percent Met	NOT MET	Percent Not Met	ECE	Percent with ECE	Total
Rural and Urban Hospitals Eligible to submit eCQMs for CY 2021 Reporting Period	4,123	92.0%	286	6.4%	71	1.6%	4,480
Location							
Rural	1,035	83.9%	188	15.2%	11	0.9%	1,234
Bed Size Rural							
0-50	768	81.1%	170	18.0%	9	1.0%	947
51-100	122	93.1%	7	5.3%	2	1.5%	131
101+	145	92.9%	11	7.1%	0	0.0%	156
Provider Rural							
CAH	672	80.2%	166	19.8%	0	0.0%	838
IQR-Eligible	327	95.1%	6	1.7%	11	3.2%	344
Voluntary**	36	69.2%	16	30.8%	0	0.0%	52

*A CAH cannot request an extraordinary circumstances exception (ECE) if it is found to be non-compliant with the requirements of a quality reporting program, but they may be able to request a Hardship Exception through the Medicare PI Program.

**Voluntary hospitals are those not required to participate in the Hospital IQR Program (located in Puerto Rico and other U.S. Territories and Maryland) as well as seven cancer centers or research hospitals that choose to report.

Data source: Hospitals are identified from eCQM data submitted via Hospital Quality Reporting for FY 2023 and PRS accessed May 18, 2022. Hospitals are included if they were eligible to submit eCQM measures for the CY 2021 reporting period.

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We believe that certain eCQMs, if adopted into the REHQR Program, could provide insightful quality measure data for monitoring REHs and potentially lower provider burden. For example, the Excessive Radiation Dose or Inadequate Image Quality for Diagnostic Computed Tomography in Adults eCQM (the Excessive Radiation eCQM) could be adopted into the REHQR Program to improve patient outcomes and patient safety. This eCQM provides a standardized method for monitoring the performance of diagnostic CT to discourage unnecessarily high radiation doses while preserving image quality. The measure is expressed as a percentage of eligible CT scans that are out-of-range based on having either excessive radiation dose or inadequate image quality, relative to evidence-based thresholds based on the clinical indication for the exam.[740] This measure is not risk-adjusted. The purpose of this measure is to reduce unintentional harm to patients and provide REHs with a reliable method to assess harm reduction efforts and modify their improvement efforts. We are finalizing adoption of the Excessive Radiation eCQM for the Hospital OQR Program in this final rule. We refer readers to section XIV.B.3.c of this final rule with comment period for a discussion of this measure in the Hospital OQR Program.

We also refer readers to section XIV of the CY 2022 OPPS/ASC proposed rule (86 FR 42232 through 42237) where we requested information on potential actions and priority areas that would enable the continued transformation of our quality measurement enterprise toward greater digital capture of data and use of the Fast Healthcare Interoperability Resources (FHIR) standard. This will be taken into consideration in future years when deciding how and when to introduce eCQMs to the REHQR Program.

We invited public comment on the use of eCQMs in the REHQR Program, any specific eCQM measures that we should consider for inclusion in the REHQR Program measure-set, including the Excessive Radiation eCQM, and any considerations or criteria we should use in identifying eCQM measures to propose for future inclusion.

Comment: Several commenters agreed that eCQMs could reduce reporting burden by eliminating the need to manually abstract data from medical charts and multiple other sources but did not support implementation of eCQMs in the REHQR Program based on concerns with operational feasibility. Many commenters expressed concerns with implementing eCQMs because small, rural hospitals often lack the resources to implement expensive EHR systems, including the human resources to operate and support them. One commenter noted that REHs may also be located in areas with limited broadband internet access. Another commenter stated that CAHs in their state reported

[740] Centers for Medicare & Medicaid Services. Pre-Rulemaking MUC Lists and MAP Reports. The Measures Management System. Available at: *https://mmshub.cms.gov/measure-lifecycle/measure-implementation/pre-rulemaking/lists-and-reports.*

significant costs and vendor-related delays to modify their current systems in order to allow for reporting of eCQMs, including every time a new eCQM is added to a CMS program.

Some commenters who did not support implementation of eCQMs in the REHQR Program noted existing challenges with data collection and interoperability. A few commenters reported that several eCQMs that have been reviewed by a CBE or already proposed for use in CMS programs often use fields that do not always appear universally across all EHRs and may require time-consuming workarounds that negate the automation inherent to eCQMs. One commenter noted that not all measure definitions lend themselves to an eCQM data collection. The commenter also expressed concern with evolving technology standards, such as the variation in FHIR versions.

Another commenter who opposed the potential future use of eCQMs in the REHQR Program stated their belief that their introduction would be shortsighted, burdensome, and fail to recognize the increasing drive towards digital quality measures (dQMs). The commenter stated their belief that through efforts to improve health information exchange and extra data for quality measurement, eCQMs will continue to require significant resources to build. The commenter recommended that CMS should instead invest its efforts towards the future development of dQMs.

One commenter expressed support for the potential future use of eCQMs in the REHQR Program. This commenter also provided recommendations for CMS' identification and development of eCQMs, including aligning measures for a given concept (for example, patient safety) across applicable settings (for example, REHs and HOPDs) and focusing on outcome and patient-reported measures. The commenter also suggested that CMS use the recommendations of a recent Office of Inspector General (OIG) report as a guide in the identification and development of eCQMs around medication errors.[741]

A few commenters suggested that prior to adopting eCQMs for the REHQR Program, CMS should explore their feasibility with participating providers, with one commenter recommending program incentives for REHs to partner with vendors in pilot programs and models.

A few commenters recommended that CMS should consider adding eCQMs as optional measures initially. One of these commenters further suggested a stair-step approach to implementation, first incentivizing milestones along the way and, at an appropriate point in the timeline, introducing a negative incentive to promote long-term adherence.

To help REHs and all hospitals with successful eCQM reporting, the same commenter also recommended slowing down the implementation of and updates to new standards in health care interoperability to allow all parties, including CMS' technology, to catch up and align as an industry. The commenter also suggested that CMS standardize reporting requirements across all quality reporting programs, which would enable utilization of software and quality measures across all care settings, allow for better continuity of care, and minimize the chances for some providers and/or care settings to be left behind.

Response: We thank commenters for their feedback and will take it into consideration as we continue to evaluate all elements of the REHQR Program.

b. Care Coordination Measures

In the CY 2024 OPPS/ASC proposed rule (88 FR 49841), we requested comment on adding measures to the REHQR Program measure-set that are relevant to the coordination of care between REHs and other kinds of healthcare providers. REHs encounter challenges in coordinating care that are specific to rural settings. Geographically isolated areas typically have fewer health care settings and providers, and experience difficulties related to workforce shortages, transportation issues, and lack of information technology capabilities, such as the availability of broadband networks.[742] Other challenges relate to shifting workforce availability (for example, issues related to the availability of traveling nurses or independent healthcare providers) and limited access to specialists, diagnostic equipment, and other resources.[743] However, REHs are required to have in effect a transfer agreement with a level I or level II trauma center,[744] such that patients that present at an REH with needs for longer-term inpatient care may receive that care. REHs must, therefore, address issues related to the coordination of care for transferred patients.

We have sought to identify measures relevant to care coordination in rural settings that are also important, impactful, reliable, accurate, and clinically relevant. In the CY 2023 OPPS/ASC final rule, we provided responses to the comments received on our request for information on additional topics for quality measures appropriate for the REH setting (87 FR 72146 through 72149). Many of these comments addressed the provision of telehealth, an issue that impacts care coordination (87 FR 72146 and 72147). The CBE provided additional information on this topic in 2021, when they identified a list of 324 measures relevant to the provision of telehealth.[745] We believe that a number of these measures are directly related to the coordination of care, such as measures CBE #0006 Care Coordination, CBE #0097 Medication Reconciliation Post-Discharge, and CBE #0326 Advance Care Plan.[746] The current Medicare Beneficiary Quality Improvement Project (MBQIP) measures also include several ''care transitions'' measures that may be relevant to the coordination of care for REHs. Relevant MBQIP measures include Emergency Department Transfer Communication (on which we invited public comment in the CY 2022 OPPS/ASC proposed rule, at 86 FR 42285 through 42289), Discharge Planning, and Medication Reconciliation.[747]

We invited public comment on the use of care coordination measures in the REHQR Program, including telehealth measures, any specific measures that we should consider for inclusion in the REHQR Program measure-set regarding care coordination, and any considerations or criteria we should use in determining which, if any, coordination of care measures to propose for future inclusion.

Comment: Several commenters expressed support for care coordination measures for the REHQR Program. Some of these commenters recommended a

[741] Department of Health and Human Services, Office of the Inspector General (2022). Adverse events in hospitals: A quarter of Medicare patients experienced harm in October 2018. Available at: *https://oig.hhs.gov/oei/reports/OEI-06-18-00400.pdf*.

[742] Healthcare Access in Rural Communities. Rural Health Information Hub. Available at: *https://www.ruralhealthinfo.org/topics/healthcare-access*. Last accessed March 13, 2023.

[743] Ibid.

[744] Section 1861(kkk)(2)(C) of the Act.

[745] Rural Telehealth and Healthcare System Readiness Measurement Framework Final Report (2021). Accessed March 28, 2023. Available at: *https://www.qualityforum.org/Publications/2021/11/Rural_Telehealth_and_Healthcare_System_Readiness_Measurement_Framework_-_Final_Report.aspx*.

[746] Ibid.

[747] Federal Office of Rural Health Policy (FORHP). MBQIP Measures (January 2023)—Current Medicare Beneficiary Quality Improvement Project (MBQIP) Measures. Available at: *https://www.ruralcenter.org/sites/default/files/2023-02/MBQIP-Measures.pdf*.

cautious approach to measure adoption because REHs are small and some measures are burdensome to report.

Several commenters recommended adoption of measures that assess appropriate use of telehealth and other remote monitoring services for the REH setting. One of these commenters stated that such a measure would be appropriate in the future, but that it is currently premature because telehealth services are not required for REHs. One of these commenters stated that anesthesiology telehealth supervision services increase costs without improving quality, and also urged CMS not to create unintended barriers to the use of Certified Registered Nurse Anesthetists (CRNAs) in rural and rural emergency settings through the use of telehealth services. Another commenter recommended that CMS' strategy for REHs should address the need for using advanced technology, such as telehealth, remote patient monitoring (RPM), and other communications-based technology services, as well as Software as a Medical Device (SaMD), in improving rural maternal and infant care.

Several commenters recommended specific care coordination measures for future adoption in the REHQR Program. These measures are Medication Reconciliation Post Discharge (CBE #0097) and the Medicare Beneficiary Quality Improvement Project (MBQIP) Emergency Department Transfer Communication (EDTC) measure. Some commenters recommended types of measures that should be considered. These commenters specifically recommended a focus on patient safety measures, patient reported outcome measures, and patient experience measures.

Response: We thank commenters for their feedback and will take it into consideration as we continue to evaluate all elements of the REHQR Program.

c. Tiered Approach Framework

In the CY 2024 OPPS/ASC proposed rule (88 FR 49841 and 49842), we requested comment on a tiered approach to quality measure reporting. We referred readers to section XVII of the CY 2022 OPPS/ASC proposed rule, where we included a request for information (RFI) on REHs (86 FR 42285 through 42289) and received comments from more than 50 commenters in response, including one suggestion to implement a multi-tiered approach for quality measures and reporting requirements to incentivize REH reporting.

In the CY 2024 OPPS/ASC proposed rule (88 FR 49841 and 49842), we explained that within such a tiered framework, Tier 1 could encompass a set of measures that would be required for all REHs and would focus on measures applicable for the required ED and observation services at REHs. Tier 2 could apply only to REHs that choose to provide additional outpatient services; the measures in that set would be related to the optional services provided.

In this final rule with comment period, we are adopting the following measures into the REHQR Program measure set: (1) Abdomen CT measure, (2) Median Time for Discharged ED Patients measure, (3) 7-Day Hospital Visit Rate After Outpatient Colonoscopy measure, and (4) 7-Day Hospital Visit Rate After Outpatient Surgery measure. Two of these measures are related to services that REHs must provide to participate in the Medicare program. The other two measures are related to services that could be furnished on an outpatient basis at the election of the REH.[748] To fit into an example scenario of a tiered approach, Tier 1 could include the measures related to required services, which are the diagnostic, claims-based Abdomen CT measure, and the chart-abstracted Median Time for Discharged ED Patients measure. Tier 2 could consist of the measures related to services the REH may elect to provide, which are the claims-based 7-Day Hospital Visit Rate After Outpatient Colonoscopy and 7-Day Hospital Visit Rate After Outpatient Surgery measures.

The aforementioned tiered measures were only examples for the purposes of the request for comment to further discussion of this concept for the REHQR Program.

Such reporting could be phased-in; for example, as suggested by the commenter, all REHs could report the Tier 1 quality measures beginning at a designated time after their REH status began, and all REHs providing additional services would begin to submit Tier 2 data at a designated time after such services begin under the new REH status.

We invited public comment on the implementation of a tiered quality measure approach in the REHQR Program, considerations in designing the structure of a tiered framework, the number of measures in each tier, and considerations for designating measures for tiers of such a framework.

Comment: Several commenters expressed support for a tiered or menu-like approach to measures because the scope of REH services is still uncertain, and this approach would thus allow REHs to focus on reporting measures applicable to the services they offer. One commenter anticipated that the scope of services will likely vary based on location and seasonality. One commenter recommended adopting this approach cautiously because the REH designation is still new.

One commenter did not support a tiered measurement strategy because this could signal to patients that they do not deserve information related to the quality of care provided by REHs in their area.

Response: We thank commenters for their feedback and will take it into consideration as we continue to evaluate all elements of the REHQR Program.

8. Display of Quality Measure Data Publicly

a. Public Reporting of Quality Data Generally

Pursuant to the CAA, 2021, the Secretary shall establish procedures to make quality measure data submitted by REHs available to the public on a CMS website.[749] Such procedures shall ensure that the REH has the opportunity to review, and submit corrections for, the data that is to be made public with respect to the REH prior to such data being made public.[750] In the CY 2024 OPPS/ASC proposed rule (88 FR 49842), we proposed to align our approach to the public display of measures with that of the Hospital OQR and ASCQR Programs. For detail on the public display of measures in the Hospital OQR and ASCQR Programs, we refer readers OPPS/ASC final rules of CY 2009 (73 FR 68777 through 67779), CY 2014 (78 FR 75092), and CY 2017 (81 FR 79791).

We proposed to make publicly reported data under the REHQR Program available to the public both on our Care Compare website and in downloadable data files found at *https://data.cms.gov.* We discussed our intent to display these data publicly for any consumer or other member of the public beginning with measure data submitted relevant to services provided in CY 2024. To the extent possible, in order to publicly display these data, we would use the same information systems, business processes, and other infrastructure that we use to display data for the Hospital OQR and Hospital IQR Programs. We described our belief

[748] See section 1861(kkk)(1) of the Act.

[749] CAA, 2021, at section 125(a)(1)(B) of Division CC, adding section 1861(kkk)(7)(D) of the Act.

[750] CAA, 2021, at section 125(a)(1)(B) of Division CC, adding section 1861(kkk)(7)(D) of the Act.

that alignment of public reporting processes and policies with other quality reporting programs would ease the understanding of such processes and policies for REHs.

Specifically, we proposed that participating REHs would be granted the opportunity to review their data before the information is published during a 30-day review and corrections period (the preview process). Similar to the Hospital OQR and Hospital IQR Programs, we would announce the timeframes for the preview period starting with the measure data submitted relevant to services provided in CY 2024 on a CMS-designated website, such as QualityNet, or on applicable listservs. We generally strive to display hospital quality measures data on the designated website as soon as possible after measure data have been submitted to CMS. However, if there are unresolved display issues or pending design considerations, we may make the data available on other, non-interactive, CMS-designated websites. This preview process would align with that of the Hospital OQR Program (81 FR 79791).

We proposed to codify this policy at § 419.95 by adding paragraph (f), ''Public reporting of data under the REHQR Program.'' In paragraph (f), we proposed that data that an REH submits for the REHQR Program would be made publicly available by a CMS Certification Number (CCN) on a CMS website in an easily understandable format after providing the REH an opportunity to review the data to be made public.

We invited public comment on the proposal.

Comment: One commenter supported our proposals related to public reporting of quality data generally under the REHQR Program. The commenter also expressed particular support for our proposal to provide a 30-day preview process in alignment with the Hospital OQR and ASCQR Programs.

Response: We thank the commenter for their support.

Comment: One commenter did not support publicly reporting performance in the REHQR Program consistent with reporting in the Hospital OQR and ASCQR Programs because of the perception that data are difficult for the public to interpret. As an example, the commenter stated that whether higher values are better or worse is not specified for each measure. Additionally, the commenter did not support reporting by CCN because the commenter believes that this obscures the individual performance of a given facility delivering the care, which the commenter believes is misleading and unhelpful to patients. The commenter encouraged CMS to work with the Office of the National Coordinator for Health Information Technology's (ONC) to utilize ONC's HTI–1 version 4 (v4), which the commenter stated could provide consistent identification of healthcare facilities by physical locations and facilitate public reporting of quality data at the facility level.

Response: We appreciate the commenter's concern regarding reporting the data in a way that is meaningful for patients. We note that we provide educational materials on the Care Compare website and in the program's Specifications Manual, both of which include information about why a measure is important and provide information about whether higher or lower percentages are better for most measures, including those being adopted for the REHQR Program. We continually evaluate our patient education materials to improve the clarity and usefulness of the data we provide and believe that publicly reporting these data helps patients to make informed decisions about their care.

Regarding the commenter's preference for reporting data at the facility level as opposed to at the CCN level, we believe that consistent reporting across quality reporting facilitates meaningful comparison; however, we will consider taking into consideration alternative data reporting levels based on program needs and evidence of validity and reliability of such a change.

We clarify that ONC, on behalf of the Secretary and under the authority provided in section 3004 of the Public Health Service Act, proposed the adoption of United States Core Data for Interoperability (USCDI) version 3 (v3) in the ''Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing'' proposed rule (HTI–1 proposed rule).[751] USCDI v4 was recently published in July 2023 and re-published with errata in October 2023.[752] USCDI v4, includes facility information, including facility identifier, type, and name, however, USCDI v4 has not yet been proposed for adoption through rulemaking nor is it in widespread use. We will continue to coordinate with ONC as to when adoption and implementation of USCDI v4 may occur and its suitability for use for the public reporting of quality data.

Comment: A few commenters encouraged CMS to delay public reporting by at least one or 2 years to allow time for the data to be reviewed for accuracy and assure that the measures appropriately reflect REH quality.

Response: We note that the four measures being adopted by the REHQR Program have been incorporated in the Hospital OQR Program and all hospitals eligible to convert to REH status, except for CAHs, have been required to participate in the Hospital OQR Program. Furthermore, many CAHs have voluntarily reported these measures in the Hospital OQR Program (88 FR 49827 through 49830). Therefore, we believe most hospitals participating in the REHQR Program will have already had data on these measures publicly reported. We believe immediate reporting under the REHQR Program will allow continuity of data and provide patients with meaningful information to make informed decisions about care. We note that there is some delay due to data collection time periods for the measures in the initial REHQR Program measure set, which will allow some time for REHs to settle into their new provider role. Each of these initial measures will also be calculated once the completion of the relevant data collection period is met. The three claims-based measures are collected on a rolling annual basis thereafter; the chart-abstracted measure will be collected quarterly.

b. Public Reporting of REHQR Program Claims-Based Measures

In the CY 2024 OPPS/ASC proposed rule (88 FR 49842), we proposed to make measure scores for the claims-based measures proposed for the REHQR Program measure set publicly available beginning with measure data submitted relevant to services provided in CY 2024. As discussed previously in section XVI.B.5 of this final rule with comment period, we are finalizing the adoption of the following three claims-based measures into the REHQR Program measure set: (1) Abdomen CT measure, (2) 7-Day Hospital Visit Rate After Outpatient Colonoscopy measure, and (3) 7-Day Hospital Visit Rate After Outpatient Surgery measure.

As explained in the CY 2024 OPPS/ASC proposed rule (88 FR 49842), public reporting measure data for a claims-based measure would not begin until completion of a data collection period specific to that claims-based measure, provided sufficient case

[751] 88 FR 23750 (April 18, 2023); *https://www.federalregister.gov/d/2023-07229/p-164.*

[752] *https://www.healthit.gov/isa/sites/isa/files/2023-10/USCDI-Version-4-October-2023-Errata-Final.pdf.*

volumes are achieved.[753] [754] For example, for the 7-Day Hospital Visit Rate After Outpatient Colonoscopy measure, the data collection period is three years; public reporting would begin after completion of an initial three-year data collection period, or CY 2027, provided the hospital had sufficient case volumes. We plan to provide additional detail on the timeline of publicly reporting this data in future rulemaking.

As we described in the CY 2024 OPPS/ASC proposed rule (88 FR 49842) and in section XVI.B.8.a. of this final rule with comment period, we proposed that the display of these data would rely on the same business processes and resources that are currently in use for the Hospital OQR and Hospital IQR Programs. The data would be available to the public both on our Care Compare website and in downloadable data files found at *https://data.cms.gov*. Data associated with these three claims-based measures would be updated annually.

We invited public comment on the proposal.

Comment: One commenter expressed broad support of CMS' proposals to support REHs' efforts to collect data, report quality measures, and improve performance, including CMS' proposal to publicly report claims-based measures under the REHQR Program.

Response: We thank the commenter for their support.

c. Public Reporting of the Median Time from ED Arrival to ED Departure for Discharged ED Patients Measure

In the Hospital OQR Program, only data for two out of the four strata of the Median Time for Discharged ED Patients measure are reported publicly. Measure data for the Median Time for Discharged ED Patients—Reported Rate is currently publicly displayed on the Care Compare website and in the downloadable data found at *https://data.cms.gov* for the Hospital OQR Program. In addition, measure data for the Median Time for Discharged ED Patients—Psychiatric/Mental Health Patients is publicly displayed in downloadable data files, in order to address a behavioral health gap in the publicly reported Hospital OQR Program measure set.[755]

While data for the Median Time for Discharged ED Patients—Transfer Patients measure stratification is not currently reported publicly for hospitals participating in the Hospital OQR Program, we believe publicly reporting measure data for this stratum for REHs is imperative to allow for the identification of REH ED throughput performance gaps for patients requiring higher levels of specialized care above what an REH is able to provide. Likewise, data for the Median Time for Discharged Patients—Overall Rate measure stratification are not currently reported publicly for hospitals participating in the Hospital OQR Program. However, we believe publicly reporting measure data for this stratum for REHs participating in the REHQR Program is important to provide an account of all patients seen in the REH's ED that have a discharge code, beyond identifying specific performance in certain patient populations as reflected by the other strata calculated for this measure. We note that the Median Time for Discharged ED Patients measure is of particular importance for the REHQR Program because care provided in EDs will be a focus of REH services; as such, we seek to provide transparency in publicly reporting of all the strata calculated for this measure. For a more detailed discussion of the Median Time for Discharged ED Patients measure for the REHQR Program measure set, please refer to section XVI.B.5.b of this final rule with comment period.

In the CY 2024 OPPS/ASC proposed rule (88 FR 49842 and 49843), we proposed to make publicly available data received from REHs to calculate the following measure strata for the Median Time for Discharged ED Patients measure: (1) Overall Rate; (2) Reported Measure; (3) Psychiatric/Mental Health Patients; and (4) Transfer Patients. We intend to display these data publicly beginning with the first quarter of measure data submitted relevant to services provided in CY 2024 in which case thresholds are met. We plan to provide additional detail on the timeline of publicly reporting these data through CMS websites or communications, and in future rulemaking. As discussed previously, display of these data would rely on the same business processes and resources that are currently in use for the Hospital OQR and Hospital IQR Programs.

We invited public comment on these proposals.

Comment: Several commenters did not support public reporting of the transfer patients stratum because the Hospital OQR program does not report this stratum.

Response: We appreciate the commenters' recommendation to align public reporting between the Hospital OQR Program and the REHQR Program. We note that in section XIV.B.6 of this final rule with comment period, we are finalizing public reporting of the transfer patients stratum in the Hospital OQR Program. Therefore, if CMS finalizes public reporting of this stratum in the REHQR Program as proposed, this policy will align across these two programs.

Comment: One commenter did not support publicly reporting these data because of concerns that low volumes will lead to unreliable data. This commenter observed that stratifying the data into four strata will lead to smaller volumes and therefore less reliable data.

Response: We thank the commenters for their feedback but note that this concern applies to all measures, and that CMS does not report measures publicly unless sufficient case volumes to allow for public reporting of the collected data are achieved. This measure has clinical importance, and even if case rates are too small for public reporting, the collection of this measure can drive hospital improvement efforts and improve timely access to care. In addition, as we state in section XVI.B.1 of this final rule with comment period, while it is not possible to identify the exact group of hospitals that will choose to convert to REH status, our analysis indicates that the services targeted by the REHQR measures are relevant for hospitals that may participate in the REHQR Program as these hospitals are currently providing the services assessed by the selected measures with case volumes sufficient to meet thresholds to allow public reporting of the collected data. We reiterate that we will only publicly report measure results with sufficient case volumes, both to protect patient privacy and to ensure that data are statistically reliable. We believe that reporting all four strata provides meaningful information regarding the care provided by addressing the various outcomes of seeking ED care which a patient may experience.

Comment: Several commenters did not support reporting these data because the measure could be affected by factors outside of the REH's control. These commenters expressed that reporting these data could affect perceptions of

[753] CMS does not report measures publicly unless measures are the result of an analysis of more than 10 cases.

[754] CMS Policy for Privacy Act Implementation & Breach Notification, July 23, 2007, Document Number: CMS–CIO–POL–PRIV01–01, p 4. Statistical, aggregate or summarized information created as a result of analysis conducted using identifiable CMS data obtained under CMS-approved projects/studies may only be disclosed if the data are not individual-specific and the data are aggregated to a level where no data cells contain 10 or fewer individuals.

[755] CMS adopted a policy to publicly report measure data for the Median Time for Discharged ED Patients—Psychiatric/Mental Health Patients in the CY 2018 OPPS/ASC final rule (82 FR 59437).

REHs and patient willingness to seek care at REHs with high throughput times.

Response: We understand the commenters' concern regarding factors outside of an REH's control that could affect ED throughput and thus the perception of the hospital; however, we believe that many hospitals face such concerns and that timeliness of care is critical aspect of quality of care, directly impacting patient outcomes, particularly for an ED episode of care. While we understand concerns that transport times may be delayed due to circumstances beyond a facility's control, such as weather, local facility transport modalities, and distance, we also note that transfer time for trauma patients is especially important, that these circumstances are not unknown or new challenges, and that REHs are statutorily required to have in effect a transfer agreement with a higher level trauma center, such that patients that present with needs for longer-term inpatient care may receive that care, particularly in a timely manner. Further, an examination of Care Compare data for hospitals that have converted to REH status shows transfer times that are more timely or on par with larger or urban hospitals. Therefore, the public reporting of these data can help patients and their caregivers identify which facilities are performing better than others despite potential challenges, and drive quality improvement efforts. Additionally, we believe that having a consistent ED throughput measure across REHs and HOPDs will allow consumers to compare across programs, especially for vulnerable populations in need of transfer to more appropriate care settings.

C. Administrative Requirements

1. Codification of Administrative Requirements

Section 1861(kkk)(7)(B)(i) of the Act provides that, with respect to each year beginning with 2023, or each year beginning on or after the date that is one year after one or more measures are first specified under section 1861(kkk)(7)(C) of the Act, an REH shall submit data to the Secretary in accordance with section 1861(kkk)(7)(B)(ii). Clause (ii) states that, with respect to each such year, an REH shall submit to the Secretary data on quality measures in a form and manner, and at a time, specified by the Secretary for purposes of section 1861(kkk)(7)(B) of the Act.

We finalized foundational administrative requirements for REHs participating in the REHQR Program in the CY 2023 OPPS/ASC final rule (87 FR 71752, 72149, and 72150). In that rule, we require REHs must (1) register on a CMS website before beginning to report data; and (2) identify and register a security official as part of that registration process. We also require REHs to submit data on all quality measures to CMS. In the CY 2024 OPPS/ASC proposed rule (88 FR 49843), we proposed to codify the participation requirements in the REHQR Program at § 419.95(b), ''Participation in the REHQR Program.''

We noted in the CY 2024 OPPS/ASC proposed rule that we intend to propose additional administrative requirements as appropriate for the REHQR Program in subsequent rulemaking.

We invited public comment on these proposals. We did not receive any comments on the proposal and are finalizing our proposal to codify the participation requirements in the REHQR Program at § 419.95(b) with one correction to fix a typographical error, in which ''paragraph (c)'' was inadvertently referred to as ''paragraph (d).''

D. Form, Manner, and Timing of Data Submitted for the REHQR Program

1. Alignment and Codification of Submission of REHQR Program Data

We refer readers to the CYs 2014, 2016, and 2018 OPPS/ASC final rules (78 FR 75110 and 75111; 80 FR 70519 and 70520; and 82 FR 59439, respectively) where we finalized our policies for clinical data submission for the Hospital OQR Program. We codified these submission requirements at § 419.46(d). In the CY 2024 OPPS/ASC proposed rule (88 FR 49843), we proposed to align the policies regarding submission of program data for the REHQR Program with those from the Hospital OQR Program.

We also proposed to codify this policy at § 419.95 by adding paragraph (c), ''Submission of REHQR Program data.'' In paragraph (c)(1), we would require that REHs that participate in the REHQR Program must submit to CMS data on measures selected under section 1861(kkk)(7)(C) of the Act in a form and manner, and at a time specified by CMS. REHs sharing the same CCN must combine data collection and submission across their multiple campuses for all clinical measures for public reporting purposes. In paragraph (c)(2), we proposed that submission deadlines by measure and by data type be posted on a CMS website. We proposed 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 non-workday 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 invited public comments on these proposals.

Comment: One commenter expressed broad support of CMS' proposals to support REHQRs' efforts to collect data, report quality measures, and improve performance, including CMS' proposals related to the form, manner and timing of data submission, to include: (1) our proposal to align the policies regarding submission of REHQR Program data with those of the Hospital OQR Program and to codify such policies at § 419.95(c); (2) our proposed data submission requirements for chart-abstracted measures beginning with the CY 2024 reporting period; (3) our proposed claims-based measure data requirements beginning with the CY 2024 reporting period; (4) our proposal to adopt a review and corrections period for measure data submitted to the REHQR Program and to codify this policy at § 419.95(c)(3); and (5) our proposal to adopt an Extraordinary Circumstances Exceptions (ECE) process for the REHQR Program and to codify this policy at § 419.95(g).

Response: We thank the commenter for their support.

After consideration of the public comments we received, we are finalizing our proposal to align the policies regarding submission of REHQR Program data with those of the Hospital OQR Program and to codify such policies at § 419.95(c).

2. Requirements for Chart-Abstracted Measures Where Patient-Level Data Are Submitted Directly to CMS Beginning With the CY 2024 Reporting Period

As discussed in section XVI.B.5.b of this final rule with comment period, we are finalizing our proposal to adopt one initial chart-abstracted measure for the CY 2024 reporting period and for subsequent years: Median Time for Discharged ED Patients. Measure data for this measure would be submitted via the HQR System (formerly referred to as the QualityNet Secure Portal). In the CY 2024 OPPS/ASC proposed rule (88 FR 49843), we explained that in developing proposed data submission requirements for this measure, we also considered proposing that REHs submit data for this measure on an annual rather than quarterly basis to help reduce burden for REHs participating in the REHQR Program. However, we noted that REHs

would have been reporting this measure on a quarterly basis under the Hospital OQR Program and would thus be acclimated to this reporting frequency. Therefore, to enhance alignment with this program, we proposed the same data submission frequency (a quarterly basis). We refer readers to the CY 2015 OPPS/ASC and CY 2023 OPPS/ASC final rules for a discussion of our previously finalized policies regarding submissions deadlines for chart-abstracted measures for the Hospital OQR Program (79 FR 66964; 87 FR 72110 through 72112).

Beginning with the CY 2024 reporting period, the applicable patient encounter quarters for chart-abstracted data and their corresponding data submission deadlines would be as follows in Table 150.

TABLE 150: CY 2024 Reporting Period and Subsequent Years*

Patient Encounter Quarter	Clinical Data Submission Deadline
Q1 2024 (January 1 – March 31)	08/01/2024
Q2 2024 (April 1 – June 30)	11/01/2024
Q3 2024 (July 1 – September 30)	02/01/2025
Q4 2024 (October 1 – December 31)	05/01/2025

*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.

We proposed to adopt these dates as quarterly deadlines for submitting chart-abstracted measure data for the REHQR Program.

We invited public comment on the proposal.

Response: We refer readers to previous section XVI.D.1 where we summarize the broad support we received for CMS' proposals related to the form, manner and timing of data submission.

After consideration of the public comments we received, we are finalizing our proposed data submission requirements for chart-abstracted measures beginning with the CY 2024 reporting period.

3. Claims-Based Measure Data Requirements Beginning With the CY 2024 Reporting Period

As discussed in section XVI.B.5 of this final rule with comment period, we are finalizing our proposal to adopt three initial claims-based measures for the CY 2024 reporting period and for subsequent years: (1) Abdomen CT; (2) 7-Day Hospital Visit Rate After Outpatient Colonoscopy; and (3) 7-Day Hospital Visit Rate After Outpatient Surgery. In the CY 2024 OPPS/ASC proposed rule (88 FR 49844), for calculating these and future claims-based measures, we proposed to use Medicare claims data for services with encounter dates on or after January 1, 2024.

We invited public comment on the proposal.

Response: We refer readers to previous section XVI.D.1 where we summarize the broad support we received for CMS' proposals related to the form, manner and timing of data submission.

After consideration of the public comments we received, we are finalizing our proposed claims-based measure data requirements beginning with the CY 2024 reporting period.

4. Adoption and Codification of a Review and Corrections Period for Measure Data Submitted to the REHQR Program

In the event that an REH submits data for a measure, such as the chart-abstracted Median Time for Discharged ED Patients measure we are finalizing in section XVI.B.5.b of this final rule with comment period, and later discovers or suspects the data provided were not accurate, it may need to submit corrected data. To address this need, in the CY 2024 OPPS/ASC proposed rule (88 FR 49844), we proposed to adopt the same policies currently in place for the Hospital OQR Program. Under the Hospital OQR Program, hospitals submit chart-abstracted data to CMS on a quarterly basis. These data are typically due approximately four months after the quarter has ended. We refer readers to the CY 2015 OPPS/ASC final rule for a discussion of our previously finalized policies regarding submissions deadlines for chart-abstracted measures for the Hospital OQR Program (79 FR 66964).

Hospitals are encouraged to submit data early in the submission schedule so that they can identify errors and resubmit data before submission deadlines. Hospitals can continue to review, correct, and change these data up until the close of each submission deadline. For example, under the Hospital OQR Program, we finalized a 4-month period as the review and corrections period for chart-abstracted data (79 FR 66964). 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. Under the Hospital OQR Program, we generally provide rates to hospitals for the measures that have been submitted for chart-abstracted, patient-level data 24 to 48 hours following the submission deadline.

We proposed to adopt this same policy under which an REH may review and submit corrections to measure data, and that for chart-abstracted measure data, an REH may review and submit corrections to measure data submitted for a period of four months after the reporting quarter has ended. We also proposed to codify this policy at § 419.95 by adding paragraph (c)(3), ''Review and corrections period.'' In paragraph (c)(3), we proposed that REHs would have a review and corrections period for all quality data submitted, which runs concurrently with the data submission period, when they would be able to enter, review, and correct data submitted prior to the submission deadline. In addition, we proposed that after the submission deadline, these data cannot be changed.

We invited public comment on these proposals.

Response: We refer readers to previous section XVI.D.1 where we summarize the broad support we received for CMS' proposals related to the form, manner and timing of data submission.

After consideration of the public comments we received, we are

finalizing our proposal to adopt a review and corrections period for measure data submitted to the REHQR Program and to codify this policy at § 419.95(c)(3).

5. Adoption of an Extraordinary Circumstances Exceptions (ECE) Process

In our experience, there have been times when facilities have been unable to submit information to meet program requirements due to extraordinary circumstances that are not within their control. It is our goal not to penalize such entities for such circumstances and we do not want to unduly increase their burden during these times. In the CY 2024 OPPS/ASC proposed rule (88 FR 49844 and 49845), we proposed an Extraordinary Circumstances Exceptions (ECE) process for REHs to request and for CMS to grant extensions or waivers with respect to the reporting of required quality data when there are extraordinary circumstances beyond the control of the REH. Under this process, CMS may grant an exception to one or more data submission deadlines and requirements in the event of extraordinary circumstances beyond the control of the REH, such as when an act of nature affects an entire region or locale or a systemic problem with one of CMS' data collection systems directly or indirectly affects data submission. Because we do not anticipate that such systemic errors will happen often, we do not anticipate granting exceptions on this basis frequently.

We proposed that CMS may grant an exception to one or more data submission deadlines and requirements upon request by an REH, pursuant to specific requirements for submission of such a request described below. In addition, we proposed that CMS may grant exceptions at its own discretion, without an accompanying request from an affected REH, when CMS determines that an extraordinary circumstance has occurred.

For an REH to request consideration of an exception to the requirement to submit quality data or medical record documentation for one or more quarters, the REH would follow specific requirements for submission of an ECE request form available on a CMS website. We note that the following information must appear on the request form: the REH's CCN; the REH's name; the REH's chief executive officer (CEO) or other REH-designated personnel contact information, including name, email address, telephone number, and mailing address (must include a physical address, a post office box address is not acceptable); REH's reason for requesting an exception; evidence of the impact of the extraordinary circumstances, including but not limited to photographs, newspaper and other media articles; and a date when the REH believes it would again be able to submit REHQR Program data and/or medical record documentation; and a justification for the proposed date.

We proposed the request form must be signed by the REH's designated contact, whether or not that individual is the CEO. A request form would be required to be submitted within 90 days of the date that the extraordinary circumstance occurred. Following receipt of such a request, CMS would provide an email acknowledgement using the contact information provided in the request notifying the designated contact that the REH's request has been received and following CMS' decision, CMS would notify the REH using the same contact information. We proposed in the case where CMS grants exceptions to REHs that have not requested them because we determine that an extraordinary circumstance has occurred in a region or locale, we would communicate this decision to REHs and vendors through routine communication channels, including but not limited to emails and notices on a CMS website.

We also proposed to codify these policies at § 419.95 by adding paragraph (g), ''Exception.'' In paragraphs (g)(1) and (2), we proposed that we may grant, upon the request of the REH or at our discretion, an exception to one or more data submission deadlines and requirements in the event of extraordinary circumstances beyond the control of the REH.

We invited public comment on these proposals.

Response: We refer readers to previous section XVI.D.1 where we summarize the broad support we received for CMS' proposals related to the form, manner and timing of data submission.

After consideration of the public comments we received, we are finalizing our proposal to adopt an Extraordinary Circumstances Exceptions (ECE) process for the REHQR Program and to codify this policy at § 419.95(g).

XVII. Changes to Community Mental Health Center (CMHC) Conditions of Participation (CoPs)

A. Background and Statutory Authority

The Consolidated Appropriations Act (CAA), 2023 (Pub. L. 117–328) was signed into law on December 29, 2022. Section 4124 of division FF of this legislation established coverage of intensive outpatient program (IOP) services in CMHC. Section 4124 of the CAA, 2023 extends Medicare coverage and payment of IOP services furnished by a CMHC beginning January 1, 2024, allowing coverage of IOP services to be furnished by CMHCs at section 1832(a)(2)(J) of the Act. Additionally, the CAA, 2023 revised section 1861(ff) of the Act to define IOP services while also amending the definition of partial hospitalization program (PHP) services. The statutory definitions provide distinctions between the two programs for Medicare purposes.

In order to implement division FF, section 4124 of the CAA, 2023, we proposed to modify the requirements for CMHC participation in Medicare to include standards for IOP services throughout the CoPs. Section 1861(ff)(3)(B)(iv) of the Act authorizes the Secretary to establish the requirements that a CMHC must meet to participate in the Medicare Program, and these CoPs are set forth in regulations at 42 CFR part 485, subpart J.

Division FF, section 4121 of the CAA, 2023, establishes a new Medicare benefit category for marriage and family therapist (MFT) services and mental health counselor (MHC) services. Thus, we also proposed to add personnel qualifications for MFTs and update the existing personnel qualifications for MHCs in the CMHC CoPs.

B. Summary of the CMHC Proposed Provisions, Public Comments and Responses to Comments

On July 31, 2023, the CY 2024 OPPS/ASC proposed rule (88 FR 49552) was published in the **Federal Register**. This section of this final rule with comment period sets out changes to the CMHC CoPs as required in section 4124 of Division FF of the CAA 2023. In response to the proposed CMHC CoP policies, we received 23 public comments. Commenters included health associations and residential and outpatient substance use disorder treatment facilities. In this section, we provide a summary of our proposed provisions, a summary of the public comments received, our responses to the public comments, and the policies we are finalizing for CMHCs.

1. General Comments

Comment: We received one comment that supported the various technical changes to codify the coverage of IOP services in CMHCs. However, this commenter noted that CMHCs do not provide screening or treatment for eating disorders.

Response: We appreciate the feedback from the commenter. While the CoPs do not explicitly address every mental

health service provided by CMHCs, we note that practitioners working in CMHCs may provide these services for the screening and treatment of eating disorders as part of individual counseling under part B if they so choose.

2. Section 485.900 Basis and Scope

We proposed to revise the basis and scope of part 485, subpart J, at § 485.900 to add the definition of IOP services to the standard in which the current definition of ''partial hospitalization services'' is located. In this standard, we also proposed to reference the statutory provision at section 1861(ff) enacted by Congress in division FF, section 4124 of the CAA, 2023. Section 1832(a)(2)(J) of the Act specifies payment of benefits covered under Medicare for CMHCs and section 1866(e)(2) of the Act specifies the provider agreement requirements for CMHCs with respect to providing PHP and IOP services. The addition of IOP services to the list of Medicare services covered when provided by a CMHC would assist in ensuring the continuum of coverage of outpatient behavioral health services under the Medicare program. Medicare coverage of IOP services in CMHCs may help address barriers to access to behavioral health care, which may also address inequities in behavioral health care and services. In order to implement division FF, section 4124 of the CAA, 2023, we proposed to modify the CMHC CoPs at § 485.900(a)(1) through (3). These modifications would allow CMHCs to receive payments for IOP services under Medicare Part B, establish requirements for the provision of IOP services in CMHCs, provide IOP services to clients, and include IOP services in the Medicare provider agreement.

Comment: We received several comments in support of the proposals at § 485.900. Commenters expressed support for the inclusion of IOP services as it aligns with the broader health care industry's shift towards recognizing and treating mental health with the same importance as physical health. Commenters also supported IOP services furnished by CMHCs as it increases access to behavioral health care.

Response: We thank and appreciate the commenters support of these proposals.

After consideration of public comments on these provisions, we are finalizing them as proposed at § 485.900. The inclusion of IOP services in a CMHC would assist in ensuring the continuum of coverage of outpatient behavioral health services under the Medicare program and may help address barriers to access to behavioral health care. We believe that this action strengthens our response to the need for increased access to behavioral health services.

3. Section 485.904 Personnel Qualifications

Section 1861(ff)(2) of the Act lists the items and services partial hospitalization programs must be able to provide to meet the needs of clients and the staff needed to provide such items and services. For example, section 1861(ff)(2)(A) of the Act states a physician, psychologist, or other mental health professional to the extent authorized under State law may furnish individual and group therapy. The programs providing PHP services must be able to meet the needs of each client under their care.

As stated above, section 4121 of division FF of the CAA, 2023, established a new Medicare benefit category for MFT and MHC services in section 1861(lll) of the Act, including a definition for MFTs and MHCs in sections 1861(lll)(2) and 1861(lll)(4) of the Act, respectively. To support the health and safety of CMHC clients and to promote consistency and clarity of CMHC personnel qualifications we proposed at § 485.904(b), ''Standard: Personnel qualifications for certain disciplines,'' to align the personnel qualifications for MFTs and MHCs with the requirements set out in the CAA, 2023. We proposed to implement the statutory definitions for MFTs and MHCs in the CY 2024 Physician Fee Schedule proposed payment rule (88 FR 52262); the final rule implementing these definitions published in the **Federal Register** of November 16, 2023 (FR Doc. 2023–24184). We proposed to add a new requirement at § 485.904(b)(12), cross-referencing the definition of an MFT at § 410.53 and we proposed to modify the MHC personnel requirement at § 485.904(b)(5) by cross-referencing the definition of an MHC at § 410.54.

Comment: Several commenters shared their support for the inclusion of MFTs and MHCs in the personnel requirements and believe these practitioners will provide vital clinical resources to support PHP and IOP services. One commenter stated that adding MFTs and MHCs to the personnel requirements could help address the workforce shortages in underserved communities, and potentially increase the availability of mental health services at CMHCs. Another commenter expressed their support for the proposed provision stating that many MFTs and MHCs already work in a variety of community mental health settings.

Response: We thank these commenters for their support of these new proposals.

After consideration of public comments on this provision, we are finalizing these provisions at § 485.904(b) as proposed. The inclusion of the definition of MFT and modification of the definition of MHC to promote consistency and clarity of the CMHC personnel qualification of these providers.

4. Section 485.914 Admission, Initial Evaluation, Comprehensive Assessment, and Discharge or Transfer of the Client

We proposed to add ''intensive outpatient services'' to existing references for ''partial hospitalization services'' at § 485.914, which establish CMHC requirements for admission, initial evaluation, comprehensive assessment, and discharge or transfer of the client in accordance with sections 1835(a)(2)(F) and 1861(ff) of the Act. These CoPs identify general areas that would be included in a client assessment and the timeframes for completing the assessments to help the CMHC ensure it is identifying the needs in all areas in a timely fashion.

At § 485.914(a)(2), we proposed to revise the paragraph by referencing IOP requirements the CMHC must meet at proposed § 485.918(g). This standard for IOP is discussed later in section XVII.A.5 of this final rule with comment period. At § 485.914(d), we proposed to add a reference to IOP services. This standard requires that the CMHC update each client's comprehensive assessment through the CMHC interdisciplinary treatment team, in consultation with the client's primary health care provider (if any), when changes in the client's status, responses to treatment, or goal achievement have occurred and in accordance with current standards of practice.

This update includes information on the client's progress toward desired outcomes, a reassessment of the client's response to care and therapies, and the client's goals. The CMHC interdisciplinary treatment team uses assessment information to guide necessary reviews and/or changes to the client's active treatment plan.[756]

Comment: Several commenters suggested that the IOP comprehensive assessment be updated no less frequently than every 60 days. The commenter noted the comprehensive

[756] *https://www.reginfo.gov/public/do/PRAOMBHISTORY?ombControlNumber=0938-1245#.*

assessment for IOP should be updated less frequently than for PHP, which would be consistent with the recertification requirements for IOP at 60 days and PHP at 30 days.

Response: We appreciate the commenters suggestions to coordinate the time frames for the update of the comprehensive assessment and the recertification of IOP to both occur at 60 days. We note that we did not propose any modifications to the comprehensive assessment time frame. We believe that for both PHP and IOP, a 60-day time frame between assessments would not support the most current changes in the client's behavioral health needs and could potentially put the client's health and safety at risk. We note that clients with ongoing behavioral health needs may be subject to frequent and/or rapid changes in status, thereby affecting the type and frequency of services that are updated in the client's active treatment plan and furnished by the CMHC.

After consideration of public comments on this provision, we are finalizing the provisions at § 485.914(d) as proposed. The inclusion of IOP in the ''update of the comprehensive assessment'' standard will support our responsibility to protect clients' health and safety by ensuring all CMHC clients receive care based on their most current assessed needs.

5. Section 485.916 Treatment Team, Person-Centered Active Treatment Plan, and Coordination of Services

We proposed to modify language at § 485.916(d) to incorporate IOP programs into requirements for active treatment plans in CMHCs and proposed to include a specific cross-reference to the proposed requirement for payment of IOP services at § 424.24(d), which is discussed in section VIII.B.3 of this final rule with comment period. The proposal reflected existing requirements in § 485.916(d) that CMHCs meet partial hospitalization program requirements specified under § 424.24(e). Review and update of the CMHC client's person-centered active treatment plan plays an integral role in guaranteeing the provision of care and services offered by the CMHC.

The active treatment plan must be updated with current information from the client's comprehensive assessment and information concerning the client's progress toward achieving outcomes and goals specified in the active treatment plan. The active treatment plan is reviewed at specified intervals but no less frequently than every 30 calendar days. The revised active treatment plan must include information from the client's initial evaluation and comprehensive assessments, the client's progress toward outcomes and goals specified in the active treatment plan, and changes in the client's goals. As noted above, the CMHC must meet PHP requirements specified under § 424.24(e). As such, we proposed to include IOP service requirements the CMHC must meet as specified under § 424.24(d), as applicable, if such services are included in the active treatment plan.

Comment: We received several comments requesting we revise the CoPs at § 485.916(a)(1) and (3). Specifically, at § 485.916(a)(1) commenters asked that MFTs and MHCs be added to the members that can lead the interdisciplinary team. In addition, commenters asked that MFTs and MHCs be identified as interdisciplinary team members at § 485.916(a)(3). Commenters stated that including MFTs and MHCs will clarify that these practitioners may lead and be members of the CMHC interdisciplinary teams.

Response: We appreciate the commenter's suggestions to add MFTs and MHCs to the list of practitioners who may lead and be a member of the interdisciplinary team. We agree with the commenter's suggestion to add MFTs and MHCs to the list of practitioners who may lead an interdisciplinary team and have modified the language at § 485.916(a)(1). We believe making this revision can increase flexibility for the CMHC and allow diversity in team leadership. However, we do not agree with the suggestion to add MFTs or MHCs under § 485.916(a)(3), the standard describing who may be included in the interdisciplinary team. The items and services set out in paragraph (a)(3) follow the clinical providers set forth in 1861(ff)(2) of the Act, and MFTs and MHCs are not specifically listed. We believe that MFTs and MHCs fall under paragraph (a)(3)(vi) (other licensed mental health professionals, as necessary). The current language in this requirement allows CMHCs the flexibility to utilize appropriate counselors, including MFTs and MHCs, who may serve on the client's interdisciplinary team.

Final action: After consideration of public comments on this provision, we are finalizing the provisions at § 485.916(d) as proposed. Additionally, we are finalizing language at § 485.916(a)(1) to include MFTs or MHCs as professionals who can lead the CMHC interdisciplinary team.

6. Section 485.918 Organization, Governance, Administration of Services, Partial Hospitalization Services

The CoP at § 485.918 establishes requirements for CMHC organization, governance, administration of services, and partial hospitalization services. We proposed to modify the section heading at § 485.918 by adding ''intensive outpatient services,'' such that the new section heading will be ''Organization, governance, administration of services, partial hospitalization services, and intensive outpatient services.''

At § 485.918(b), ''Standard: Provision of services,'' specifies a comprehensive list of services that a CMHC would be required to provide; this provision would implement section 1861(ff)(3) of the Act. We proposed to add IOP services to the requirement at § 485.918(b)(1)(iii) for the provision of services. These proposed changes would recognize IOP services, along with day treatment and PHP, as services that can be provided by a CMHC, other than in an individual's home or an inpatient or residential setting or psychosocial rehabilitation services.

We proposed to redesignate the current requirements at § 485.918(g) to § 485.918(h) and add a new standard for IOP services at § 485.918(g). This new requirement would specify the additional requirements a CMHC providing IOP services must meet based on the proposed requirements at §§ 410.2, 410.44, 410.111, and 424.24(d). See sections VIII.B.2 and VIII.C.2 of this final rule with comment period for a discussion of these additional requirements.

Comment: One commenter suggested that the coverage of IOP services by Medicare be extended beyond CMHCs to include any licensed Medicare provider. They also stated that Medicare coverage should extend the full continuum of care for mental health and substance use disorder treatment across all services.

Response: We recognize that access to behavioral health services is an important need for Medicare beneficiaries. Starting January 1, 2024, Medicare will cover IOP services furnished in hospitals, CMHCs, RHCs, and FQHCs. In addition, CMS is finalizing coverage of IOP services furnished at Opioid Treatment Programs (OTPs) for the treatment of Opioid Use Disorder using the existing statutory authority at section 1861(jjj)(1)(F) and 1834(w) of the Act. The statute sets forth covered services for all provider types, and at this time only these providers may furnish IOP services.

Comment: We received several comments requesting that we revise the CoPs at § 485.918(b)(1)(vi) to specifically list MFTs similarly to the other practitioners who may lawfully provide psychotherapy services in a CMHC.

Response: Section 485.918(b)(1) requires CMHCs to provide a set of services. These services align with the requirements in section 1861(ff)(2)(A) of the Act. Additionally, § 485.918(b)(1)(vi) requires a CMHC to provide individual and group psychotherapy utilizing a psychiatrist, psychologist, or other licensed mental health counselor, to the extent authorized under State law. This requirement aligns with the items and services outlined in the statute, and MFTs or MHCs are not specifically listed. However, we note that MFTs and MHCs would be included in this provision under ''other licensed mental health counselor, to the extent authorized under State law.''

After consideration of public comments on this provision, we are finalizing the changes to § 485.918 as proposed. The inclusion of IOP throughout this provision promotes consistency and clarity of IOP services in a CMHC.

6. Request for Information Regarding the Impact of the Proposed IOP Requirements on CMHC Populations and Meeting the 40 Percent Requirement

In the CY 2024 OPPS/ASC proposed rule (88 FR 49847), we stated our interest in better understanding the impact of providing IOP services on the requirement that CMHCs provide at least 40 percent of their items and services to individuals who are not eligible for benefits under title XVIII of the Act, as specified at § 485.918(b)(1)(v) [757] and section 1861(ff)(3)(B)(iii) of the Act. Under this requirement, CMHCs must submit a self-attestation certification statement upon initial application to enroll in Medicare, and as a part of revalidation, including any off-cycle revalidation, noting the CMHC's compliance with this requirement. Medicare enrollment will be denied or revoked in instances in which the CMHC fails to provide the certification statement as required. We solicited public comment on how the provision of IOP services may impact the populations CMHCs serve as well as the potential impact on meeting the 40 percent requirement.

Comment: Many commenters requested clarification on the CMS interpretive guidance (IG) addressing the 40 percent requirement. Specifically, commenters asked CMS to clarify that the percentage of services furnished to non-Medicare-eligible persons is determined based on all clients who received care at CMHCs, not based solely on the provision of services coinciding with the PHP and IOP services that Medicare-certified CMHCs may provide.

Response: Thank you for the suggestion to update the CMHC Interpretive Guidance. The Medicare State Operations Manual (SOM), Appendix F (CMHC Interpretive Guidance) is identical to our regulations at § 485.918(b)(1)(v) without change, and states that the 40 percent is measured by the *total* number of CMHC clients treated by the CMHC for whom services are not paid for by Medicare, divided by the total number of clients treated by the CMHC for each 12-month period of enrollment.[758] This computation is done with respect to the whole behavioral health service array furnished by the Medicare-certified CMHC and not only those who receive PHP/IOP or similar services covered by another payor. We acknowledge that the interpretive guidance mirrors the regulation text and does not expand on the regulation. However, at this time we do not believe the interpretive guidance for this requirement must be updated.

Comment: Several commenters requested that CMS monitor concerns relating to the provision of services by Medicare-enrolled CMHCs to dual-eligible beneficiaries. Specifically, commenters encouraged CMS to monitor and require state Medicaid agencies to monitor the challenges faced by CMHCs obtaining secondary payment from state Medicaid agencies for PHP and IOP services.

Response: We appreciate the commenters concerns and suggestions regarding CMS monitoring for issues related to obtaining secondary payment from State Medicaid Agencies. However, note that this is outside the scope of this final rule with comment period. We agree this is an important issue and will share this information with the appropriate CMS component for their review.

Comment: We received many comments regarding the impact of the standard at § 485.918(b)(1)(v), requiring CMHCs provide at least 40 percent of its items and services to individuals who are not eligible for benefits under title XVIII of the Act. The commenters believe that because Medicare will cover a wider range of outpatient behavioral health services via PHP and IOP, it may encourage more community behavioral health providers to enroll as Medicare-certified CMHCs. The commenters also stated that the inclusion of IOP services and the potential growth in the number of Medicare-certified CMHCs providing care would help make these services more broadly available to the Medicare population. One commenter believes that the total number of clients served would only slightly increase when Medicare covers IOP services in CMHCs. The commenter also stated that for those community behavioral health entities enrolling as a CMHCs Medicare provider, furnishing IOP services would be an opportunity to provide more intensive services to Medicare clients who require them and a step towards aligning the benefits covered under State Medicaid programs. One commenter stated that many clients will likely be directly admitted into the IOP program, as their IOP program already admits clients from other insurance companies. This commenter also stated that generally, half of their PHP clients step down to the IOP level of care, and that they currently admit clients to the IOP level of care who are receiving office-based therapy. This commenter does not expect the 40 percent requirement to be an issue when adding the Medicare IOP service level to their services.

Response: We appreciate the feedback we received regarding the 40 percent rule. We will continue to consider this further.

XVIII. Updates to Requirements for Hospitals To Make Public a List of Their Standard Charges

A. Introduction and Overview

1. Statutory Basis and Background

Section 1001 of the Patient Protection and Affordable Care Act (Pub. L. 111–148), as amended by section 10101 of the Health Care and Education Reconciliation Act of 2010 (Pub. L. 111–152), amended Title XXVII of the Public Health Service Act (the PHS Act), in part, by adding a new section 2718(e). Section 2718 of the PHS Act, titled ''Bringing Down the Cost of Health Care Coverage,'' requires each hospital operating within the United States (U.S.) for each year to establish and update and make public a list of the hospital's standard charges for items and services provided by the hospital, including for diagnosis-related groups established under section 1886(d)(4) of the Social Security Act (the Act).

[757] *https://www.reginfo.gov/public/do/PRAOMBHISTORY?ombControlNumber=0938-1245#.*

[758] *https://www.cms.gov/files/document/som107apfcmhc.pdf.*

Section 2718(b)(3) of the PHS Act requires the Secretary of the Department of Health and Human Services (Secretary) to promulgate regulations to enforce the provisions of section 2718 of the PHS Act, and, in so doing, the Secretary may provide for appropriate penalties.

In a final rule dated November 2019 (84 FR 65524) (herein referred to as the CY 2020 HPT final rule), we adopted requirements for hospitals to make public their standard charges in two ways: (1) as a comprehensive machine-readable file (MRF); [759] and (2) in a consumer-friendly format. We codified these requirements at 45 CFR part 180. We also explained our belief that these two different methods of making hospital standard charges public are necessary to ensure that such data are available to consumers of healthcare where and when they are needed, including through data aggregation methods (for example, via integration into price transparency tools, electronic health records (EHRs), and consumer apps), and direct availability to healthcare consumers searching for hospital-specific charge information. Additionally, we believe such data can be used specifically by employers, researchers, and policy officials, and other members of the public to drive competition and help bring more value to healthcare.

Subsequently, in the CY 2022 OPPS/ASC final rule with comment period (86 FR 63941), we strengthened the hospital price transparency (HPT) enforcement scheme in order to improve compliance rates and made other updates to the requirements. Specifically, we (1) increased the penalty amount for noncompliance through the use of a scaling factor based on hospital bed count; (2) deemed state forensic hospitals that meet certain requirements to be in compliance with the requirements of 45 CFR part 180, and (3) prohibited certain conduct that we concluded were barriers to accessing the standard charge information, specifically including prohibiting hospitals from coding their MRF in a fashion that made it inaccessible to automated searches and direct downloads.

In both of those final rules, we stated that our policies requiring public release of hospital standard charge information are a necessary and important first step in ensuring transparency in prices of healthcare services for consumers. We also recognize that the release of hospital standard charge information is not itself sufficient to achieve our ultimate price transparency goals. The regulations are, therefore, designed to begin to address some of the barriers that limit price transparency, with a goal of increasing competition among healthcare providers to bring down costs. Competition in the healthcare industry benefits consumers because it helps contain costs, improve quality, expand choice, and encourage innovation.[760]

2. General Comments

Comment: All commenters, including, for example, hospitals and hospital associations, IT developers, researchers, employers, payers, healthcare consumers, and consumer advocates, expressed general support for transparency in healthcare pricing. Many expressed appreciation that CMS has made healthcare price transparency a priority, including CMS' commitment to continual refinement of the regulatory requirements across all its price transparency initiatives, including Hospital Price Transparency (HPT), Transparency in Coverage (TIC), and the No Surprises Act (NSA). Commenters explained that patients, plan sponsors, and employers need easily understandable cost and quality information to encourage the use of high-value care options, citing the financial stress caused by medical bills and the need to effectively manage healthcare expenses. Many commenters expressed the view that price transparency efforts are integral in supporting a transition to value-based care. One commenter stated their belief that the societal benefit of pricing disclosure would be substantial as transparency enables comparison shopping and competitive dynamics to contain prices and noted that, as hospitals and insurers continue to invest resources and effort to build the technology and administrative infrastructure for pricing disclosure the incremental burden of compliance would steadily diminish.

Response: We appreciate the overwhelming support for CMS price transparency initiatives, which include HPT, TIC, and the NSA. We agree with commenters who believe that price transparency can stimulate provider competition, empower healthcare consumers, and result in lower healthcare costs. We agree that transparency in healthcare pricing is integral to supporting a transition to value-based care. We further agree that transparency in healthcare pricing is a societal benefit that can facilitate competition and comparison shopping to lower healthcare costs, and that the burden on providers and payers should decrease over time.

Comment: Many commenters were generally supportive of the statutory requirement for hospitals to disclose their standard charges, noting that such transparency stimulates provider competition to lower health care costs and can also benefit healthcare consumers by providing them with more accurate information and choice in their care. One commenter specifically recognized HPT data disclosure as a necessary first step in achieving these goals and encouraged CMS to take bolder steps to lower costs and make healthcare more affordable by increasing transparency of healthcare information with employers, researchers, and policymakers as the primary audience. Other commenters continue to express opposition to the requirement for disclosing hospital standard charges, stating that more regulation is not the answer and that payers, not providers, should be responsible for disclosing pricing information to the public. One commenter characterized hospital standard charge information as 'extraneous' and expressed concern that their disclosure may cause patients to delay care as they seek to understand the information.

Response: We agree that disclosure of hospital standard charges represents a critical first step for stimulating provider competition and facilitating consumer shopping to lower health care costs. We continue to disagree that making standard charges public would deter patients from seeking necessary care. Rather, as we explained in the CY 2020 HPT final rule, we believe that disclosure of this information, once presented in a consumer-friendly manner, allows consumers to include price considerations in their treatment plan for elective procedures, which may result in their selecting the most appropriate setting for their care and increased patient satisfaction (84 FR 65541).

Comment: One commenter expressed the belief that CMS does not have authority and discretion to require price transparency disclosure, including negotiated rates. Hospitals and patient advocates alike indicated that hospital standard charges fail to provide patients with individualized cost of care information, such as an individual's out-of-pocket costs or 'guaranteed, real

[759] We have previously generally described the machine-readable file (MRF) as a single digital file that is in a machine-readable format (as defined at 45 CFR 180.20), and we are finalizing the proposal to codify that definition in our regulations.

[760] *https://www.justice.gov/atr/health-care#:~:text=Competition%20in%20the%20healthcare%20industry,and%20to%20prevent%20anticompetitive%20conduct.*

prices in dollars.' One commenter requested that CMS require hospitals to make public their standard charges ''in dollars and cents'' and asserted that anything less would ''violate the intent of the regulation.'' Hospital commenters expressed concern that display of hospital standard charges serves only to lead to scrutiny of hospital operations and have generated ''unfounded ire'' and been used as ''a sounding board for special interest groups'' and allowed third-party payers to ''lowball payment proposals,'' thereby harming competition. One hospital commenter observed that, instead of providing directly actionable information to patients, the current requirements are more useful for academic studies, health care finance professionals and insurance companies, which use the data to compare rates among peers.

Response: The HPT regulation implements sections 2718(b)(3) and (e) of the PHS Act and represents a significant first step toward increasing competition through transparency of hospital standard charges. As we stated in the CY 2020 HPT final rule, we believe there is a direct connection between transparency in hospital standard charge information and having more affordable healthcare and lower healthcare coverage costs. We believe healthcare markets could work more efficiently and provide consumers with higher-value healthcare if we promote policies that encourage choice and competition. As we have stated on numerous occasions, we believe that transparency in healthcare pricing is critical to enabling patients to become active consumers so that they can lead the drive towards value. (84 FR 65526) As we stated in the CY 2020 HPT final rule, we continue to encourage hospitals to provide consumers with cost information in a consumer-friendly manner.

To be clear, as upheld by the courts, we have authority to require hospitals to disclose payer-specific negotiated charges. We continue to believe that disclosure of hospital standard charges, including payer-specific negotiated charges, is critical for driving competition and are pleased that the intended users of this information, including payers, [761] researchers,[762] providers, employers,[763] [764] [765] policy officials, innovators,[766] industry experts,[767] and other members of the public are actively using the information to develop consumer-friendly displays, compare rates, drive efficiencies and lower costs.

As we explained in the CY 2020 HPT final rule, each of the standard charges were chosen specifically because they are relevant to a specific group of consumers, including the rate negotiated between a hospital and third-party payer which is a critical component for determining an individual's out-of-pocket obligations. Thus, we finalized a requirement for hospitals to disclose the rate they have negotiated with third party payers (a standard charge called the 'payer-specific negotiated charge' defined at 45 CFR 180.20). As explained in more detail in XVIII.B.3.b of this final rule with comment period, hospitals establish their payer-specific negotiated charges in various ways which may result in the display of a payer-specific negotiated charge in dollars or as an algorithm, depending on what payer-specific negotiated charge meets the definition of a 'standard charge'. In the CY 2020 HPT final rule, we concluded that ''requiring hospitals to post on the internet a machine-readable file containing a list of all standard charges for all items and services would be a good first step for driving transparency in healthcare pricing because the access to such data would allow integration into price transparency tools or into EHR systems for use at the point of care or otherwise where and when the information is necessary to help inform patients.'' Thus, while the data contained in a MRF is critical for driving competition and directly beneficial for patients, the MRF format is designed to be used by machines for further processing of the data and is not tailored for direct use by individual patients. In short, MRF formats are not consumer friendly.

In recognition of this, we finalized a requirement in the CY 2020 HPT final rule for hospitals to make public a subset of standard charges for some frequently provided hospital services in a form and manner that we believed would be more directly available to individual patients and consumer friendly. Specifically, we finalized a requirement for hospitals to make public some standard charges for common services for which healthcare consumers may have the opportunity to shop, in a consumer-friendly manner, or, alternatively, offer an online price estimator tool that ''[a]llows healthcare consumers to, at the time they use the tool, obtain an estimate of the amount they will be obligated to pay the hospital for the shoppable service.'' (45 CFR 180.60) Since finalizing these policies, additional Federal price transparency initiatives that rely on other authorities that more directly empower consumers with pricing information have been, or are in the process of being, implemented. Specifically, since publication of the CY 2020 HPT final rule in 2019, the TIC rule (85 FR 72158, finalized in 2020) and the NSA (enacted as part of the Consolidation Appropriations Act of 2021) have been promulgated or enacted. Information about these additional Federal price transparency authorities can be found in the Request for Information in the CY 2024 OPPS/ASC PPS proposed rule (88 FR 49552).

We acknowledge and agree with commenters that, although critical for determining an individual's out-of-pocket obligation, hospital standard charges do not represent either an individual's out-of-pocket obligation or a ''real, guaranteed price.'' However, we note that individualized estimates in dollars may be obtained directly, in many circumstances, from providers and payers through other Federal price transparency efforts such as those implementing the NSA and TIC requirements. As such, we strongly encourage individual consumers to avail themselves of hospital and payer price estimator and comparison tools, and to seek out 'good faith estimates' from hospitals which, in order to comply with separate requirements implementing the NSA, may provide up-front pricing that can be used to dispute final charges that are substantially in excess of the up-front

[761] Pierce, S. Why BlueCross Blue Shield Tennessee is Renegotiating Provider Network Contracts. The Tennessean. August 18, 2022. Available at: *https://www.tennessean.com/story/opinion/2022/08/18/bluecross-blue-shield-tennessee-health-insurance-contracts/10333329002/.*

[762] Mouslim, M., Henderson, M. How New Data on Hospital ''Discounted Cash Prices'' Might Lead to Patient Savings. Health Affairs. November 8, 2021. Available at: *https://www.healthaffairs.org/do/10.1377/forefront.20211103.716124/full/.*

[763] Minemyer, P. New Playbook Aims to Help Employers, Plan Sponsors Negotiate Hospital Prices. Fierce Healthcare. September 8, 2022. Available at: *https://www.fiercehealthcare.com/payers/new-playbook-aims-help-employers-plan-sponsors-negotiate-hospital-prices.*

[764] Hansard, S. One County Combed Hospital Data to Slash Health Plan Costs 43 percent. Bloomberg. February 6, 2023. Available at: *https://news.bloomberglaw.com/health-law-and-business/employer-health-plan-eyes-43-savings-from-payment-data-audits.*

[765] Hansard, S. Employer, Hospital Tensions Rise Over Price Transparency. Bloomberg. August 2, 2022. Available at: *https://news.bloomberglaw.com/health-law-and-business/tensions-between-employers-hospitals-up-with-transparency-push.*

[766] Turquoise Health. Patients- Shop Healthcare Like You Shop Anything Else. Available at: *https://turquoise.health/patients.*

[767] Smith, C., et al. Hospital Price Transparency Data: Case Studies for How to Use It. Milliman. May 3, 2022. Available at: *https://us.milliman.com/en/insight/hospital-price-transparency-data-case-studies-for-how-to-use-it.*

amounts.[768] Additionally, as we stated in the CY 2020 HPT final rule, we continue to encourage hospitals to provide consumers with cost information in a consumer-friendly manner.

Furthermore, we understand the desire for individual patients to access hospital prices in dollars and cents. We believe that the policies we are finalizing in this final rule with comment period are consistent with our authority under section 2718(e) of the PHS Act and will greatly improve the transparency of payer-negotiated rates, including whether the standard charges should be interpreted by the user as a dollar amount, or if the standard charges are based on a percentage or algorithm. We discuss in XVIII.B.3.b.(2) of this final rule with comment period a new requirement to include an estimated allowed amount (referred to as the 'consumer-friendly expected allowed amount' in the CY 2024 OPPS/ASC proposed rule) which is designed to provide contextual information to the payer-specific negotiated charge when it can only be expressed as a percentage or algorithm.

Additionally, we welcome the scrutiny and discussion related to healthcare financing, which we believe are important for driving needed cost efficiencies in the healthcare marketplace, putting patients first, and ultimately empowering patients and their clinicians to make value-based decisions. We will continue to educate interested parties about CMS price transparency initiatives in general and the intent and limitations of the hospital price transparency regulations for consumers in particular.

In summary, we continue to affirm that the HPT regulations requiring hospitals to make public standard charges are a necessary and important first step for driving competition and in ensuring transparency in healthcare prices for the public, but that, while foundational, the release of hospital standard charge information is not sufficient by itself to achieve our ultimate goals for price transparency for driving competition in the marketplace or for consumer shopping. Additional barriers must be overcome to promote healthcare market efficiencies and for individual patients to identify appropriate sites of care for needed services, determine out-of-pocket costs in advance, and utilize indicators of quality of care to make value-based decisions. We believe authorities granted to CMS through, for example, TIC and the NSA are specifically designed to address some of the additional barriers for individual patients. As such, we strongly encourage individual consumers to avail themselves of hospital and payer price estimator and comparison tools, and to seek out 'good faith estimates' from hospitals which, in order to comply with separate requirements implementing the NSA, may provide up-front pricing that can be used to dispute final charges that are substantially in excess of the up-front amounts.[769]

Comment: Several commenters made comments related to the overall direction of the proposed policies as a whole. Many commenters, for example, generally supported the proposals, stating they agreed the proposals would strengthen price transparency through data standardization and additional enforcement tools, although one commenter stated their belief that some proposals would ''substantially weaken and rollback existing law'' without specifying a particular law.

Several commenters expressed concern related to the additional burden imposed on hospitals by the proposed requirements, and the short timeline for implementation. At least one commenter requested that CMS hold off on any new HPT requirements until such time as other price transparency initiatives, such as the NSA, are fully implemented. Additionally, the commenter noted that Congress is currently considering multiple pieces of legislation that would, if implemented, affect price transparency activities, and that CMS should await the outcome of all current legislative proposals before either proposing or finalizing any additional changes to HPT regulations.

Response: We appreciate the support we received from many commenters for the proposals, which we believe will strengthen HPT through standardization of hospital MRFs and expansion of enforcement tools. Additionally, we believe the benefits of these proposals to the public outweigh the burden on hospitals. However, after consideration of the comments, we are finalizing a phased implementation timeline (as described in XVIII.B.3.c of this final rule with comment period) for hospitals to implement the changes that we are finalizing in this final rule with comment period. We do not believe we should pause our efforts to improve the HPT regulations while we await implementation of companion price transparency initiatives, such as the NSA, because we believe the HPT requirements we proposed to modify are complementary to those efforts. We did, however, seek comment on alignment related to the consumer-friendly display requirements at § 180.60 that we may consider in future rulemaking. Although we are aware of various legislative efforts that may, at some point in the future, affect hospital price transparency, we do not view that potential possibility as a reason to put on hold our efforts to strengthen the current HPT regulations.

3. Summary of Final Policies

In this final rule with comment period, we are finalizing our proposals to revise several of our HPT requirements in order to improve our monitoring and enforcement capabilities by improving access to, and the usability of, hospital standard charge information; reducing the compliance burden on hospitals by providing CMS templates and technical guidance for display of hospital standard charge information; aligning, where feasible, certain HPT requirements and processes with requirements and processes we have implemented in the TIC initiative; and making other modifications to our monitoring and enforcement capabilities that will, among other things, increase its transparency to the public. Specifically, we are finalizing: (1) definitions of several terms; (2) a requirement that hospitals make a good faith effort to ensure standard charge information is true, accurate, and complete, and to include a statement affirming this in the MRF; (3) new data elements that hospitals must include in their MRFs, as well a requirement that hospitals encode standard charge information in a CMS template layout; (4) a phased implementation timeline applicable to the new requirements we are finalizing in this final rule with comment period; (5) a requirement that hospitals to include a .txt file in the root folder that includes a direct link to the MRF and a link in the footer on its website that links directly to the publicly available web page that hosts the link to the MRF; and (6) improvements to our enforcement process by updating our methods to assess hospital compliance, requiring hospitals to acknowledge receipt of warning notices, working with health system officials to address noncompliance issues in one or more hospitals that are part of a health system, and publicizing more information about CMS enforcement

[768] *https://www.cms.gov/files/document/nosurpriseactfactsheet-whats-good-faith-estimate508c.pdf.*

[769] *https://www.cms.gov/files/document/nosurpriseactfactsheet-whats-good-faith-estimate508c.pdf.*

activities related to individual hospital compliance.

Specifically, and as discussed in more detail below, we are finalizing that the effective date of the changes to the hospital price transparency regulations at 45 CFR part 180 will be January 1, 2024. However, the regulation text will specify later dates by which hospitals must be in compliance with some of these new requirements, and we will begin enforcing those requirements on those specified dates.

B. New Requirements for Making Public Hospital Standard Charges Under 45 CFR 180.50

In the CY 2020 HPT final rule, we finalized, at 45 CFR 180.50, specific requirements with which hospitals must comply for the purpose of making public a single comprehensive list of standard charges for the items and services they provide, including requirements that govern the format, data elements, location and access to the list, as well as the frequency by which they must update the list.

In this section, for the reasons discussed below, we proposed to substantially modify § 180.50(a) through (d) of our regulations, which govern some of the requirements for how hospitals must make public their standard charges for all items and services they provide. Specifically, we proposed to (1) define several new terms; (2) require hospitals to affirm the accuracy and completeness of the standard charges displayed in the MRF; (3) require hospitals to display additional data elements in their list of standard charges; (4) require display of standard charge information using a CMS template; and (5) adopt new requirements to improve automated access to the machine-readable file.

1. New Definitions

We proposed to add the following definitions to § 180.20:

- ''CMS template'' is a CSV format or JSON schema that CMS makes available for purposes of compliance with the requirements of § 180.40(a).
- ''Consumer-friendly expected allowed amount'' is the average dollar amount that the hospital estimates it will be paid by a third party payer for an item or service.
- ''Encode'' is entering data items into the fields of the CMS template.
- ''Machine-readable file'' is a single digital file that is in a machine-readable format.

We also proposed several technical and conforming revisions to ensure consistency of the use of these terms across the HPT regulations. Specifically, we proposed to replace references to ''the file'' and ''the digital file'' in § 180.50(d)(4) through (5) with the proposed defined term ''machine-readable file.'' We also proposed to make revisions to references to the ''file'' in the introductory text of § 180.50(c) and at § 180.50(e), which we addressed in the CY 2024 OPPS/ASC proposed rule as a part of other proposed changes.

We received a few comments on our proposed definitions.

Comment: One commenter recommended that the term ''consumer-friendly expected allowed amount'' be modified to reflect an emphasis on using patient claims to calculate an average dollar amount, and to permit grouping at the service package level. One commenter objected to defining a 'consumer-friendly expected allowed amount' as an 'average,' stating that a 'consumer-friendly expected allowed amount' should instead be the expected dollar amount to be charged to the healthcare consumer. A few commenters suggested alternative names, indicating that, as proposed, the term is cumbersome, using extra verbiage that is unnecessary, and could be misleading to consumers. These commenters suggested renaming the term ''estimated average price'' or ''average historical allowed amount'', or a revision to the definition to indicate that the amount is the average amount received by the hospital in the past, rather than suggesting it is the amount the hospital expects to receive in the future.

Response: We thank the commenters for their detailed comments on the proposed definition. Because the comments related to the definition itself are inextricably intertwined with the proposal to add the consumer-friendly ''expected allowed amount'' as a new data element and the method of its calculation, we will address them in more detail in XVIII.B.3.b.(2) of this final rule with comment period. For reasons described there, we decline to revise the definition to be more prescriptive regarding the underlying data hospitals use to establish this data element or to revise it to indicate that it is representative of the dollar amount a hospital would charge to an individual patient. We note that the definition of ''items and services'' is inclusive of service packages, thus we do not believe the definition requires the suggested modification for that reason. We agree that the term ''consumer-friendly expected allowed amount'' is cumbersome and could generate confusion for individuals about the limitations of this allowed amount as an estimate, rather than a cost guarantee. We are therefore revising the definition to reflect that the amount is based on the average amount the hospital has historically received from the payer, rather than an average amount the hospital expects to receive from the payer. Additionally, we will revise the term to ''estimated allowed amount'' in response to comments indicating that this data point, while necessary to contextualize the standard charges established by the hospital, is not particularly consumer-friendly.

Comment: One commenter stated that the definition of ''encode'' is technically imprecise. The commenter indicated that rather than meaning 'to enter' information into a template, the term means taking information and converting it to a particular form or specification.

Response: We thank the commenter for raising this concern and agree that the definition of ''encode'' could be more precise. According to the Oxford Advanced American Dictionary, to ''encode something'' in a computing context means ''to change information into a form that can be processed by a computer.'' [770] This definition captures the policy goal underlying the standardization requirements we are finalizing in this final rule with comment period, which is that the MRF display standard charge information that the hospital has converted into the form and manner we specify in § 180.50(c). We will therefore finalize that the term ''encode'' means ''to convert hospital standard charge information into a machine-readable format that complies with § 180.50(c)(2).''

Comment: We received one comment on each of our proposed definitions of ''machine-readable file'' and ''CMS template.'' One commenter indicated that the term ''machine-readable file'' is circular because ''machine-readable'' appears in both the term and its definition. Another commenter suggested improving the definition of ''CMS template'' to indicate that existing hospital files would need to transition from already established CSV files into a new mandated format.

Response: We appreciate the opportunity to clarify the definitions of ''machine-readable file'' and ''CMS template.'' We do not believe the definition of ''machine-readable file'' is circular because it refers to the defined term ''machine-readable format'' which

[770] *https://www.oxfordlearnersdictionaries.com/us/definition/american_english/encode#:~:text=encode%20something%20(computing)%20to%20change,be%20processed%20by%20a%20computer.*

also appears in 45 CFR 180.20. Regarding the definition of ''CMS template,'' we clarify that in order to comply with § 180.40(a), CMS is finalizing a requirement at § 180.50(c)(2) that would require hospitals to conform to the CMS template layout, data specifications, and data dictionary for purposes of making public their standard charge information. A detailed discussion of this requirement is found in XVIII.B.3.c of this final rule with comment period in which we discuss the CSV formats and JSON schema from which hospitals may choose. We believe the regulatory expectation for hospitals to conform to a CMS template layout is clear and therefore decline to revise the definition of ''CMS template.''

Comment: One commenter suggested we revise the definition of ''negotiated rate'' to refer to both simple fee schedule dollar amounts as well as the proposed consumer-friendly ''expected allowed amount.''

Response: We believe the commenter was referring to the defined term ''payer-specific negotiated charge'' because the regulations at 45 CFR 180.20 do not include a definition for ''negotiated rate'' and we did not propose to add a definition of this term in the CY 2024 OPPS/ASC proposed rule. The term ''payer-specific negotiated charge'' is defined at 45 CFR 180.20 as ''the charge that a hospital has negotiated with a third party payer for an item or service'' and it is also referenced in the definition of ''standard charge'' as being one type of standard charge. As explained both in this section and in more detail in section XVIII.B.3.b.(2)(b) of this final rule with comment period, we are finalizing the definition of ''estimated allowed amount'' as the average dollar amount that the hospital has historically received from a third party payer for an item or service. The estimated allowed amount would not meet the definition of a standard charge because estimates and averages do not meet the definition of a 'payer-specific negotiated charge,'

Final action: After consideration of comments, we are finalizing the following definitions at § 180.20:

- ''CMS template'' is a CSV format or JSON schema that CMS makes available for purposes of compliance with the requirements of § 180.40(a).
- ''Encode'' is converting hospital standard charge information into a machine-readable format that complies with § 180.50(c)(2).
- ''Estimated allowed amount'' is the average dollar amount that the hospital has historically received from a third party payer for an item or service.
- ''Machine-readable file'' is a single digital file that is in a machine-readable format.

Additionally, we are finalizing as proposed several technical and conforming revisions to ensure consistency of the use of these terms across the regulation. Specifically, we are finalizing our proposal to replace references to ''the file'' and ''the digital file'' in § 180.50(d)(4) through (5) with the newly defined term ''machine-readable file.''

2. Requirement That Hospitals Affirm the Accuracy and Completeness of Their Standard Charge Information Displayed in the MRF

We stated in the CY 2024 OPPS/ASC proposed rule that since we implemented the HPT regulations, we have received questions from the public regarding the accuracy and completeness of the standard charge information displayed by hospitals. Similar questions have also arisen in the course of our enforcement activities. Although section 2718(e) of the PHS Act requires hospitals to make public each standard charge the hospital has established, a hospital may not have established certain types of standard charges defined by the regulation. For example, under our current regulations, a hospital that has not established any discounted cash prices for any item or service would not have any discounted cash prices to display in its MRF. Depending on the type of MRF format chosen by the hospital, the file may contain 'blanks' without explanation. Although a hospital that chooses to leave the discounted cash price field blank under this scenario would (with respect to this element) be in compliance with our regulations, a user of the MRF count not be certain whether the hospital had not established such charges, or, instead, had not complied with the requirement to disclose them in the MRF. Although many hospitals include explanatory information on the web page associated with the MRF or within the MRF itself (for example, in a CSV format, inserting 'N/A' in blank cells or adding an explanatory note), they currently do so on a voluntary basis.

We indicated in the CY 2024 OPPS/ASC proposed rule that we believe that requiring the hospital to affirm the accuracy and completeness of its MRF would lessen the potential for public confusion as to whether the MRF is accurate and complete by clarifying that blank cells left in some formats (such as CSV which can be opened in a human-readable format) are intentional. Specifically, an affirmation would streamline our assessments of hospital compliance by removing ambiguity surrounding blank cells and the overall accuracy and completeness of a hospital's MRF. We therefore proposed to require that each hospital affirm directly in its MRF (using a CMS template, which we proposed in more detail at XVIII.B.2 of the CY 2024 OPPS/ASC proposed rule) that it has included all applicable standard charge information in its MRF as of the date in the MRF. We indicated our belief that requiring the hospital to add this affirmation directly in its MRF would make it clear to the public that the affirmation relates directly to that MRF and would mitigate the potential for confusion if we only required that the affirmation appear on a website that links to the hospital's MRF, especially if that website also links to other hospital MRFs.

We therefore proposed to add new paragraph (a)(3) at § 180.50 to require that, in its MRF, each hospital add a statement affirming, to the best of its knowledge and belief, that the hospital has included all applicable standard charge information in its MRF, in accordance with the requirements of § 180.50, and that the information displayed is true, accurate, and complete as of the date indicated in the file.

We sought comment on the proposal.

Comment: Several commenters supported or strongly supported the proposal to require hospitals to include an affirmation of the accuracy and completeness of standard charge information in the MRF because the statement in the MRF would provide assurance to users of the files that the data contained within them are accurate and complete to the best of the hospital's knowledge and belief. These commenters further agreed that including this statement in the MRF is better than requiring an affirmation to reside at a location separate from the file. One commenter requested clarification as to whether the affirmation would be made by the hospital at the organizational level, as opposed to being made personally by an individual hospital official, while another recommended that CMS require a senior hospital official to make the affirmation.

One commenter indicated their belief that it would be impossible for hospitals to make such an attestation when CMS has the sole authority to determine hospital compliance and argued that ''CMS does not mandate attestation for other CMS requirements, apart from equity, which has recently been introduced.''

Response: We appreciate the support for our proposal. We clarify that we are only requiring the hospital as an organization to make the affirmation.

Although we acknowledge that HPT enforcement is CMS' role, the law puts the responsibility on hospitals to establish and make public complete and accurate standard charge information. Additionally, there are many instances in which CMS requires regulated entities to make statements of accuracy and completeness, for example: Qualifying Medicare Advantage Organizations are required to attest that they are meaningful EHR users (42 CFR 495.210) and are required by CMS to certify as to the accuracy and completeness of its requests for payment from CMS (42 CFR 422.504(l)); Accountable Care Organizations in the Medicare Shared Savings Program must attest that certain information submitted to Medicare is true, accurate, and complete (42 CFR 425.302); Merit-based Incentive Payment System (MIPS) eligible clinicians must certify that the data and information they submit to CMS for the purposes of MIPS is true, accurate, and complete (42 CFR 414.1390); and Entities that contract with the State under a separate child health program must certify the accuracy, completeness, and truthfulness of information in contracts and proposals, including information on subcontractors, and other related documents, as specified by the State (42 CFR 457.945), finally, a hospital CFO or Administrator must certify that the information submitted to CMS in its annual cost report is true, correct, and complete, to the best of their knowledge and belief.[771]

Comment: A few commenters questioned why such an affirmation would be necessary because they indicated they are already putting forth good faith efforts to ensure MRF data are accurate and complete by virtue of posting the information. Others welcomed this additional requirement stating they viewed it as an opportunity to communicate to the public their good faith effort to comply.

A few interested parties commented on the intent or purpose of the affirmation, stating the affirmation should be used as an additional layer for enforcement and oversight, rather than using it to streamline enforcement, or that it be paired with continued strong enforcement. Other commenters viewed the proposed affirmation the hospital would make as part of the MRF as duplicative of the proposal to require a certification of completeness and accuracy by a hospital executive as part of the enforcement process (as discussed in XVIII.C.1 of this final rule with comment period).

Response: As we stated in the CY 2024 OPPS/ASC proposed rule, we believe an affirmation in the hospital's MRF will lessen public confusion related to the completeness of the data in the file and also improve CMS' ability to assess both the completeness and accuracy of the MRF, and that by improving assessment of compliance, CMS will improve its enforcement capabilities. We believe that a requirement that the hospital affirm the completeness and accuracy of the MRF is not duplicative of a requirement that an authorized hospital official certify the accuracy and completeness of the MRF if asked by CMS as part of the enforcement process (as discussed in XVIII.C.1 of this final rule with comment period) because the two requirements serve different purposes. The general affirmation statement within the MRF will provide some assurance to the public and to CMS that the hospital has made a good faith effort to ensure the data displayed is true, accurate, and complete, while a certification would be signed by an authorized hospital executive as part of a specific enforcement effort by CMS. Thus, we do not believe that requiring this policy would in any way erode our strong enforcement to which we are committed. If there is evidence to suggest a hospital has not made a good faith effort to make public its standard charge information accurately and completely, the public is invited to submit a complaint to CMS through its website so that CMS can conduct a comprehensive compliance review.

Comment: Several commenters requested that CMS delay the affirmation requirement, if we elected to finalize it, until hospitals have had adequate time to familiarize themselves with the new format and adapt their data accordingly. One commenter recommended that CMS add sample language to the CMS template.

A few commenters suggested additions or alternatives that were not proposed, including that CMS should: concurrently increase penalties or that CMS should require the statement to apply to both the machine-readable file and the consumer-friendly disclosures of the 300 shoppable services.

Response: We appreciate the suggestion for sample language and will finalize a modification to the proposal such that the hospital would be required in its MRF to affirm, rather than to include an affirmation statement, that the hospital, to the best of its knowledge and belief, has included all applicable standard charge information in accordance with the requirements of this section, and that the information displayed is true, accurate, and complete as of the date indicated in the machine-readable file. Specifically, we will include affirmation language in the MRF template which will read: ''To the best of its knowledge and belief, this hospital has included all applicable standard charge information in accordance with the requirements of 45 CFR 180.50, and the information encoded in this machine-readable file is true, accurate, and complete as of the date indicated in this file.'' To reduce hospital burden and maximize machine readability, we will require the hospital to encode either ''true'' or ''false'' as a valid value, where a value of ''false'' will generate a deficiency. Because, as described in XVIII.B.3.c of this final rule with comment period, hospitals will be required to adopt a CMS template format beginning July 1, 2024, this requirement to affirm the accuracy and completeness of the data would also be required beginning July 1, 2024. However, nothing in this final rule with comment period would preclude hospitals from voluntarily adding an affirmation statement to their existing MRFs immediately, and we encourage hospitals to do so.

Finally, we appreciate the additional suggestions offered by commenters, such as concurrently increasing penalties for noncompliance and extending the requirement for an affirmation apply to the hospital's consumer-friendly display. Because these policies were not proposed, we decline at this time to finalize them. However, we will evaluate the need for such changes in the future as we continue to evaluate hospital compliance and consider alignment with the consumer-friendly requirements under the TIC regulations and the NSA.

Comment: Several commenters opposed the proposal to require hospitals to affirm the completeness and accuracy of the standard charge information in the MRF because they believed that doing so would be ''operationally unfeasible'' because the complexity of the data would render it nearly impossible to validate or validate without mistakes. These commenters explained their belief that the inclusion of such an affirmation in the MRF would shift focus away from acknowledging good faith compliance efforts and instead mandate perfection, which could have legal implications.

[771] *https://www.cms.gov/files/document/medicare-cost-reporting-e-filing-system-user-manual.pdf.*

These commenters recommended that CMS provide a ''safe harbor policy'' for hospitals that make a good faith effort, which they believed would ensure reasonable accuracy without imposing undue burdens on hospitals or penalizing them for unintentional and minor data inconsistencies.

By contrast, some supporters of the proposal recommended that such an affirmation be used as an additional layer for enforcement rather than to just streamline the enforcement process. These commenters indicated their belief that the proposal should be strengthened by removing the statement ''to the best of the hospital's knowledge and belief'' and deeming such affirmations as ''material to payment,'' thereby incorporating potential liability under the False Claims Act (FCA) for hospitals that knowingly violate the rule and falsely attest to the accuracy and completeness of the file.

Response: We appreciate the public's need for assurance that the standard charge information contained in the MRFs are true, accurate, and complete, which is why we proposed that hospitals include an affirmation statement in the MRF. We believe inclusion of an affirmation statement by the hospital would serve to reassure the public, including CMS, that the hospital has made a good faith effort to present its standard charge information accurately and completely. As such, we disagree that it is operationally 'unfeasible' for a hospital to be accountable for the information they display publicly and to provide such an assurance to the public.

However, we also disagree with commenters that an affirmation would (or should) serve to establish a guarantee of perfection, because even with a good faith effort, mistakes may be made as hospitals encode potentially hundreds of thousands of data points, many of which, at least initially, may need to be encoded manually. Moreover, the standard charge information contained in the hospital MRF is not updated in real time, rather, in accordance with statute and 45 CFR 180.50(e), hospitals must update their files not less than annually. The FCA is outside the scope of this final rule with comment period.

We decline the commenters' recommendation to establish a ''safe harbor'' and finalize the requirement that hospitals include an affirmation of completeness and accuracy in the MRF, but we also finalize a requirement at § 180.50(a)(3)(i) that, effective January 1, 2024, hospitals make a 'good faith effort' to ensure the standard charge information displayed in the MRF is true, accurate, and complete. This additional language will emphasize our expectation of a good faith effort on the part of the hospital, and we disagree that such an expectation, and the ability to streamline CMS' assessment of hospital MRFs as a result, would diminish CMS' ability to enforce hospital standard charge information display requirements. To the contrary, we believe that requiring a hospital affirmation will impress upon hospitals their obligation to ensure the data they display is true, accurate, and complete, to the best of their knowledge and belief. Such an affirmation will not preclude CMS from taking enforcement action against a hospital that posts verifiably inaccurate or incomplete information, nor will it prevent CMS from requesting a certification from an authorized hospital executive as part of the enforcement process (addressed in more detail at XVIII.C.1 of this final rule with comment period).

Comment: A few commenters objected specifically to affirming the 'completeness' of the file, stating that this could be a challenge if the hospital cannot obtain reimbursement information from the insurance company. Others suggested that an affirmative indicator encoded in the file would go further in signaling the file's 'completeness.'

Response: We believe hospitals should have access to the documents and contracts that they signed with third party payers when they established their payer-specific negotiated charges, as well as records of the reimbursement received, and therefore these data should be available to them for encoding into the MRF. We decline to require indicators of non-applicability to be included in MRFs because we believe that would create additional burden for hospitals, and because they would be unnecessary by virtue of the affirmation statement.

Final action: After considering public comments, we are finalizing the proposal with modification. We finalize as proposed a requirement at § 180.50(a)(3)(ii) that, beginning July 1, 2024, the hospital must affirm in its MRF that, to the best of its knowledge and belief, the hospital has included all applicable standard charge information in its MRF, in accordance with the requirements of § 180.50, and that the information encoded is true, accurate, and complete as of the date indicated in the MRF. We also are finalizing a new general requirement at new § 180.50(a)(3)(i) that, beginning January 1, 2024, each hospital must make a good faith effort to ensure that the standard charge information encoded in the MRF is true, accurate, and complete as of the date indicated in the MRF.

3. Improving the Standardization of Hospital Machine-Readable File (MRF) Formats and Data Elements

In this section, we proposed to revise several requirements at § 180.50(b) and (c). We also proposed to adopt technical edits to other sections of the HPT regulations that are related to the revisions for alignment, conformity, and clarity.

a. Background

In the CY 2020 HPT final rule, we expressed our concern that lack of uniformity in the way that hospitals display their standard charges leaves the public unable to meaningfully use, understand, and compare standard charge information across hospitals (84 FR 65556). We stated that we agreed with commenters that standardization in some form is important to ensure high utility for users of hospital standard charge information, and we finalized an initial set of rules for making public all standard charges in an MRF at § 180.50. Section 180.50(a)(1) of our regulations states that a hospital must establish, update, and make public a list of all standard charges for all items and services online in the form and manner specified in that section, and § 180.50(a)(2) states that each hospital location operating under a single hospital license (or approval) that has a different set of standard charges than the other location(s) operating under the same hospital license (or approval) must separately make public the standard charges applicable to that location. If a hospital location operating under a single hospital license or approval shares the same set of standard charges as another hospital location operating under the same license or approval, then both hospital locations may post the same MRF. In other words, in the interest of burden reduction, hospital locations may share a file so long as the standard charge information displayed in the file are applicable to the indicated locations.

Section 180.50(b) of our regulations describes the required data elements that must be included, as applicable, in the hospital's MRF, which are the following:

- A description of each item or service provided by the hospital.
- The corresponding gross charge that applies to each individual item or service when provided in, as applicable, the hospital inpatient setting and outpatient department setting.
- The corresponding payer-specific negotiated charge that applies to each

item or service when provided in, as applicable, the hospital inpatient setting and outpatient department setting. Each payer-specific negotiated charge must be clearly associated with the name of the third party payer and plan.

- The corresponding de-identified minimum negotiated charge that applies to each item or service when provided in, as applicable, the hospital inpatient setting and outpatient department setting.
- The corresponding de-identified maximum negotiated charge that applies to each item or service when provided in, as applicable, the hospital inpatient setting and outpatient department setting.
- The corresponding discounted cash price that applies to each item or service when provided in, as applicable, the hospital inpatient setting and outpatient department setting.
- Any code used by the hospital for purposes of accounting or billing for the item or service, including, but not limited to, the CPT code, HCPCS code, DRG, NDC, or other common payer identifier.

When we finalized this set of standardized data elements, we stated our belief that they would help ensure that the public could compare standard charges for similar or the same items and services provided by different hospitals. Commenters had provided many additional suggestions for how to standardize the standard charge information displayed by hospitals, but we declined at the time to be more prescriptive in our approach. Instead, we indicated that we might revisit the requirements in future rulemaking should we find it necessary to make improvements in the display of and access to hospital standard charge information.

At § 180.50(c), the regulation specifies that the required (but ''as applicable'') data elements must be published in a single digital file that is in a machine-readable format. The term ''machine-readable format'' is defined at § 180.20 to mean a digital representation of data or information in a file that can be imported or read into a computer system for further processing.

Since we first implemented the regulation in January 2021, feedback in reports developed and made public by interested parties, particularly from IT specialists, researchers, employers, and others, indicates that more standardization of the files (including a specified template and standardization of additional contextual data elements) may be necessary to improve the public's use and understanding of, and ability to make comparisons among, hospital standard charge information.[772] [773] [774] [775] [776] In particular, IT specialists have indicated that the current flexibilities and lack of encoding specifications hinder the machine-readability of the data in the files, presenting a barrier to the intended use of the data. Additionally, hospitals have asked us for more specificity on how they should publicly display their standard charge information, with an emphasis on how they should explain and display their payer-specific negotiated charges. Some hospitals have suggested that a template developed by CMS could be useful to improve hospital compliance and reduce hospital burden. Further, the flexibilities that the current regulation permit insofar as the format of hospital standard charge information, and the very limited set of data elements required to be displayed under § 180.50, have presented an enforcement challenge. For example, because hospitals are permitted to display their information using a wide variety of file formats and data encoding practices, we must manually, via time and resource-intensive processes, review the information in the files to assess whether the information is consistent with the data element requirements at § 180.50(b). Some hospitals rename data elements, include additional data elements, or exclude, without explanation, data elements that are not applicable, which can make it difficult to assess whether the information contained in the file is accurate and complete. This, in turn, slows compliance reviews and often requires us to engage in one-on-one discussions with hospitals. We therefore came to believe that requiring more specificity in formatting and encoding the MRFs, as well as increasing the number of required corresponding data elements that hospitals must provide, would not only create efficiencies for public users of the MRFs and our efforts to enforce the requirements, but also improve the meaningfulness of the hospital's standard charges.

As a result, in the CY 2022 OPPS/ASC proposed rule (86 FR 42321), we sought comment on improving standardization of the data disclosed by hospitals in the MRF. In response, many commenters urged CMS to create a standard template for hospitals to use for posting their MRF, noting that such standardization could ease operational burdens, improve the public's (including employers and researchers) ability to make price comparisons across hospitals, and better enable third party data aggregation services to develop user-friendly patient tools for displaying this information. Some commenters recommended that CMS work with providers and vendors to better understand the benefits of a standard template. Some hospitals also urged CMS to be more prescriptive, requesting that CMS standardize the MRF format and contents and provide additional clarification on how hospitals should indicate that they have not established all five types of standard charges for a particular listed item or service.

We requested that the HHS Health Federally Funded Research and Development Center (FFRDC) [777] more fully explore the feasibility of these commenters' recommendations and identify technical specifications and categories of information (referred to as ''data elements'') that we could consider proposing in future rulemaking to improve the usability and meaningfulness of the standard charges display. The FFRDC convened a technical expert panel (TEP) and used the TEP members' advice to make informed recommendations to CMS in the summer of 2022.[778] The TEP was comprised of both MRF developers, (specifically, hospitals representatives of large and small acute and specialty care hospitals), and primary users of MRF data, (specifically, researchers and IT innovators). The TEP members discussed the challenges and complexities of displaying, in a meaningful way, all hospital standard charges in an MRF. The TEP members noted that increasing standardization of the MRF and the number of required data elements may improve the public's ability to make price comparisons across hospitals. TEP members indicated their

[772] *https://www.healthsystemtracker.org/brief/ongoing-challenges-with-hospital-price-transparency/.*

[773] *https://energycommerce.house.gov/events/improving-drug-pricing-transparency-and-lowering-prices-for-american-consumers.*

[774] *https://familiesusa.org/wp-content/uploads/2023/04/Power-of-Price-Transparency-final-4.19.23.pdf*

[775] *https://blog.turquoise.health/hospital-compliance-assessments/.*

[776] *https://static1.squarespace.com/static/60065b8fc8cd610112ab89a7/t/60de0380cc0972060d0354eb/1625162631437/PRA+OPPS+Recommendations+June+2021%5B3%5D.pdf.*

[777] MITRE operates HHS' Health FFRDC, a federally funded research and development center. For more information, see: *https://www.mitre.org/our-impact/rd-centers/health-ffrdc.*

[778] MITRE, Hospital Price Transparency Machine-Readable File Technical Expert Panel Report and MITRE Recommendations to the Centers for Medicare & Medicaid Services, November 2022. *https://mitre.box.com/v/MITRE-MRF-TEP.*

belief that public display of hospital standard charge information is an important step toward price transparency for hospital items and services but cautioned that hospitals use different methods to establish standard charges for items and services, resulting in charge/item and charge/service combinations that are often unique to that hospital. Therefore, some direct comparisons of hospital standard charges may continue to be a challenge if such comparisons are made under the assumption that hospitals always use the same methods to establish their standard charges and that the same charge/item and charge/service combinations are consistent across hospitals. As such, attempting to use hospital standard charges in isolation, without additional contextual information, can result in erroneous conclusions and comparisons. The members went on to discuss the potential benefits to both hospitals and the public if CMS required hospitals to display standard charge information that better described or contextualized their standard charges, including standard charge information related to complex contracting arrangements between hospitals and third party payers. The TEP also weighed the benefits with the potential burden hospitals would incur to display those new data elements and encode data in a more specified way.

First, the TEP members discussed what general machine-readable format(s) would be best suited to display hospital standard charges. The TEP members indicated that the ideal formats would be those that are non-proprietary, as they are widely and freely available to the MRF developers (the hospitals) and users (for example, IT developers and researchers). The TEP members then considered different types of non-proprietary formats, and first considered whether a single non-proprietary format, such as JSON, should be recommended because of its ability to represent hierarchical relationships better than tabular non-proprietary formats, such as CSV. JSON's use of a hierarchical format could be beneficial because it would eliminate the need to leave data fields, sometimes numerous, blank if the hospital has no applicable corresponding information. However, TEP members noted that existing hospital systems often produce files in CSV, and that smaller, less-resourced, hospitals often lack the in-house capacity to develop and manage a JSON file. The TEP members therefore suggested that hospitals have a choice of JSON and CSV formats. The TEP members also discussed the specific technical layout of a CSV file, including a:

- ''tall'' format, with separate payer and plan data elements that provide the benefit of static header naming with less opportunity for standardization error and that is similar to existing output files that many hospitals are using to build their MRFs; and
- ''wide'' format, with variable payer-specific negotiated charge data elements that incorporate the payer and plan name into a single column header; this may reduce the file size because many data elements would not need to be repeated as frequently.

Ultimately, the FFRDC, as informed by TEP members, recommended to CMS that CMS provide hospitals with an option to use one of three layouts representing two types of machine-readable formats for displaying their standard charge information in an MRFs: (1) JSON schema (plain format), (2) CSV (''tall'' format), or (3) CSV (''wide'' format). TEP members indicated that this choice would balance the need for greater standardization for automated machine use of the files, while providing a hospital some flexibility to select the least burdensome format and layout to incorporate into its current MRF development process.

The TEP also discussed the data elements, or categories of standard charge information, that they believed should be included in the MRF, with a goal of improving the public's understanding and use of hospital standard charges. These discussions focused on the challenges of displaying payer-specific negotiated charges, given the variety of ways that hospitals establish this type of standard charge, and data elements that would be necessary to help the public understand them. TEP members discussed several types of commercial contracting methodologies commonly used by hospitals to establish their payer-specific negotiated charges, including: fee schedule, case rate, per diem, percentage of total billed (or gross) charges, and others. Ultimately, the TEP agreed on the following data elements to improve the meaningfulness and facilitate automated aggregation of hospital standard charges: (1) general information such as file version and date of most recent update of the file; (2) hospital-specific information (such as hospital name and location, license number, financial aid policy); (3) data elements corresponding to the types of standard charges defined by the HPT regulation (that is, the gross charge, payer-specific negotiated charges by payer and plan, discounted cash price, and minimum and maximum de-identified negotiated rates) and, for payer-specific negotiated charges, the type of contracting methodology and whether the payer-specific negotiated charge established by the hospital is being expressed as a dollar amount versus an algorithm or percentage; and (4) data elements that enhance understanding of the item or service to which the standard charge applies, such as a general description of the item/service, billing class (for example, whether the standard charge is billed as a facility or professional service), the hospital setting in which the item or service is provided (for example, the inpatient or outpatient setting), drug-specific information such as the drug unit and type of measurement (such as number of milligrams), and information related to corresponding codes (such as common billing codes, revenue center codes, modifiers). TEP participants also suggested including an open field that a hospital could use, as needed, to provide additional contextual information should it believe the template's data elements are insufficient to ensure a user's understanding of a standard charge displayed in the file.

The TEP members discussed a number of other data elements,[779] but concluded that the burden on hospitals to gather and display such information would outweigh their benefit to users, or that it would be infeasible to include such information in an MRF. As such, the FFRDC did not recommend that CMS adopt them.

The FFRDC presented its findings and recommendations to CMS in the fall of 2022. After considering them, we announced in November of 2022 the availability of several 'sample formats,' that may be found on the HPT

[779] Those data elements included: 'Billing Code Version' which would be the version of a code set used by providers and payers; 'Unit of Measurement' which would be used for items and services other than drugs; 'Place of Service Code' used by Medicare to indicate where in a hospital a service would be provided; 'Insurance Plan ID' such as a Health Insurance Oversight System (HIOS) identifier779 or employer identification number (EIN) of the payer; 'Contract Expiration Date' to indicate how long a contract would be in place; 'Bundled Codes' which would indicate all individualized items and services that comprised a payer-specific negotiated rate or discounted cash price; 'Covered Services' which would indicate all the codes for services covered under a capitation arrangement; and a 'Payment Learning & Action Network' field which would indicate whether the hospital's commercial contract met criteria for different types of value-based arrangements as defined by the Learning & Action Network's Alternative Payment Model Framework (*https://innovation.cms.gov/innovation-models/health-care-payment-learning-and-action-networ*).

website,[780] that hospitals could voluntarily use to make public their standard charge information in an MRF. At the same time, we developed and made available a supplemental data dictionary that provides technical instructions to hospitals on how to conform to the sample formats and encode standard charge information. The sample formats and data dictionary can be found on the HPT website: *https://www.cms.gov/hospital-price-transparency/resources.* We encouraged commenters to review the sample templates and data dictionary to inform their comments on these proposals. Additionally, we hosted a webinar [781] to educate interested parties about the voluntary sample formats. In the webinar, we highlighted differences between the voluntary sample formats and the CMS templates as proposed and encouraged interested parties to adopt one of the sample formats and submit comments on the proposals through the **Federal Register** by the indicated due date.

Comment: Many commenters supported improving standardization of the hospital's MRFs, stating that such standardization is crucial for researchers and policymakers to access and analyze the data, and for the development of consumer facing tools used to display prices. Commenters agreed that such standardization would also serve to support CMS' enforcement efforts.

A few commenters expressed strong opposition to the proposals for standardization, stating their belief that the proposals are 'extreme' and would make hospital standard charge information 'unusable' for patients and too complex and burdensome for hospitals to complete.

Response: We appreciate the support for improving standardization of the hospital's MRF and agree that greater standardization will benefit public use of hospital standard charge information, including for promoting competition and developing consumer-facing healthcare pricing tools. We also agree that standardization will further strengthen and support CMS assessment and enforcement efforts by streamlining its processes through, for example, automation. We disagree that the proposals related to standardization are 'extreme' or would be too complex and burdensome for hospitals to complete. To the contrary, efforts were undertaken by the FFRDC to develop recommendations for standardization that reflected feedback from small and large hospitals with a goal of balancing the need to improve the clarity and context of hospital standard charges with the burden of the data collection effort. We therefore believe the proposals for improving standardization represent a balanced approach and that hospitals will be able to achieve compliance. We do not agree with the premise that hospital standard charge information must be directly usable for patients, and we continue to believe that the hospital's standard charges are a necessary and important first step in ensuring transparency in healthcare prices. As explained in the CY2024 OPPS/ASC proposed rule, we believe that standardization in display, as finalized in this rule, will help provide both hospitals and the public with some assurance of hospital compliance with 45 CFR 180.50 and facilitate more meaningful use of these data by the public. We continue to believe this is the case because we believe standardization will promote a common understanding of the data displayed in the file, thus mitigating misunderstandings of both hospitals and the public about hospital standard charges that are required for display under this regulation.

b. Requirement That Hospitals Encode All Data Items for Additional Data Elements in Their MRF

(1) Encoding, as Applicable, All Data Items in the MRF

Currently, the introductory text at § 180.50(b) states that a hospital must include all of the data elements (as specified in the paragraph) in its list of standard charges, ''as applicable.'' We proposed to revise the introductory text for clarity to indicate that each hospital must encode, as applicable, all standard charge information corresponding to each required data element in its MRF.

That proposed revision would differentiate the standard charge information, or data values, that must be encoded in the MRF from the ''data elements,'' or categories of data as the basis for the CMS template. The term ''data element'' is currently used at § 180.50(b) in both ways, which, at the time we implemented the regulations, seemed appropriate because of the wide latitude of flexibility we were giving hospitals to display their standard charges. However, now that we have proposed to require hospitals to display complete standard charge information for an expanded set of data elements and to be much more prescriptive in how such data is encoded, we indicated that we believe that adopting more precise terminology will make the display requirements easier to understand.

In making the proposal, we indicated our belief that this revision was necessary in light of our other proposals to be more prescriptive in the form and manner in which hospitals display their standard charge information and would clarify that the term ''data element'' refers to a required category of data items encoded in the MRF, and not the standard charge information itself.

Under our proposal, we stated that the term ''as applicable'' would no longer refer to data elements and instead would qualify the standard charge information that the hospital encodes in the MRF. Hospitals would thus be required to encode their MRF with all applicable standard charge information that corresponds to each of the required data elements. We noted that the phrase ''as applicable'' does not mean that encoding standard charge information that corresponds to a required data element is ''optional.'' Rather, if a hospital has established standard charge information for a required data element at proposed new § 180.50(b)(1) through (4), the hospital would be required to display that information accurately and completely, in its MRF.

Final action: We did not receive any specific comments related to the proposal. We are finalizing a technical revision to redesignate the policies finalized in this final rule with comment period related to required data elements under new § 180.50(b)(2). We are therefore finalizing a revision to the introductory text at § 180.50(b)(2) for clarity to indicate that unless otherwise specified in § 180.50(b)(2), beginning July 1, 2024, each hospital must encode, as applicable, all standard charge information corresponding to each required data element in its MRF. Additionally, as discussed in XVIII.B.2 of this final rule with comment period, we are finalizing a related requirement that each hospital make a good faith effort to ensure that the standard charge information encoded in the MRF is true, accurate, and complete as of the date indicated in the MRF.

(2) Revising and Expanding the Required Data Elements

At new § 180.50(b)(1) through (4), we proposed to revise and expand the required data elements which describe the categories of information the hospital must encode in its MRF. We proposed to include most of the data elements suggested by the TEP and recommended by the FFRDC in its

[780] *https://www.cms.gov/hospital-price-transparency/resources.*

[781] The sample format webinar slides and recording can be found on the CMS website: *https://www.cms.gov/hospital-price-transparency/resources.*

report to CMS,[782] and noted that many of the proposed data elements are incorporated in the CMS 'sample formats' currently available for voluntary use by hospitals on CMS' HPT website.[783]

We proposed to require hospitals to encode all applicable standard charge information for an expanded set of data elements in their MRF, noting our belief that they would improve the public's ability to better understand, and, therefore, more meaningfully use hospital standard charges. We stated that we believed this expanded set of data elements will make hospital standard charges more understandable and comparable across hospitals. We decided to make these proposals after considering: the feedback discussed above; our experience with enforcing the current HPT requirements; the FFRDC recommendations as informed by their TEP; and our evolving understanding of how hospitals establish payer-specific negotiated charges with third party payers.

We indicated that we agree with the feedback we have received from various interested parties, the FFRDC recommendations, and publicly available reports that the machine-readable data needs to be contextualized and more precisely encoded to improve the public's ability to understand and use hospital standard charges. We stated that we believed that this could largely be accomplished by requiring hospitals to conform to a CMS template layout and encode all applicable standard charge information in a consistent form and manner specified by CMS.

Comment: Several commenters expressed general support for revising and expanding data elements indicating that inclusion of some of the additional data elements will help with the identification and utilization of the standard charge information. One commenter objected to including any data element that was not also recommended by the FFRDC. Another suggested that any new data elements should be gradually incorporated into the file over time, enabling hospitals to create and encode the information accurately.

By contrast, several commenters objected to including any new data element, including recasting existing required information as separate data elements (such as whether an item or service is provided in the inpatient or outpatient setting), stating that CMS should require hospitals to adopt a standardized format for only the existing required data elements as they are currently described. Several commenters indicated their belief that including additional data could render the files inaccessible to most of the public due to size and present a burden for hospitals because they would have to manually collect and encode the data.

A few commenters renewed their concerns that no data element, let alone additional data elements, would achieve the aims of hospital price transparency and provide information to individual patients related to out-of-pocket costs, nor would they be able to fit every hospital's contracting approaches, including contracting approaches related to value-based purchasing contracts.

Response: We appreciate the support for the proposal and agree with commenters that including some additional data elements will help with the identification and utilization of the hospital's standard charge information. For example, (as discussed in section XVIII.B.3.(2) of this final rule with comment) we are finalizing a policy for hospitals to include an estimated allowed amount in order to bring context to a payer-specific negotiated charge when such a charge can only be expressed as a percentage or algorithm, rather than a standard dollar amount. In the CY 2020 HPT final rule, and for the reasons we discussed there, we defined and finalized payer-specific negotiated rates as a type of standard charge that, in accordance with the law, a hospital must make public, and continue to affirm that such standard charges are fundamental for determining an individual's out-of-pocket costs. For reasons discussed in the CY 2024 OPPS/ASC proposed rule, we believe that expanding the data elements will provide needed context to hospital standard charges. Although these requirements may increase the file size, we believe these changes will ultimately make the data in the MRF more readily available to the public because it will be easier to be machine read and interpreted/summarized in order to facilitate consumer-friendly displays. We appreciate the additional burden on hospitals. Responses to these comments can be found in the economic analysis at section XXVI of this final rule with comment period. Additionally, we are modifying the timeline for implementation (in section XVIII.B.3.c of this final rule with comment period) to provide hospitals more time to fully comply.

We agree with commenters who pointed out that hospital contracting approaches are varied and challenging for the public to understand, including for individual patients. Because of this, as indicated in the CY 2024 OPPS/ASC proposed rule, we believe the expansion of data elements is necessary and will add clarity to the contracting approaches the hospital has employed in the process of establishing its standard charges, and, in particular, its payer-specific negotiated charges. We further agree that not all payment arrangements negotiated by hospitals and third party payers, such as value-based payments, will necessarily result in the establishment of a standard charge for a specific item or service provided by a hospital or be easily encoded in a MRF. For example, a hospital may have agreed to receive a 'per member per month' payment from the payer for each member of the payer's plan which remains the same amount, regardless of the number or types of hospital items and services provided during a month. Although we believe such negotiated charges can play a role in driving competition, they can be difficult for a hospital to encode in its MRF and even more difficult to those who seek to use hospital pricing data to assess or estimate individual costs or to compare across hospitals for particular items or services. We therefore reiterate that the intended use of the data in the MRFs is to drive competition because competition in the healthcare industry benefits consumers by helping to contain costs, improve quality, expand choice, and encourage innovation,[784] including innovations for using hospital standard charges to facilitate consumer shopping. Further, in order to assist hospitals and improve standardization, we will keep these various contracting methodologies in mind as we develop technical guidance and examples for including them in the MRF.

Comment: A few commenters supported requiring data elements that are currently included in the voluntary sample templates as a result of the recommendations made by the FFRDC TEP, but that we did not propose to require. For example, a few commenters recommended requiring hospitals to include their financial aid policy in the MRF, indicating that doing so would be helpful for researchers studying prices, medical debt, and predatory billing practices, and enable patients to access

[782] MITRE, Hospital Price Transparency Machine-Readable File Technical Expert Panel Report and MITRE Recommendations to the Centers for Medicare & Medicaid Services, November 2022. *https://mitre.box.com/v/MITRE-MRF-TEP.*

[783] *https://www.cms.gov/hospital-price-transparency/resources.*

[784] *https://www.justice.gov/atr/healthcare#:~:text=Competition%20in%20the%20healthcare%20industry,and%20to%20prevent%20anticompetitive%20conduct.*

hospital financial aid policies as they examine the MRF's pricing data. One commenter suggested that CMS should go further and require hospitals to display their financial aid or charity care policy on a hospital website.

Several other commenters expressed disappointment that CMS did not propose to include ''billing class'' as a required data element. Commenters explained that knowing the ''billing class'' is necessary to distinguish between facility and professional standard charges because there are many instances where hospitals display the same item or service (with the same description and billing code) but have different standard charges. These commenters noted that the current hospital price transparency regulation requires hospitals to disclose their standard charges for all items and services, including those provided by employed physicians and nonphysician practitioners.

Response: We appreciate the additional suggestions for data elements. Although we decline at this time to require hospitals to encode these additional data elements because we did not propose them, we will not prohibit hospitals from including them in the CMS template. To aid standardization of the ''billing class'' and ''financial aid policy'' should hospitals wish to voluntarily include these data, CMS will include recommended technical instructions in the CMS templates and data dictionary located in a CMS GitHub repository. We will continue to consider whether these additional data elements would improve the meaningfulness of hospital standard charge information and may revisit them for inclusion in future rulemaking.

(a) Requirement To Encode General Data Elements

We proposed in new § 180.50(b)(1) that hospitals would be required to encode standard charge information for each of the following ''general'' data elements: Hospital name(s), license number, and location name(s) and address(es) under the single hospital license to which the list of standard charges apply.

Under the proposal, a hospital would be required to include the location to which its list of standard charges applies within the MRF itself, instead of simply on its website, as is currently required at 45 CFR 180.50(d). We stated our belief that this change is necessary because we have found that a single public website may host several hospitals' files and identify each hospital location in text on the web page. Because the hospital location is currently not listed on the file itself, the hospital information sometimes becomes disassociated from the file as it is further processed, making it difficult for end users of the data to connect standard charge information to a particular hospital, hospital location, or address. This is a result we did not intend when we finalized the initial display requirements in the CY 2020 HPT final rule. We stated we believed that requiring hospitals to encode standard charge information for these data elements directly in the MRF would permit the public, including end users creating various aggregation tools, to connect the standard charge information in the file to a particular hospital's site of care as they seek to make the information more actionable. Additionally, we noted that the current requirement at § 180.50(a)(2) indicates that each hospital location operating under a single hospital license (or approval) that has a different set of standard charges than the other location(s) operating under the same hospital license (or approval) must separately make public the standard charges applicable to that location. However, there is no current requirement for a hospital to indicate under what license the hospital is operating, making enforcement of this requirement challenging. We explained that by including the license number of the hospital in the file, CMS would better be able to validate and ensure that hospitals are complying with the requirements because CMS would be able to directly connect the hospital name, license, and MRF.

- The file version and date of the most recent update to the standard charge information in the MRF.

We proposed that hospitals indicate in their MRF the file version that corresponds to the CMS template that the hospital is using to display the standard charge information. File version information is necessary to provide certainty to users of the file (including CMS for purposes of automating review of MRFs) that they have coded to the correct format for processing the data. We further noted that hospitals are currently required at § 180.50(e) to update, at least once annually, the standard charge information in the MRF and to clearly indicate the date that the standard charge information was most recently updated. Hospitals also currently have the flexibility to indicate the updated date in the file itself or otherwise in a manner that is clearly associated with the file. We noted that such flexibility would be eliminated with the proposal because, if finalized, we would require the date of last update to be indicated in the file itself. We therefore proposed to make a necessary corresponding revision to § 180.50(e) to remove the sentence ''The hospital must clearly indicate the date that the standard charge data was most recently updated, either within the file itself or otherwise clearly associated with the file.'' Requiring a hospital to include the date of the last update in the file itself is necessary for a machine to be able to automatically validate that the standard charge information in the file has been updated by the hospital at least once annually, as is required under section 2718(e) of the PHS Act and 45 CFR 180.50(e). Moreover, by placing the date of the most recent update within the MRF, we stated that file users would be assured that the file they are using is the most recently available. Finally, we indicated that nothing in the proposal would prohibit a hospital from continuing to also indicate the date of the last update on its website in addition to indicating the date of the last update within its MRF.

Comment: Most commenters expressed broad support for requiring hospitals to encode general information including the hospital name(s), license number, and location name(s) and address(es) under the single hospital license to which the list of standard charges apply, as well as the file version and most recent date of update. These commenters indicated that the additional hospital information would ensure that users of the file can match MRFs found on hospital websites to specific hospital locations where items and services are provided for the standard charges indicated in the file. Additionally, commenters expressed appreciation for including the file version and date of last update as necessary to code to the correct schema and ensure the use of the most recent data posted by the hospital.

By contrast, a few commenters specifically objected to the proposed requirement to include hospital address(es) as a new data element. These commenters indicated their belief that the proposal would impose burdensome requirements to list every address at which the hospital furnishes items or services, including each hospital outpatient department that uses the same standard charges. One commenter went on to explain that they interpreted the CY 2024 OPPS/ASC proposed rule's intent to move current hospital location information under paragraph (d)(2) into the data encoded in the machine-readable file but not to require the addition of new name and address information for every hospital

outpatient department, which could represent hundreds of locations.

Response: We appreciate the broad support expressed by commenters for hospitals to include general information about the hospital and file. We agree this information is necessary to ensure hospital compliance with requirements at § 180.50(a)(2), (d)(2), and (e) and improve the data's clarity and use for the public. Under § 180.50(a)(2), each hospital location operating under a single hospital license (or approval) that has a different set of standard charges than the other location(s) operating under the same hospital license (or approval) must separately make public the standard charges applicable to that location. Under § 180.50(d), hospitals must ensure that the standard charge information in the MRF is ''clearly identified with the hospital location with which the standard charge information is associated.'' As we explained in the CY 2020 HPT final rule, we believed it would be sufficient for a hospital to post a single file of standard charges for a single campus location, if the file includes charges for all items and services offered at the single campus location. In cases where such off-campus and affiliated sites operate under the same license (or approval) as a main location but have different standard charges or offer different items and services, these locations would separately make public the standard charges for such locations (84 FR 65564). Therefore, hospitals will be required to include both the geographic location of the hospital (for example, ''123 Main Street, Baltimore, MD'') as well as the location name of the campus (for example, Smithville Campus), in addition to the hospital license under which the location operates. As we indicated in the CY 2024 OPPS/ASC proposed rule, we believe that requiring hospitals to encode standard charge information for ''these data elements'' (referring to the hospital name(s), license number, and location name(s) and address(es)) directly in the MRF would permit the public, including end users creating various aggregation tools, to connect the standard charge information in the file to a particular hospital's site of care as they seek to make the information more actionable. Additionally, we believe that including location information (including the address(es)) in the MRF will ensure hospital compliance with the requirements of § 180.50(a)(2). However, we agree with commenters that if the hospital has established a single set of standard charges for all inpatient and outpatient departments across many different locations, it could be cumbersome to list all their location names and addresses in a single MRF. To reduce burden, we will therefore finalize a modification to the requirement. Specifically, we will require that hospitals encode the name(s) and address(es) of each hospital inpatient location and each standalone emergency department in the MRF. While strongly encouraged, it will not be required to encode all outpatient locations. We note, however, that even though we are making this practical accommodation, hospitals must still include all standard charge information in the MRF, including standard charge information for outpatient locations not encoded for this data element. In other words, this accommodation should not be interpreted to mean that hospitals need not include the standard charges that apply to outpatient locations that operate under the single hospital license but whose location names and addresses are not required to be encoded. We believe this change will reduce burden and make the requirement technically feasible for even very large health systems that have a single set of standard charges across many inpatient and outpatient locations.

Comment: A few commenters made suggestions for additional general data elements. One commenter recommended requiring hospitals to encode their CMS Certification Number (CCN) in the MRF, stating their belief that most hospitals have CCNs and they are more universal than state license numbers. One commenter requested guidance for how a state-owned hospital, for which some states may not issue a license number, should encode licensure information in the MRF.

Response: At this time, we decline to require hospitals to include their CCN in the MRF because this data point is unrelated to the requirements of § 180.50. As discussed above, as finalized, hospitals would be required to encode standard charge information for all data elements, as applicable. Therefore, if a hospital does not have a hospital license number, the field would be left blank because there would be no applicable information to encode.

Final action: After considering public comments, we are making a technical revision to finalize required data elements under new § 180.50(b)(2), and finalizing as proposed new § 180.50(b)(2)(i) that will require a hospital to encode standard charge information for each of the following ''general'' data elements:

- Hospital name(s), license number, and location name(s) and address(es) under the single hospital license to which the list of standard charges apply. Location name(s) and address(es) must include, at minimum, all inpatient facilities and stand-alone emergency departments.
- The version number of the CMS template and the date of the most recent update to the standard charge information in the machine-readable file.

We believe these data elements will improve CMS' assessment of hospital compliance with the requirements of § 180.50 and will improve the public's ability to effectively use the data by encoding to the correct format and correlating the standard charge information displayed in the file with the correct hospital and its location(s).

(b) Required Data Elements Related to Types of Standard Charges

First, we proposed, at proposed new § 180.50(b)(2), to consolidate into a single data element the standard charges (that is, the gross charge, payer-specific negotiated charge, de-identified minimum and maximum negotiated charge, and discounted cash price) that were currently listed as required data elements at § 180.50(b)(2) through (6). We noted that this revision would remove the phrase ''that applies to each individual item or service when provided in, as applicable, the hospital inpatient setting and outpatient department setting'' from each of the individually referenced type of standard charge at § 180.50(b)(2) through (6). We stated that this concept, however, would be retained and incorporated (as addressed in more detail below) as a separate data element (''setting'') and used to contextualize hospital items and services at new § 180.50(b)(3).

Comment: One commenter indicated that proposing consolidation of the types of standard charges into a single data element would be 'redundant' because hospitals are already required to make them public. Another expressed concern about consolidating the five types of standard charges into a ''single'' data element.

Response: We agree that hospitals are already required to make public in their MRFs the five types of standard charges identified as separate data elements at § 180.50(b)(2) through (6). Consolidating these data elements into a single data element and referring to the defined term ''standard charges'' reorganizes the regulatory text but does not change the requirements. In other words, we will continue to require hospitals to make public their standard charges for each of the five types of standard charges separately. We are therefore finalizing this as proposed.

Comment: One commenter specifically objected to separating out the ''setting'' as a separate data element due to burden.

Response: This comment is addressed in detail in section XVIII.B.3.b.(2)(c) of this final rule with comment period. For reasons discussed there, we are finalizing ''setting'' as a separate data element.

Final action: We are making a technical revision to finalize required data elements under new § 180.50(b)(2). We are thus finalizing as proposed the consolidation of existing § 180.50(b)(2) through (6) into a single requirement at new § 180.50(b)(2)(ii). We are also finalizing, as proposed, to establish ''setting'' as a separate data element; specifically, whether the item or service is provided in connection with an inpatient admission or an outpatient department visit.

Second, we noted that, under the proposal, we would continue to require that the payer-specific negotiated charges be displayed by name of the third-party payer and plan(s), each indicated as a separate data element (for example, ''payer name'' and ''plan name''). However, as a result of our acquiring a better understanding of hospital and commercial payer contracting, we proposed that hospitals may indicate plan(s) as categories (such as ''all PPO plans'') when the established payer-specific negotiated charges are applicable to each plan in the indicated category. We stated that this modification was necessary because we have learned that many hospital contracts are designed to negotiate the same rates across a grouping of payer plans, and not always on a plan-by-plan basis. For example, some hospitals have contracts stipulating that the payer-specific negotiated charges they establish with third party payers are for ''all plans'' offered by the third party payer, without specifying plan names. Similarly, a hospital's contract with a payer may set forth the payer-specific negotiated charges for ''all PPO plans'' or ''all managed care plans'' without listing specific plan names. As a result, hospitals would be required to indicate payer-specific negotiated charges that apply to ''Payer A'' for ''all PPO plans,'' for example, rather than having to research and insert repetitious standard charge information for each named PPO plan offered by Payer A. We indicated that we believed this modification was necessary to ensure hospitals are not penalized for displaying information that is consistent with their contracting practices. Moreover, we stated that this practice could improve access to the MRF by avoiding repetition of standard charge information that would unnecessarily increase file size. Additionally, because we proposed to require hospitals to encode standard charge information in an MRF that conforms to a CMS template layout, the use of such template would ensure that the payer-specific negotiated charges remain 'clearly associated' with the name of each payer and plan. Accordingly, we proposed to remove the phrase 'clearly associated' from the regulatory text as a separate and distinct requirement in relationship to the data elements. Finally, we are aware of interested parties' recommendations that the payer and plan be indicated in the MRF using some uniform, nationally applicable set of abbreviations. To the extent that a uniform nationally applicable set of abbreviations is available, we sought comment on a publicly available data source(s) that we could consider as we develop the technical instructions.

Comment: Several commenters expressed support and appreciation for allowing hospitals to indicate plan(s) as categories (such as ''all PPO plans'') when the established payer-specific negotiated charges are applicable to each plan in the indicated category, noting that this is a reasonable accommodation. A few commenters noted that they had a single contract with a payer that may tie to multiple plans, but that the hospital did not know the plan names assigned by the payer for all of the multiple plans. The commenters indicated that payers don't seem to have these data readily available for providers upon request. Overall, commenters agreed the proposed policy was practical and aligned with the realities of commercial contracting. Commenters agreed it would create efficiencies and reduce file size. One commenter indicated that contracts with payers will oftentimes indicate a line of coverage (such as ''Medicare Advantage'' or ''Commercial'' or ''Work Comp'') instead of a plan category (such as PPO, HMO, etc) and sought clarification on whether this situation would also be covered under the proposed exception. One commenter requested that CMS consider allowing hospitals to aggregate this information into groups of payors with similar contracting terms (that is, 102 percent of Medicare rates). This commenter explained that under the proposal, specific payors could be specified in a ''notes'' field of the template and stated this practice could further improve access to the MRF by avoiding repetition of standard charge information that would unnecessarily increase the file size of the MRF.

A few commenters appeared to misunderstand that we were not proposing to change the existing requirement that hospitals must clearly associate the payer-specific negotiated charges with the payer and plan. These commenters expressed concern that a requirement to list standard charges by payer and plan would be burdensome and make MRFs unwieldy, recommending that CMS take steps to protect hospital and payer names to prevent discernment of individual contracts. One commenter expressed concern that in the absence of specific plan names, users of the file may have some difficulty discovering exactly what plan or plans are included in contracting categories. Another commenter stated that the rationale discussed in the CY 2024 OPPS/ASC proposed rule for removing the phrase ''clearly associated'' was confusing because, under the proposal to allow general plan categories to be indicated, specific plan names may not always be associated with the standard charges going forward.

Response: We appreciate the support for the proposal and agree that providing hospitals with a method to address situations in which they do not know the specific plan names will serve to align this policy with contracting practicalities, support efficiencies, and avoid access challenges due to file size. We clarify that this policy would extend to plans included in a 'line of coverage' so long as the established payer-specific negotiated charges are applicable to each plan in the indicated category. We further clarify that this policy would be consistent with current CMS guidance.

We emphasize that we *did not* propose to revise the existing requirement that hospitals clearly associate the payer-specific negotiated charges with the payer and plan. Instead, we proposed to carve out an exception such that, in instances where the hospital, within the contract with the third-party payer, has negotiated the same payer-specific charges for a category of plans, the hospital may indicate the category of plans rather than the specific name(s) of the plans.

Comment: A few commenters supported specifications that would standardize the name of payers and plans in the MRF. Some commenters recommended that CMS require hospitals to encode, in a standardized way, the names of payers and plans. Although a few commenters stated their belief that standard payer and plan names exist, others supported our belief that there is no nationally recognized

source of such information. One commenter suggested that CMS revive the National Plan Identifier.

A few commenters supported the development of specifications for categories of plans. One commenter suggested that CMS allow hospitals to define their own categories but also require them to provide a key that lists out each of the plans included in the groups. Another commenter suggested CMS create a separate data element for plan category and include this in the CMS template. One commenter suggested using the Unified Rate Review Public Use Files to describe types of plans as a starting point.

Response: We appreciate the suggestion for standardizing valid values for plan categories and we will take this into consideration as the data dictionary specifications are developed, although we note that the current data dictionary specifications for plan name are not prescriptive. We appreciate the suggestion to require, if hospitals use a plan category, that they must also provide a companion key with plan names. However, as explained in the CY 2024 OPPS/ASC proposed rule and by commenters, we understand that some hospital contracts are nonspecific and hospitals may not have the information with which to populate a key. We also appreciate the suggestion for an additional data element and may consider this in future rulemaking. We further appreciate the response to our request for comment related to a national standard. We are also unaware of a national standard for plan names, with the exception of the National Plan Identifier, which rulemaking HHS rescinded (*see* Administrative Simplification: Rescinding the Adoption of the Standard Unique Health Plan Identifier and Other Entity Identifier (84 FR 57621)).[785]

Final action: We are making a technical revision to finalize required data elements under new § 180.50(b)(2). After taking comments into consideration, we are finalizing a requirement at § 180.50(b)(2)(ii)(A) that, for payer-specific negotiated charges, the payer and plan would be required as separate data elements. Further, we are finalizing as proposed that plan(s) may be indicated as categories (such as ''all PPO plans'') when the established payer-specific negotiated charges are applicable to each plan in the indicated category. We believe this exception is necessary to ensure that hospitals are not penalized for displaying information that is consistent with their contracting practices. Moreover, we believe that this practice could improve access to MRF data by avoiding repetition of standard charge information that would unnecessarily increase file size.

Third, we proposed to require that hospitals indicate the contracting method they used to establish the payer-specific negotiated charge. TEP members indicated that including the contracting method within the MRF would bring necessary context to the payer-specific negotiated charges established by the hospital. For example, a hospital may have established a payer-specific negotiated charge as a 'base rate' for a service package.[786] Without knowing that, a file user might assume that the listed payer-specific negotiated charge included every charge applicable to the provision of the item or service when, in fact, a 'base rate' charge likely would include non-standard adjustments and other added charges. Additionally, including this data element would align with the data element in the TIC template. We sought comment on contracting types that we should consider as allowed values in the CMS template, should this data element be finalized.

Comment: Several commenters, including some hospitals and consumer advocates, expressed strong support for including the contract method used to establish the payer-specific negotiated charge. These commenters indicated that including this data element would aid in the public's understanding of the payer-specific negotiated charge established by the hospital. Several commenters provided suggestions and recommendations for valid values in response to our request on contracting types that should be considered. One commenter indicated they expected to encounter unique technical questions related to their contracting methodologies and expressed a desire to work with CMS on guidance. One commenter suggested that CMS should routinely revisit the list of contracting arrangements and modify it as needed based on feedback from hospitals.

Response: We appreciate the support for the proposal and the additional suggestions for valid values. We welcome the opportunity to work with hospitals to establish technical specifications for unique methods hospitals use to establish their standard charges. We agree with commenters that including this data element will bring needed context to the payer-specific negotiated charges the hospital has established. As we continue to gain experience with hospital use of the CMS Template, we will periodically review and update the technical instructions to ensure suitability of the valid values for hospitals to encode applicable standard charge information.

Comment: Several commenters opposed the proposal, citing the burden this data element would impose on hospitals that don't already have this information encoded in existing systems, stating that this would require manual effort to encode the data into the file on a line-by-line basis. One commenter recommended allowing hospitals to provide high level information instead; for example, a given field could read: ''percent of charge with the exception of radiology and laboratory services carve outs paid at fee schedules'' as opposed to individual charge lines for each payor. Another commenter expressed concern that the technical specifications may not be broad enough to accommodate all types of contracting methodologies and recommended CMS allow hospitals to encode ''other.''

A few commenters raised concerns that divulging the contracting method could hamper future negotiations with payers. For example, one hospital stated that a simple description of general contracting methodologies would fail to account for factors that drive some hospital costs higher than others. One commenter indicated that insights into the method(s) used by hospitals to establish their negotiated rates could potentially undermine a hospital's negotiation strategy, as competitors might gain insights into a specific hospital's tactics.

Response: We agree that new data elements may increase burden for some hospitals and have taken this into consideration as we developed the economic analysis at section XXVI of this final rule with comment period. We continue to believe that the benefits of these data and the standardization of them outweigh the burden on hospitals. Additionally, after consideration of the comments, we are finalizing a phased implementation timeline (as described in XVIII.B.3.c of this final rule with comment period) for hospitals to implement the changes that we are finalizing in this final rule with comment period. We appreciate the implementation suggestions for streamlining the requirement and will take them into consideration as we develop the technical instructions. We note that the currently available sample formats and corresponding data dictionary include an ''other'' option. A primary goal of price transparency is to increase competition, and we do not

[785] *www.govinfo.gov/content/pkg/FR-2019-10-28/pdf/2019-23507.pdf.*

[786] For additional discussion, please see the CY 2020 HPT final rule, 84 FR 65534.

believe that this data element will hamper hospital negotiations. As proposed, this data element will provide contextual information related to the hospital's payer-specific negotiated charges. However, we will finalize a clarifying revision to the name of this data element and refer to it as ''standard charge methodology.'' If a hospital believes its standard charges are not reflective of other important aspects of the methods used by the hospital to establish them, nothing in this final rule with comment period would preclude the hospital from offering additional context and information to the public in its MRF, so long as the MRF conforms to the formatting requirements required at § 180.50(c)(2).

Comment: One commenter sought clarification on whether CMS' intention was to add ''standard charge or negotiated rate information,'' stating their view that adding more fields to the MRF that align with a contracted payment methodology and not the chargemaster will create more confusion among end users of the data. This commenter further cautioned that negotiated rate information is ''meaningless'' for consumers. Another asserted that contracting information does not reside in hospital chargemasters and could therefore not be displayed as one-to-one matches for individual items and services as listed in chargemasters. Others questioned the value of the information to users of the file, stated that it would create confusion for patients, or that the data would only be useful to app developers. A few commenters expressed concern that, although knowing the method used to establish the payer-specific negotiated charge may increase its context, it would not completely resolve the public's ability to make meaningful comparisons across hospitals.

Response: We are uncertain of the clarification sought by the commenter. In the CY 2020 HPT final rule, we finalized five types of standard charges, including the gross charge (as found in a hospital's chargemaster) and payer-specific negotiated charge, which is defined § 180.20 as the charge that a hospital has negotiated with a third party payer for an item or service. Moreover, as explained in the CY 2020 HPT final rule, such payer-specific negotiated charges often do not reside in the hospital's chargemaster. We also do not agree that negotiated rate information is ''meaningless'' for consumers. We believe that competition in the healthcare industry benefits consumers because it helps contain costs, improve quality, expand choice, and encourage innovation [787] and refer the commenters to a fulsome discussion of the utility of such rates for consumers in the CY 2020 HPT final rule at 84 FR 65537. We agree with commenters that including an indication of the method used by the hospital to establish its standard charges will increase context for payer-specific negotiated charges, but it will not resolve every barrier for price comparisons for every type of contracting methodology.

Final action: We are making a technical revision to finalize required data elements under new § 180.50(b)(2). After taking comments into consideration, we are finalizing the establishment of a new data element at § 180.50(b)(2)(ii)(B). Specifically, for payer-specific negotiated charges, hospital will be required to encode the type of method it used to establish the standard charge. Going forward, we will refer to this data element as ''standard charge methodology.''

Fourth, we proposed to require that hospitals indicate whether the payer-specific standard charge listed should be interpreted by the user as a dollar amount, percentage, or, if the standard charge is based on an algorithm, the algorithm that determines the dollar amount for the item or service. We indicated our belief that specifying whether the number indicated as the standard charge should be interpreted as a dollar figure or percentage would ensure that the data is machine-readable and would minimize confusion about the value inserted into a particular standard charge column. Further, we stated that knowledge of the algorithm for a standard charge that can only be expressed as an algorithm is necessary for consumer-friendly tools to estimate in dollars an individual's payer-specific negotiated charge. Similar to the existing technical instructions for the sample templates, we indicated that CMS would provide technical instructions for hospitals to display standard charges expressed in dollars, percentages, and algorithms in order to ensure consistency and machine-readability.

Comment: Several commenters supported the proposal to require hospitals to indicate the standard algorithm that a hospital has established, stating that such information is necessary for the public to understand how a charge would be determined for an individual's care, including for use by third parties such as employers, researchers, and pricing tool developers to develop more accurate individualized out-of-pocket pricing estimates. These commenters expressed optimism about the positive effects of the proposal for encouraging competition and enhancing the ability to create accurate out-of-pocket estimates in consumer-friendly pricing tools. For example, one commenter theorized that display of hospital payer-specific negotiated charges as either a standard dollar amount or as an algorithm would afford consumers the opportunity to make a choice regarding whether they want to go to a hospital that has established its standard charges in dollars, even if the price might be higher at that hospital, over a hospital that establishes its standard charges based on an algorithm, even if its estimated allowed amount in dollars might be lower. This commenter went on to suggest that the policy ''pushes the industry even further towards simplification, standardization, and overall predictability among business and consumer healthcare transactions'' and expressed hope that, in the future, ''cost certainty will win out over ambiguous algorithms.'' By contrast, another commenter expressed concern that requiring disclosure of algorithms would become ''more commonplace as hospitals seek to avoid providing guaranteed up-front pricing to consumers'', presumably, as a result of hospitals choosing to more frequently establish their standard charges as algorithms. Another commenter noted that requiring ''hospitals and health plans to only disclose how they do business and not forcing them to change how they do business'' appropriately balances the ''need to provide pricing information to patients without undermining the development of new payment models.'' Other commenters expressed concern that such information would only be useful to competitors or to insurers who would seek to drive down hospital reimbursement.

Response: We appreciate commenters' support of the proposal. We agree with commenters that greater transparency in hospital standard charges, and payer-specific negotiated charges in particular, is necessary to minimize confusion about the data hospitals are currently displaying in MRFs. Further, we agree with commenters that knowledge of the algorithms used by hospitals for establishing payer-specific negotiated charges is necessary for consumer-friendly tools to estimate (in dollars) an individual's payer-specific negotiated charge and subsequent out-of-pocket cost obligations. We also agree with commenters who are optimistic about the potential for positive effects of

[787] *https://www.justice.gov/atr/health-care.*

understanding whether the payer-specific negotiated charge has been established by the hospital as a dollar amount, percentage, or algorithm, specifically, that it may drive a desire for contracting simplicity and patient-centric healthcare financing. We believe that such simplicity would benefit both consumers and hospitals by promoting consumer shopping and reducing hospital administrative costs. Finally, we agree with commenters that this regulation is designed to tell hospitals how to make public their standard charges and does not tell hospitals how to establish their standard charges. The goal of the disclosure is to increase price transparency to drive competition and reduce healthcare costs. As we stated in the CY 2020 HPT final rule, we continue to encourage hospitals to provide consumers with cost information in a consumer-friendly manner.

Comment: One commenter noted that all payer-specific negotiated charges are established via algorithm such that none could be displayed as a standard dollar amount. By contrast, another commenter insisted that ''hospitals know the prices in dollars'' because ''that's how they charge'' and that formulas, percentages or referenced prices, or algorithms are used by hospitals to make prices harder to access. Yet another indicated hospital standard charges can be a hybrid or combination of both standard dollar amount and algorithm, noting, for example, that some algorithms allow for the identification of a standard ''base rate'' in dollars, which are then modified further, depending on additional terms and conditions, such as ''outlier'' payments or stop loss protections, within the hospital's contract with the payer. The commenter concluded there is no need for hospitals to display their payer-specific negotiated charges as a percentage or algorithm and instead urged CMS to require hospitals to display their payer-specific negotiated charge in ''dollars and cents.'' A few commenters requested that CMS clarify that the hospital would continue to be required to express standard charges in dollars to the extent it is possible and only indicate the algorithm or estimated allowed amount (discussed in more detail below) at the point at which the rate becomes truly individualized. Commenters indicated that the file specifications should ensure clarity about whether the standard charge is presented as a standard dollar amount, percentage, or algorithm.

Response: Based on our experience, we understand that hospitals establish payer-specific negotiated charges in many ways, ranging from basic fee schedules (in which dollar amounts for specific items and services are known) to grouper methodologies (in which a base rate in dollars has been established but may then be modified depending on other factors like transfers or outliers), to ''percent of billed charges'' schemes (in which the dollar amount varies from person to person). We therefore disagree that all hospital payer-specific negotiated charges can only be expressed as an algorithm. For the same reason, we disagree that all hospitals can produce a payer-specific negotiated charge in dollars that meets the definition of a 'standard charge.' Finally, we believe that section 2718(e) of the PHS Act directs the Secretary to tell hospitals how to display their standard charges, not how to establish them or that they must establish them.

We clarify that allowing hospitals to display a payer-specific negotiated charge as a standard algorithm is appropriate to the extent a standard algorithm is the manner in which hospitals establish their standard charges with third party payers. Hospitals are required to display the standard charges as they are established, such that, if the hospital established a standard charge as a dollar amount, the hospital would display the standard charge as a dollar amount. If the hospital has established a standard charge as a percentage or algorithm such that a standard dollar amount is not available, then the hospital would display the standard charge as a percentage or algorithm. Using the examples discussed earlier, we anticipate that most if not all payer-specific negotiated charges will fall into one of three categories, depending on how a hospital has established them: (1) standard dollar amount, (2) standard algorithm or percentage, or (3) hybrid where a standard dollar amount can be identified but the final allowed amount is dependent on additional variables. An example of where we would expect to see a standard charge in dollars would be standard charges established under a fee schedule or where an identifiable dollar amount has been established for an item or service (for example, a per diem rate, a gross charge for an itemized item or service, or a cash discounted price for a service package). An example of a where we would expect to see a standard charge expressed as an algorithm would be when a hospital has negotiated a reimbursement for defined service packages (for example, hip replacement or colonoscopy) that are based on differential percentages of total billed (gross) charges (for example, 50 percent of total billed charges for hip replacement and 75 percent of total billed charges for colonoscopy). A hybrid would be a situation in which the hospital has established both a standard charge in dollars and there are additional variables that would modify the negotiated rate for a particular item or service. For example, a hospital may have established a payer-specific negotiated charge under the MS–DRG methodology where an adjusted base rate in dollars has been established for each DRG code, but the adjusted base rate may be further modified due to certain variable factors (such as outlier cases or transfers). In general, we recommend that each hospital, as a starting point, inspect their contracts with each third-party payer to identify all standard charges established as dollar amounts. Next, the hospital should populate, by payer and plan, the MRF with those standard charges in dollars and describe the item or service associated with each of the standard charges (along with any relevant billing or accounting codes). After that has been done, the hospital should identify whether the standard charge (in dollars) is subject to modification and what factors or variables (for example, algorithm) might cause the standard charge to change, and indicate those as instructed by the data dictionary for the particular format selected. If the hospital's payer-specific negotiated charge is based on an algorithm within which no standard dollar amount can be determined, then the hospital should specify what percentage or algorithm determines the dollar amount for the item or service. As discussed in more detail in the next section, we are finalizing, a requirement for hospitals to display an estimated allowed amount which would provide needed context, in dollars, for instances in which the hospital's standard charge can only be expressed as a percentage or algorithm for a specified payer's plan. The CMS data dictionary will provide examples and technical instructions for displaying this information in a standardized manner.

Comment: A few commenters opposed the proposal, stating that algorithms are not consumer friendly and could make price comparisons among hospitals challenging for individual patients. A few commenters noted that algorithms are complex, burdensome for hospitals to produce, and potentially the source of new access issues to the files due to their expanded size. Additionally, these commenters indicated that algorithms do not provide

consumers the out-of-pocket dollar amounts they want and would be challenging for users of the file to understand without a third party to interpret.

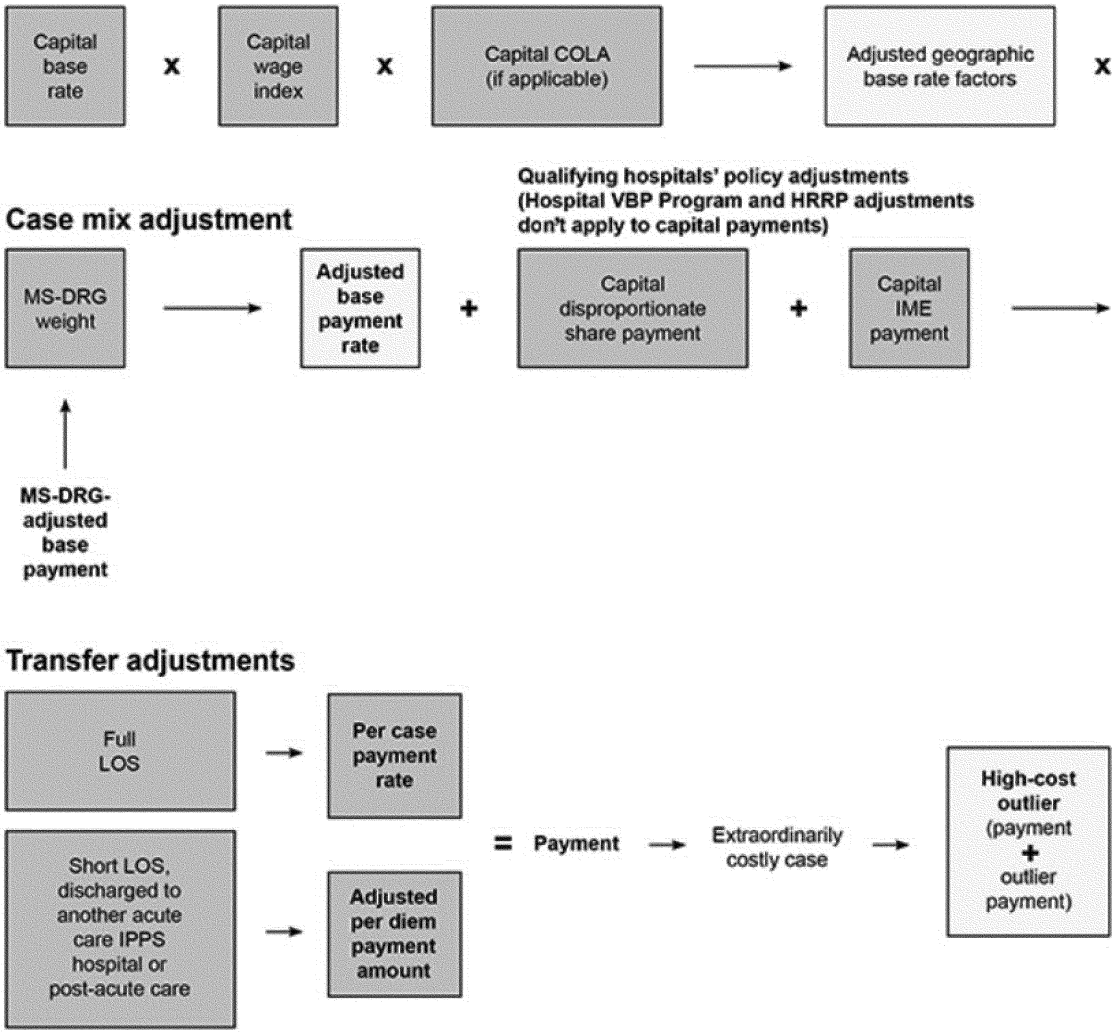
A few commenters provided additional implementation suggestions. At least one commenter supported posting actual algorithms and formulas used to establish the payer-specific negotiated charge. One commenter suggested requiring the hospital to produce a separate formula sheet with the algorithms it uses to establish payer-specific negotiated charges in order to limit the file size. Another commenter recommended that instead of trying to insert a complex algorithm into an MRF field, CMS should permit hospitals to insert a high-level description of the algorithm and the reasons a modification could be made to the amount indicated, or factors that are accounted for when calculating the charge that would apply to the individual. Yet another commenter suggested that instead of inserting detailed algorithms into the MRF, hospitals should be allowed to insert a footnote to indicate that the estimated allowed amount presented in the file is built from an algorithm.

Response: We agree with commenters that having to display a detailed algorithm within an MRF would be unwieldy and burdensome. Although we believe that a detailed algorithm would provide more precision and understanding of the individual's payer-specific negotiated charge, at this time, in the interest of reducing burden and complexity of files, we will allow hospitals provide a description of the algorithm that includes any conditions that may alter the total reimbursement, rather than attempting to insert the detailed algorithm itself in the MRF. For example, if a payer-specific standard charge is negotiated using a common ''hybrid'' algorithm, such as the MS–DRG, then a hospital would indicate the adjusted base rate (in dollars) plus either a high-level description (''MS–DRG'') or a link to the formula used to determine the payer-specific negotiated charge for an individual rather than inserting the algorithm formula itself (see Figure A). Alternatively, since the corresponding code type would already indicate that the standard charge was established under the MS–DRG system, the hospital could indicate that the adjusted base rate indicated (in dollars) may be further adjusted for transfers and outliers.

We appreciate the practical implementation suggestions offered by commenters. In order to assist hospitals in meeting the requirement, we will provide a CMS template and specifications for encoding hospital standard charges as a dollar amount, percentage, or algorithm in a way that will allow file users to readily distinguish between them. Additionally, although we agree that a detailed algorithm would provide more precision and understanding of what the individual's payer-specific negotiated charge might be, at this time, in the interest of reducing burden and complexity of files, we will allow hospitals provide a description of the algorithm, rather than attempting to insert the specific algorithm itself in the MRF. We are therefore finalizing that if the standard charge is based on a percentage or algorithm, the MRF must also describe (instead of specify) what percentage or algorithm determines the dollar amount for the item or service. By describing, rather than specifying, what percentage or algorithm determines the dollar amount for the item or service, we believe this will balance the need for exact information versus MRF complexity, hospital burden, and the limitations of data processing. However, given how critical the allowed amount is for estimating an allowed amount (and therefore individual out-of-pocket costs), we believe that more precision in understanding how the dollar amount is determined by the hospital and payer is better. We will therefore continue to consider this issue and may revisit it in future rulemaking.[788]

[788] *https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/html/images/OP.jpg.*

Figure A: MS-DRG algorithm[788]



Final action: We are making a technical revision to finalize required data elements under new § 180.50(b)(2). After reviewing comments, we are finalizing a new requirement at § 180.50(b)(2)(ii)(C) whereby, with respect to payer-specific negotiated charges, the hospital will be required to indicate in its MRF whether the standard charge indicated should be interpreted by the user as a dollar amount, or if the standard charge is based on a percentage or algorithm. Additionally, if the standard charge is based on a percentage or algorithm, the MRF must also describe the percentage or algorithm that determines the dollar amount for the item or service. Descriptions for algorithms could include, for example, a link to the algorithm used, a descriptor of a commonly understood algorithm, or a list of factors that would be used to determining the individualized or variable allowed amount in dollars.

Fifth, we proposed a consumer-friendly data element called the 'expected allowed amount' that we would require a hospital to display in situations where the payer-specific negotiated charge cannot be expressed as a dollar figure. As finalized in the CY 2020 HPT final rule, the definition of a standard charge is the 'regular rate' established by the hospital for items and services provided to a 'specific group of paying patients.' In other words, the standard charge displayed in the MRF represents the exact rate that applies to all individuals in the group, for example, all individuals covered by a particular payer and plan. This amount is generally considered to be analogous to the 'allowed amount' that is established in the contract the hospital has with the third-party payer, and that appears in a patient's explanation of benefits. This is the maximum payment the plan will pay for a covered health care service, and may also be called ''eligible expense,'' ''payment allowance,'' or ''negotiated rate.'' [789] A portion of this allowed amount is reimbursed to the hospital by the third-party payer, while the hospital bills the consumer for the remainder, which is described as the 'out-of-pocket' amount. As we explained in the CY 2020 HPT final rule, knowledge of the rate the insurer has negotiated with the hospital on the consumer's behalf is essential for helping consumers determine their out-of-pocket cost estimates in advance. However, while essential, the standard charge information is not sufficient because the individual must obtain additional information from his or her third-party payer related to the circumstances of their particular insurance plan (for example, what portion of the payer-specific negotiated

[789] *https://www.cms.gov/files/document/nosurpriseactfactsheet-health-insurance-terms-you-should-know508c.pdf.*

charges would be paid by the plan and other plan dependencies such as the patient's co-insurance obligations or where the patient has not satisfied their deductible for the year).

Since implementation of the HPT regulation, hospitals have become more transparent about how they establish their payer-specific negotiated charges. Based on our experience in enforcing the requirements of the regulation, we have learned that most commercial contracting methods result in a hospital's ability to identify and display as a dollar figure the payer-specific negotiated charges they have established with third party payers. For example, a negotiated rate is established as a dollar amount for an item or service or service package (that is, the 'base rate'), or is established as a percent discount off the gross charge for each item or service provided, or as a percentage of the Medicare rate which can be translated and displayed by the hospital as a standard dollar amount.

At other times, however, hospitals and payers establish the payer-specific negotiated charge by agreeing to an algorithm that will determine the dollar value of the allowed amount on a case-by-case basis after a pre-defined service package has been provided. This means that the standard charge that applies to the group of patients in a particular payer's plan can only prospectively be expressed as an algorithm, because the resulting allowed amount in dollars will be individualized on a case-by-case basis for a pre-defined service package, and thus cannot be known in advance or displayed as a rate that applies to each member of the group.

For example: Patients X and Y are under the same payer's plan. They both go to a hospital for the same procedure. The hospital submits a claim to the payer for the total gross charges associated with itemized items and services provided to each patient. The payer analyzes the claims and assigns the same DRG code. The gross charges (that is, the charges billed on the claim to the payer) for each itemized item and service provided by the hospital for Patient X's procedure total $1500, while Patient Y's gross charges for each itemized item and service provided by the hospital total $2000. The hospital and payer have negotiated a payer-specific negotiated charge that is calculated as an amount equal to 50 percent off the total gross (or billed) charges for the procedure identified by the DRG code. The resulting charge (in dollars) for Patient X would be $750 while resulting charge (in dollars) for Patient Y would be $1000. In this example, the payer-specific negotiated charge (as an algorithm) is the same for each patient in the payer's plan for the procedure, but it is possible that each patient covered under this payer's plan would have a different resulting charge, in dollars, for the same procedure. In other words, in this example, there is no single dollar amount that would be appropriate for the hospital to post in its MRF as the payer-specific negotiated charge. Instead, the only payer-specific negotiated charge that applies to the group is the algorithm used to calculate the individualized dollar amount (in this example, the algorithm would be ''50 percent of the total gross charges'' that are billed on the claim for the procedure).

The reality of commercial healthcare contracting practices highlights a tension that sometimes exists between a hospital's establishment of a 'standard charge' that applies to a group of paying patients and the desire for individuals within the group to know and understand the specific cost of their individualized care in dollars for specific hospital items or services. Currently, this tension is largely mitigated by price estimator tools that typically display 'estimated' dollar amounts that are based on past claims and, when available, knowledge of the contracting arrangements to predict, often with very high accuracy,[790] the most likely or expected allowed amount that will apply to an individual. When combined with the individual's insurance information, the individual's out-of-pocket can be determined and displayed. Therefore, as an alternative to leaving a 'blank' or 'N/A' in the MRF when no standard dollar amount is available, we have allowed hospitals to make public the standard algorithm that applies to the group. The publication of the algorithm makes it possible for a user of the file (such as a price estimator tool developer) to use that algorithm in conjunction with educated assumptions about the items or services likely to be utilized by a given patient for a given procedure, along with their corresponding gross charges, to estimate an allowed amount in dollars for the individual. This amount can be further personalized by including insurance information (such as the copay, co-insurance, or deductible) to determine the individual's estimated out-of-pocket dollar amount.

While we continue to support efforts via other methods, such as price estimator tools, for providing consumer-friendly and personalized out-of-pocket information, we have heard from interested parties that, when a hospital has negotiated a standard charge that can only be expressed as an algorithm, some estimate displayed in dollars within the MRF may be useful, particularly for making comparisons across hospitals. For example, an estimate displayed in dollars would permit users to make price comparisons across hospitals when, with respect to the same procedure and payer/plan, one hospital has established a payer-specific negotiated charge as an algorithm and a second as a dollar amount. We therefore considered whether and what data element could be required in the MRF to provide additional needed context for a payer-specific negotiated charge that is expressed as an algorithm.

We proposed that when a hospital has established a payer-specific negotiated charge that can only be expressed as a percentage or algorithm, it must display alongside that percentage or algorithm a consumer-friendly 'expected allowed amount' in dollars for that payer/plan for that particular item or service. The 'expected allowed amount' would be the amount, on average, that the hospital estimates it will be paid for the item or service based on the contract with the third party payer. We expressed our understanding that hospitals often have such information already calculated and available as part of their revenue cycle management systems to provide a back-end check on their reimbursement from the third-party payer, so we did not expect that the inclusion of such data in the MRF would represent a large burden. We indicated that the consumer-friendly 'expected allowed amount' was likely to represent reimbursement for an average patient, rather than an exact amount, since, for a payer-specific negotiated charge based on an algorithm, the amount in dollars is known with certainty only after the patient has been discharged. As such, we said that it was an estimate of the average amount that the hospital expects to receive for the item or service across all group members but not the final exact amount in dollars that would actually apply to each group member. Even so, we stated we believed this information would provide context to the public that is necessary to compare payer-specific negotiated charges across hospitals and a valuable benchmark against which price estimator tools can use to develop and estimate an individual's personalized out-of-pocket costs. We proposed to add this consumer-friendly 'expected allowed

[790] Stults, et al. Assessment of Accuracy and Usability of a Fee Estimator for Ambulatory Care in an Integrated Health Care Delivery Network. JAMA Network Open. 2019;2(12):e1917445.

amount' to the list of required data elements at § 180.50(b)(2).

Comment: Several commenters expressed strong support for a data element that would provide an estimated dollar amount when the hospital can only express their standard charge as an algorithm. These commenters asserted that this information must be paired with knowledge of the algorithm itself in order to facilitate comparisons between hospitals and would be useful to consumers. By contrast, other commenters objected to the inclusion of an estimated amount in dollars on the basis that such a dollar amount would not be consumer-friendly and would not be useful for comparing across hospitals. As a result, these commenters indicated that it would be a burdensome 'waste of time and money' to require hospitals to calculate and display estimated dollar amounts and that such amounts may generate consumer confusion and generate additional controversy over hospital charges. A few commenters noted that estimates are not 'guaranteed' prices.

A few commenters recommended that should we finalize the proposal, then we should not also require hospitals to have to display algorithms. A few commenters indicated that hospitals have 'allowed amounts' in their systems while others said they did not, or that they did but it was different than what was proposed for display.

Response: We appreciate the support for expressing an estimated dollar amount when the hospital has established a payer-specific negotiated charge for an item or service that can only be expressed as a percentage or algorithm. We agree that this information, when paired with the algorithm, will promote greater transparency of hospital standard charges that can be useful to users of the MRF data; however, they are averages and therefore would not represent 'guaranteed' prices because they would not apply to an individual, nor would they necessarily represent the amount an individual would pay for an item or service. We note, however, that under the NSA, individual patients may obtain a good faith estimate from a hospital, which can be used by the patient to dispute final charges that are substantially in excess of the up-front amounts.[791] Additionally, in accordance with 45 CFR 180.60 a hospital may elect to offer a price estimator tool in order to meet requirements for a consumer-friendly display. In accordance with 45 CFR 180.60(a)(2)(ii), the price estimator tool must allow ''healthcare consumers to, at the time they use the tool, obtain an estimate of the amount they will be obligated to pay the hospital for the shoppable service.'' As we stated in the CY 2020 HPT final rule, we continue to encourage hospitals to provide consumers with cost information in a consumer-friendly manner.

Comment: A few commenters expressed misunderstandings or requested clarifications about the proposal. For example, one commenter appeared to believe that the hospital would be required to create an estimate across all standard charges for a defined set of services or service packages such that it would take into account average billed amounts (for example, gross charges), discounted cash prices, and all negotiated rates. Other commenters indicated that such an amount could not be calculated on the basis of an ''individual line item within the chargemaster.'' A few commenters sought clarification on whether this average amount was intended to be prospective or whether it would represent a retrospective calculation based on the amount received by the hospital for past services (for example, an historical allowed amount).

Response: We clarify that, as proposed, a hospital would only be required to calculate an estimated allowed amount, in dollars, when the hospital has established a payer-specific negotiated charge that can only be expressed as a percentage or an algorithm. This algorithm or percentage is based on the contract the hospital has with a particular payer for a particular plan, and the estimated allowed amount would be the average reimbursement in dollars that it has received from the payer in the past, that is, what some might call an 'historical allowed amount.' This estimated allowed amount is therefore not prospective and is also not based on the hospital's chargemaster or claims submitted to the payer which, as we understand it, contains only gross charges for itemized items and services. Because the ''expected allowed amount'' data element is meant to provide an estimate of what the algorithm produces in dollars, across the group of people covered by a particular payer's plan, we clarify that such an amount should reflect the amount the hospital expects to be reimbursed for the item or service (or service package), on average. To avoid confusion, we will modify the definition to refer to the average amount 'historically received' (rather than 'expects to be paid', and also rename the data element ''estimated allowed amount.''

Comment: We received few comments on the proposed definition of ''consumer-friendly expected allowed amount.'' One commenter agreed with the additional definitions and recommended that the definition of ''consumer-friendly expected allowed amount'' be modified to read ''the average dollar amount that the hospital estimates it will be paid by a third-party payer for patient claims that include items, services or service packages,'' arguing this would emphasize using patient claims due to their belief that patient claims data are the only ''level'' where hospitals would calculate or store such data. This commenter further indicated their belief that it would be important to emphasize the term ''service package'' in order to provide consistency with the definition of ''standard charge'' and permit appropriate disclosure of claim-driven values which would be grouped at the service package level. By contrast, another commenter objected to defining a 'consumer-friendly expected allowed amount' as an 'average,' stating that a 'consumer-friendly expected allowed amount' should instead be the expected maximum dollar amount to be charged to the consumer, and that hospitals be prohibited from charging a patient more than that amount. Several commenters requested more detailed information on the methodology and data source a hospital should use to calculate the estimated average allowed amount in dollars. A few commenters suggested that using 835 remittance files would be the simplest method. One commenter suggested that hospital claims data should be used exclusively.

Response: For the reasons discussed in more detail above, we are finalizing a new data element, the consumer-friendly ''estimated allowed amount'' to reflect an estimated dollar value when a standard charge (such as a payer-specific negotiated charge) can only be expressed as an algorithm. As we understand it, hospitals submit claims to payers that include gross charges for the items and services furnished to an individual, along with various additional information (such as a diagnosis code) that may be necessary for the hospital to receive the negotiated rate (or ''allowed amount'') from the payer. Sometimes the allowed amount (for example, the dollar amount reimbursed to the hospital) is static (a payer-specific negotiated charge represented as a dollar amount) and sometimes the allowed amount is variable (a payer-specific negotiated represented as an algorithm). Because

[791] *https://www.cms.gov/files/document/nosurpriseactfactsheet-whats-good-faith-estimate508c.pdf.*

the estimated allowed amount data element is meant to provide an estimate of what the algorithm produces in dollars, across the group of people covered by a particular payer's plan, we clarify that such an amount should reflect the amount the hospital has historically received from the payer for the item or service (or service package). Thus, we decline to revise the definition in such a way that it might suggest that hospitals should calculate and display the average total gross charges on the claims submitted to the payer, rather than calculating and displaying the average negotiated or allowed amount that is received by the hospital, because the total gross charges are not representative of the rate negotiated between the hospital and payer. However, nothing in the hospital price transparency regulation would preclude a hospital from voluntarily including such information in the MRF in addition to including the ''estimated allowed amount.'' Moreover, we believe hospitals should retain flexibility, in the interest of reducing burden, to determine the best data source for calculating the estimated allowed amount. We therefore decline at this time to be prescriptive. However, we agree that using information from the EDI 835 electronic remittance advice (ERA) transaction, the electronic transaction that provides claim payment information, including any adjustments made to the claim, such as denials, reductions, or increases in payment, would appear to meet this requirement as the data in the 835 form is used by hospitals to track and analyze their claims and reimbursement patterns.

We agree that display of a maximum allowed amount could provide some clarity of the maximum amount that a consumer might be obligated to pay (once the consumer calculates their own potential out-of-pocket obligation based on the displayed maximum allowed amount). For example, if the maximum allowed amount for an item or service (including a service package) was displayed as $1500 and a person covered under that particular payer/plan has a 20 percent coinsurance and has not yet met their deductible (if applicable to their insurance plan) then the individual would have a very high probability of not being obligated to pay more than $300 for the indicated item or service. However, because a calculated maximum derived from past remittances or other data sources may include other costs, such as costs incurred for outlier cases, we believe the display of the maximum amount could be skewed to the point where it would not present as much useful information to the public as an average estimated allowed amount. Additionally, because the estimated allowed amount may be established based on past remittances, any calculated maximum for an algorithm that does not have an upward bound would be, by definition, not guaranteed. Moreover, we do not believe we have authority to prohibit hospitals from charging a patient more than the estimated amount. We note, however, that under the NSA, patients may obtain a good faith estimate from a hospital, which can be used by the patient to dispute final charges that are substantially in excess of the up-front amounts.[792]

Final action: We are making a technical revision to finalize required data elements under new § 180.50(b)(2). We are finalizing the requirement at § 180.50(b)(2)(ii)(C) that, beginning January 1, 2025, if the standard charge is based on a percentage or algorithm, the MRF must also specify the estimated allowed amount for that item or service.

(c) Required Data Elements Related to Hospital Items and Services

At new § 180.50(b)(3), we proposed that hospitals be required to provide standard charge information for additional data elements. We indicated that these data would describe hospital items and services that correspond to the standard charges established by the hospital as follows:

- Recasting as a separate data element, but otherwise without change, the presently required description of the item or service and whether the standard charge is for an item or service provided in connection with an inpatient admission or an outpatient department visit.
- If a standard charge has been established for a drug, we proposed that the hospital would be required to indicate the drug unit and type of measurement as separate data elements. We stated that we have seen hospital MRFs in which the drug unit and type of measurement are either not specified or are included in the same field as the description of the item or service. In the first case, when the drug unit and type of measurement is not specified, the user of the file has no basis for understanding the standard charge that the hospital has established. In other words, the description is not sufficient for the user to understand what quantity of the item or service the user would receive at the indicated standard charge amount. In the second case, when the drug unit and type of measurement are included in the same field as the description of the drug, the information is not easily machine-readable because computers are unable to parse the description if expressed as a 'string' of characters that are unique and undefined. We noted that under the proposal, if the hospital has established a standard charge for a drug, the hospital would be required to encode the file with a description of the drug, including the applicable drug unit and type of measurement as a separate and distinct data element from the description. For example, if a hospital establishes a gross charge of $2 for an item or service it describes as 'aspirin 81mg chewable tablet—each,' the hospital would be required to input data for each of the required separate data elements, which would look something like this in the MRF, based on the current technical specifications in the data dictionary that accompanies the currently available sample templates: gross charge: 2; description: aspirin 81mg chewable tablet; unit of measurement: 1; type of measurement: UN.[793] This indicates to the public that the standard charge established by the hospital for this item or service is $2.00 for a single tablet of a drug described as 'aspirin 81mg chewable tablet.'

We stated that we are aware that hospitals may at times establish standard charges for units of items and services other than drugs. While we would encourage hospitals to be transparent about such information in the MRF, we only proposed to add data elements for the unit and type of measurement of drugs because the codes (such as HCPCS codes) for non-pharmaceutical items and services typically include instructions or additional descriptions that clarify the unit and type of measurement for the indicated item or service, but the codes (typically National Drug Codes (NDC)) used for pharmaceutical agents do not, and we did not believe it was necessary to burden the hospital with a requirement to publicly disclose information that is already available to the users of the file. Additionally, the TEP members discussed this issue and concluded that drugs are a unique class of items and service when it comes to a user's ability to clearly understand how hospitals are representing their standard charges. TEP members

[792] *https://www.cms.gov/files/document/nosurpriseactfactsheet-whats-good-faith-estimate508c.pdf.*

[793] Where ''UN'' in the sample format data dictionary (found here: *https://www.cms.gov/hospital-price-transparency/resources*) stands for ''unit'' which, in this example, comes in the form of a tablet.

speculated that such challenges may arise because hospitals establish and display their standard charges for drugs using different methodologies. For example, it is often unclear in the hospital's MRF whether the payer-specific negotiated charge for a drug is based on the billing unit for the NDC associated with the drug or the billing unit associated with the drug's HCPCS code.

Based on our own experience in reviewing MRFs, we agreed with the TEP members that more prescriptive requirements are necessary when it comes to display of standard charges for drugs and believe that requiring the drug unit and type of measurement as separate data elements would facilitate machine-readability and ensure clarity for the users of these files. We also agreed with the TEP members that the proposal may introduce a burden on some hospitals that are already including such information in the description but would have to separate it for display in the CMS template. Because of this potential burden, we considered an alternative approach by which we would require the drug unit and type of measurement to be included in the description or encoded as separate data elements. This alternative would ensure availability of the data to users of the MRF, albeit in a way that would not be optimized for machine-readability. However, in this case we stated we believed the burden on hospitals was outweighed by the need for improvements in data machine-readability, and therefore proposed to require hospitals to report this information as separate data elements. We noted that nothing would preclude the hospital from also including the information in its description of the drug. We sought comment on the proposal and the alternative we considered but we did not propose.

Comment: We received a few comments on our proposed revision to retain the ''description'' and ''setting'' information but requiring them to be encoded as two separate data elements. A few commenters expressed support for the separation of these data elements, stating they are necessary to provide context and improve the machine-readability of the MRF. A few other commenters objected to the separation, stating that this information is not currently encoded in hospital systems and would be a burden to encode manually for each item or service. One commenter suggested that CMS technical instructions allow hospitals to designate a standard charge as being applicable to the inpatient setting, outpatient setting, or both settings.

Response: We appreciate the support for the proposal. We agree that separation of a data element that distinguishes between the inpatient versus the outpatient setting is necessary to improve the meaningfulness of the standard charge. Although we recognize that encoding the ''setting'' data element, at least initially, may increase the burden for some hospitals, we believe that this data element is necessary to contextualize the standard charge established by the hospital and will improve the meaningfulness and usability of the data. Thus, we believe the benefit of including this data element will outweigh the initial burden for hospitals to collect and encode it. However, in light of comments, as discussed at section XVIII.B.3.c of this final rule with comment period, we are implementing a phased implementation timeline with respect to the requirements we are finalizing in this final rule with comment period, which will provide hospitals additional time to collect and encode the data completely and accurately. The valid values currently indicated by the data dictionary for the voluntary sample formats include ''inpatient'', ''outpatient'' and ''both'' and we do not intend to change these technical instructions in the data dictionary for the required CMS templates.

Comment: We received many comments about the proposal to require drug unit and type of measurement as separate data elements, and to separate them from the description of the item or service. Several commenters supported the addition of the drug unit and drug type of measurement as separate data elements. One commenter indicated that the addition of drug prices in the MRF would be crucial to give patients a comprehensive understanding of their cost of care, given that dosage and quantity factor heavily into pricing. Moreover, commenters believe that drug reporting poses a number of unique challenges compared to other types of charges (for example, room and board, operating room time), given dosage and quantity factor heavily into pricing. One commenter sought clarification as to whether the unit and measurement of a drug is the equivalent of a 'dose'.

By contrast, several hospitals expressed opposition, citing concerns related to administrative burden. For example, a few commenters indicated that standard charges for drugs can change frequently which would then require the hospital to frequently update the MRF. Others indicated that some hospitals maintain separate drug files and that merging payer data with drug and supply data would be burdensome, or that the information is already included in the description and separating the information in the MRF would take time. These commenters suggested that the user of the file should be responsible for parsing out the information. Others indicated, without further explanation, that they believed these data elements would be confusing for end users. Regarding the timing of implementation, one commenter specifically noted that CMS postponed the requirement for payers to including drug information in the TIC files. Several commenters recommended that, given such data is often not already in hospital systems in a format conducive to automatic inclusion in an MRF, CMS either make this data element optional or delay implementation of the data element.

Response: We appreciate commenters' support for the proposal. We agree that more prescriptive requirements are necessary when it comes to display of standard charges for drugs and believe that requiring the drug unit and type of measurement as separate data elements will facilitate machine-readability and ensure clarity for the users of these files. The drug unit and type of measurement are intended to bring context to the standard charge a hospital has established for the drug, which typically (but may not always be) expressed as a dose, leveraging HCPCS or NDC dosing descriptions. We recognize that hospital charges for drugs may vary throughout the course of a year, however, hospitals are only required to update MRFs at least once annually. Although we recognize these data elements may increase burden for some hospitals, in this case we believe the burden on hospitals is outweighed by the need for improvements in data machine-readability, and in bringing clarity and context for the standard charges hospitals have established for drugs and therefore we are finalizing this requirement. These data are not the same as the data required under the TIC regulation, which CMS postponed pending further rulemaking.[794] However, we are swayed by those who indicate that these data elements may require additional time to encode. Therefore, as discussed at section XVIII.B.3.c of this final rule with comment period, we are implementing a phased implementation timeline with respect to the requirements we are finalizing in this final rule with

[794] *https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/FAQs-Part-49.pdf.*

comment period, which will provide hospitals with additional time to encode the standard charge information accurately and completely.

Comment: A few commenters made recommendations related to technical instructions, for example, a commenter suggested that the valid values specified in the data dictionary align with those that are considered 'industry standard', and one requested CMS allow valid values for units of measures beyond the four (GR (gram), ME (milligram), ML (milliliter), and UN (unit)) that are currently found in the data dictionary for the voluntary sample formats. One commenter requested that CMS provide an example for how to encode standard charge information for drugs when the charges are based on an algorithm (such as the average wholesale price or actual acquisition cost of the drug) rather than a ''hardcoded'' amount. The commenter suggested that such charges could be represented as an average dollar amount or as a ''null'' value.

Response: We appreciate the suggestions related to technical instructions and will consider them as we develop the data dictionary and other technical guidance. The current valid values reflect industry standards, specifically, we are adopting both the NDC standards (which include UN (unit), ML (milliliter), GR (gram), F2 (International Unit), ME (milligram)) and the NCPDP standards (which include ''EA'' (each), ''ML'' (milliliter), and ''GM'' (gram)), however if there are additional industry standards that are not reflected or that are needed to ensure each hospital is able to maximally contextualize the standard charge information for drugs, then we would consider adding them for inclusion. Such an inclusion would serve to expand hospital flexibility. We note that, in accordance with the discussion related to display of hospital standard charges that can only be expressed as an algorithm (in section XVIII.B.3.b.(2)(a) in this final rule with comment), if a hospital has established a standard charge that can only be expressed as a percentage or algorithm, then the hospital must describe the algorithm and calculate and display an estimated allowed amount in dollars.

Final action: We are making a technical revision to finalize required data elements under new § 180.50(b)(2). After considering comments, we are finalizing as proposed new § 180.50(b)(2)(iii) that, in its MRF, a hospital must encode a description of the item or service that corresponds to the standard charge established by the hospital, including:

- general description of the item or service (at new § 180.50(b)(2)(iii)(A));
- whether the item or service is provided in connection with an inpatient admission or an outpatient department visit (at new § 180.50(b)(2)(iii)(B)); and
- beginning January 1, 2025, for drugs, the drug unit and type of measurement (at new § 180.50(b)(2)(iii)(C)).

We note that we are making a technical correction to insert the word ''the'' which was inadvertently dropped from the phrase ''standard charge established by [the] hospital, including:'' As discussed at section XVIII.B.3.c of this final rule with comment period, we are implementing a phased implementation timeline with respect to the requirements we are finalizing in this final rule with comment period, which will provide hospitals with additional time to collect and accurately encode the standard charge information.

(d) Required Data Elements Related to Item or Service Billing

At new § 180.50(b)(2)(iv), we proposed to specify data elements related to item or service billing. We indicated that we believed data elements related to item or service billing were necessary because the standard charges that a hospital establishes are often dependent on the way an item or service is billed. As such, we stated we believed that including billing information may improve the public's understanding of the standard charge that has been established for the item or service. In specifying these data elements, we noted we would retain, without modification, the current requirement that the MRF include any code used by the hospital for purposes of accounting or billing for the item or service (the example of such codes would be removed from the reg text as unnecessary). We proposed to add a requirement that the hospital specify any relevant modifier(s) needed to describe the established standard charge, and the code type(s) (for example, whether the code is based on HCPCS, CPT, APC, DRG, NDC, revenue center, or other type of code). As discussed by the TEP members, there are instances where a hospital has established different standard charges for the same item or service description, depending on additional factors such as modifiers or revenue centers that are not included in the file. As such, TEP members agreed that some distinction to ensure meaningfulness of the standard charge would be helpful to users of the file and impose minimal hospital burden. Based on our experience in reviewing MRFs, we have also seen such instances and believe that requirements to include applicable codes that include modifiers and revenue center codes would help make necessary distinctions when multiple standard charges have been established for the same items or services. We stated that separating the code itself (for example, the numbers of the code) from the code type (for example, ''HCPCS'') would directly improve machine-readability.

Comment: Most commenters recognized that billing codes can be critical for contextualizing the standard charges a hospital has established. Several commenters indicated that, more often than not, combinations of billing codes and modifiers (including place of service) are necessary to describe the possible standard charge amounts. A few commenters requested that CMS require hospitals to use only nationally recognized code types so that users of the standard charge information can more readily compare 'apples to apples', for example, they requested that CMS mandate hospitals solely use CPT or HCPCS codes to contextualize the standard charges the hospital has established. One commenter requested clarification on whether the intent of including billing codes was to limit codes to only those that are included in a hospital chargemaster, or whether it was to try to describe every scenario that might result in a different negotiated rate under a third party payer contract, noting that managed care contracts can differentiate rates based on age, ICD–10 codes, birth weight, what day of the week a service was performed on, what other CPT codes are billed with it, and other factors.

Response: We agree that billing codes bring necessary context to the standard charges established by hospitals. We additionally agree that more than one code may be necessary to establish that context (for example, a HCPCS code plus a revenue center code may be needed for describing a gross charge). For this reason, the current data dictionary used for the voluntary sample formats allows hospitals to repeat code and code type data elements as many times as is necessary to define an established standard charge. We would retain this instruction in the data dictionary for the CMS templates. Although we agree with commenters that comparing prices across hospitals would be easier for users of MRFs if all hospitals were to establish their standard charges against a nationally recognized set of billing codes, not all

hospitals do so. We therefore do not believe it would be in the public's best interest to limit the types of codes hospitals can use to describe the standard charges they establish because it may increase the ''N/As''. Additionally, we agree that gross charges that are established by the hospital for itemized items and services are often associated with CPT and HCPCS codes in the hospital's chargemaster, whereas it may be more appropriate to contextualize the payer-specific negotiated charges that hospitals have established with third party payers with DRGs, APCs, or other types of payer codes. We further recognize that payer-specific negotiated charges may depend on a variety of factors, which may make it challenging to display as a single dollar amount. In such cases (as discussed in more detail in section XVIII.B.3.b.(2)(b) of this final rule with comment), a hospital may have established payer-specific negotiated charges that can only be expressed as an algorithm. When this occurs, as finalized in this final rule with comment period, the hospital will be required to describe the algorithm that applies and calculate and encode an estimated allowed amount.

Comment: A few commenters expressed strong concern related to the removal of the examples of types of codes a hospital might use to describe an item or service for which the hospital has established a standard charge. These commenters characterized the change as ''a step backwards'' and a ''serious weakening'' of the current rule, explaining that the omission of the language might be mistaken by some hospitals to mean that they need only include ''any'' single code. Additionally, commenters indicated their belief that removing the examples of code types would permit hospitals to use only proprietary codes, preventing consumers from making comparisons across files. One commenter stated that hospitals must be required to provide all codes, including nationally recognized codes such as CPT, HCPCS, DRG, or NDC, to ensure the public's ability to compare across hospital files. Another commenter expressed concern that some organizations bundle complex treatment plans under unique ''house codes'' and unbundling these treatments would be difficult and time-consuming.

Response: We disagree that removing examples of codes that hospitals may use to describe items and services for which the hospital has established a standard charge weakens the requirement. That requirement, which we did not propose to change, requires that hospitals include in their MRFs ''[a]ny code used by the hospital for purposes of accounting or billing for the item or service'' which included, and would continue to include, local or proprietary codes. However, in light of concerns raised by commenters, we will not finalize our proposal to remove from current § 180.50(b)(7) the examples of codes hospitals may use to describe the standard charge established by the hospital. We will, however, revise the text so that it requires the hospital to encode ''[a]ny code(s) used by the hospital'', which will emphasize that more than one code may be necessary to contextualize the standard charge established by the hospital and provide the technical ability for hospitals to associate more than one code and code type with a standard charge. We clarify that the retention of the examples has no effect on the requirement that, to the extent a hospital uses one or more codes to bill/account for items and services for which the hospital has established a standard charge, the hospital must indicate these in its MRF. Common types of codes used by hospitals include such nationally recognized codes as CPT, DRG, HCPCS, NDC, and other code types such as revenue center codes, place of service codes, modifiers, or ''local'' codes. The data dictionary specifications will ensure these and other code types are included in the list of valid values (similar to the data dictionary currently available for the voluntary sample formats). We note that there may be times that a hospital has established a standard charge for an item or service for which there is no nationally recognized code type, for example, as one commenter pointed out, for complex treatment plans. In such cases, the hospital's only option may be to indicate the internal or local code established by the hospital or payer to describe the item or service. By allowing for these types of circumstances, we believe this will avoid situations in which there is no code or code type associated with a standard charge, which could have the unintended consequence of increasing the number of blanks and raising public concern or confusion. However, if a standard charge established by the hospital can be contextualized using either a common billing code or a local code, then the hospital must either display both codes or must preferentially display a common billing code in order to maximize the meaningfulness and comparability of the MRF data for the public.

Comment: Several commenters expressed support for the inclusion of modifiers whenever they are applicable, even though they may increase the size of MRFs. These commenters indicated that modifiers are critical to accurately specify standard charges and necessary to help compare prices across hospital files, and that the benefit to the public outweighs the larger file size. Commenters explained their belief that lack of modifiers in some cases had resulted in many different standard charges being posted for one procedure type, with no explanation of what accounts for the differences.

By contrast, a few commenters opposed the proposal to add modifiers as a separate data element, indicating that the file size would increase dramatically due to the ''endless number of permutations'' of coding combinations. One commenter indicated that because modifiers are typically added manually at the time of billing, they would not be known in advance and are unnecessary because they are patient-specific and non-standard. Another noted that modifiers are often not included in a hospital's chargemaster. Others stated that modifiers are not consumer friendly and that including modifiers in the MRF would confuse consumers even more than CPT and DRG codes already do, and that individual patients should seek out personalized estimates from payers or from price estimator tools. Others objected to the proposal on the basis of burden and stated that if CMS were to require modifiers as a separate data element, then hospitals would need significant lead time to adopt the changes.

Response: We appreciate commenters' support for the proposal to continue to require hospitals to include coding information, including modifiers as necessary, in the MRF. We agree that including modifiers and revenue center codes are useful for making distinctions between different hospital standard charges that have the same item/service description. Thus, we believe that requirement to include any applicable code(s) that include modifiers and revenue center codes will help distinguish cases where multiple standard charges have been established for the same items or services. A revenue center code may contextualize a standard charge for a procedure when the standard charge amount varies depending on where in the hospital the procedure was provided. For example, the gross charge for a certain procedure may be different when that procedure is performed in a general inpatient setting compared to when the procedure is performed in the ICU. Similarly, a modifier may contextualize a standard charge for a procedure, but when the

standard charge amount varies based on factors specific to the procedure. For example, a hospital may have established a payer-specific negotiated charge ($X) with a third party payer for a procedure and a higher payer-specific negotiated charge (150 percent × $X) when the procedure is performed bilaterally. We agree that hospitals may have to collect modifier information from sources other than the hospital's chargemaster in order to contextualize their standard charges (particularly payer-specific negotiated charges). To the extent that a hospital has established a payer-specific negotiated charge that is dependent on a modifier (or revenue center code, or any other code), we are finalizing that the hospital must include it in the MRF. Although including modifiers increases MRF complexity, the data are essential for consumers to understand costs of care prior to receiving a hospital item or service through, for example, the data's use in building consumer-friendly displays tools such as online price estimators. As such, we continue to encourage individual patients to seek out personalized estimates from providers (including hospitals) and payers through other Federal price transparency efforts such as TIC and the NSA. We also will continue to require hospitals to provide consumers with pricing information in a consumer-friendly manner, in accordance with hospital price transparency's consumer-friendly requirements at 45 CFR 180.60.

Comment: A few commenters requested clarification of the proposal to require hospitals to encode modifiers as a separate data element and wondered if the agency was intending for hospitals to list modifiers for billing purposes that affect reimbursement. These commenters recommended that CMS specify that hospitals only need to include combinations of procedures and modifiers that represent a distinct service and result in a separate reimbursement rate. Others noted that many modifiers do not change the payer-specific negotiated charge established between the hospital and third party payer and sought clarification as to whether CMS would require such modifiers to be included in the MRFs. Another commenter suggested that modifiers would be 'out of scope' because they are appended to patient claims at the end of a hospital visit and are not known in advance.

Response: As proposed, hospitals would be required to include modifiers only when they are necessary to provide the additional context needed for the standard charges the hospital has established. We agree it is unnecessary to include modifiers that do not impact or change the standard charges established by the hospital. Given that modifiers are often necessary for hospitals to make public the standard charges established by the hospital, we disagree that modifiers are 'out of scope'.

However, in order to reduce burden, we are finalizing modifiers as a separate data element. We clarify that in doing so, a hospital would not be required to encode all combinations of codes, including modifiers, for each standard charge established. Instead, the hospital would be required to separately encode the modifiers and indicate what effect the modifier would have on the standard charge established by the hospital when used in combination with a procedure or service. For example, a hospital's contract with a third party payer may indicate that when the service(s) provided by the hospital are greater than that usually required for the listed procedure, the hospital may identify this by adding modifier '22' to the usual procedure number and the payer will increase the allowed amount for the procedure by 125 percent of the 5-digit procedure code 'allowable'.[795] To reduce burden, the hospital would encode the standard charge associated with each 5-digit code, as they have been established, and then separately encode each modifier that may change the standard charge by including a description of the modifier and the way it modifies the standard charge.

Final action: We are making a technical revision to finalize required data elements under new § 180.50(b)(2). As a result of comments, we are finalizing a requirement at § 180.50(b)(2)(iv) coding information as a required data element, including: Any code(s) used by the hospital for purposes of accounting or billing for the item or service at new § 180.50(b)(2)(iv)(A); and corresponding code type(s) at new § 180.50(b)(2)(iv)(B). Such code types may include, but are not limited to, the Current Procedural Terminology (CPT) code, the Healthcare Common Procedure Coding System (HCPCS) code, the Diagnosis Related Group (DRG), the National Drug Code (NDC), Revenue Center Codes (RCC), or other common payer identifier. Additionally, at new § 180.50(b)(2)(iv)(C), beginning January 1, 2025, the hospital must encode any modifier(s) that may change the standard charge that corresponds to a hospital item or service, including a description of the modifier and how it would change the standard charge.

(e) Response To Request for Comment and Summary of Finalized Required Data Elements

We sought comment on these proposed revisions to § 180.50(b). Specifically, we sought comment on whether we should consider additional data elements to ensure the public's understanding and ability to meaningfully use the standard charge information as displayed in hospital MRFs. In particular, we sought comment from hospitals related to display of payer-specific negotiated charges and solicited specific examples of complex contracting methodologies so that we can provide specific recommendations and technical instructions on display of standard charges resulting from such methodologies in the CMS template.

Comment: We received several suggestions for additional data elements such as ''type'' of gross charge that would indicate ''any specialty pricing schedules'' maintained by the hospital, for example, special lab, imaging, or clinic prices, ''Average Standard Gross Charge'' found on claims, the ''realization rate'' from payers which would take into consideration claim/benefit denials from payers, and others. We also received a few specific examples of complex contracting methodologies.

Response: We thank the commenters for the additional data element suggestions that we may consider in future rulemaking. We note that nothing would preclude a hospital from voluntarily including additional data elements in its MRF, and we may develop recommended specifications for optional data elements in the data dictionary. We also thank commenters for providing examples of complex contracting methodologies, which will be helpful for developing specific recommendations and technical instructions on the display of standard charges resulting from them.

Final action: We are finalizing as proposed the modifications to § 180.50(b), which we believe are necessary to improve hospitals' ability to display their standard charges in a more specific, clear, and standardized way. We believe the final policies will increase the meaningfulness of the standard charge information and heighten the public's ability to understand and more efficiently aggregate and use the data. Further, as described above, we believe these final

[795] One example of how American Medical Association (AMA) modifiers can effect hospital payer-specific negotiated charges can be found here: *https://www.aapc.com/codes/webroot/upload/general_pages_docs/document/09-14_10_Modifiers.pdf.*

policies will improve and streamline CMS' ability to enforce the HPT requirements. In so doing, we are making a technical revision to existing § 180.50(b), specifically, redesignating the introductory paragraph as (b)(1) and renumbering paragraphs (b)(1) through (7) as paragraphs (b)(1)(i) through (vii). Additionally, the existing introductory paragraph is revised to apply to dates prior to July 1, 2024. The policies finalized in this final rule with comment period for newly required data elements are added under new § 180.50(b)(2). Table 151A summarizes the implementation timeline for encoding required data elements in a CMS template.

c. Formatting Requirements for Display of Standard Charge Information Using a CMS Template and Implementation Timeline

We proposed to require each hospital to conform to the CMS template layout, data specifications, data dictionary, and to meet any other specifications related to the encoding of the hospital's standard charge information in its MRF. We made these proposals in order to improve automated aggregation of the standard charge information in the hospital's MRFs. Additionally, we stated that we believed these proposals would streamline our enforcement capabilities.

While most hospitals are ensuring that the data they display appears in a machine-readable format (such as JSON or CSV), as required under the current regulation, many are not taking as much care to display the data that encodes the file in a way that improves machine-readability to facilitate automated aggregation of standard charge information. Even when individual hospitals make an effort to optimize the machine-readability of the data they include in the MRF, the lack of standardization in the MRF format data encoding limits the ability of users to aggregate MRF data in an automated way. This is because the format of the data encoded in the MRF is unknown to the user and therefore cannot be coded by them for further processing. This lack of standardization in format presents a barrier to the intended use of the MRFs as expressed in the CY 2020 HPT final rule—that is, for enhancing the public's ability to use the data in, for example, consumer price estimator tools and in EHRs at the point of care for value-based referrals, or to aggregate and use the data to increase competition.

As indicated throughout the CY 2020 HPT final rule, we believed the flexibility that we initially afforded to hospitals was necessary to ensure that ''each hospital operating in the United States'' could implement the law and regulatory requirements. Now that hospitals have experience in making their standard charges public in an MRF and we have a better understanding of how hospitals establish their standard charges, we stated that we believe our data formatting requirements can be made more prescriptive to enhance the public's ability to use the hospital standard charge information to its fullest potential. These evolutionary changes may serve to decrease hospital burden.

To accomplish this, we proposed to revise the introductory text at § 180.50(c) to require that each hospital must conform to the CMS template layout, data specifications, and data dictionary when making public the standard charge information required under paragraph (b).

We proposed to make at least one CMS template available to hospitals, and hospitals would be required to conform to its layout and comply with technical instructions (located in the template, corresponding data dictionary, and other technical guidance) to be published on a CMS website (such as the HPT website or CMS GitHub). A hospital's failure to display its standard charge information in the form and manner specified by CMS could lead to a compliance action. We indicated that the CMS template and accompanying technical specifications would describe the form and manner in which the hospital must organize, arrange, and encode its standard charge information for the required data elements in its MRF.

For purposes of this requirement, we proposed to make available a CMS template in CSV and JSON formats. Additionally, we proposed to make available three different layouts. We indicated that the three layouts would be similar to the three 'sample formats' that are currently available on the HPT website.[796] The three sample layout are: (1) JSON schema (plain format), (2) CSV (''wide'' format), and (3) CSV (''tall'' format). Although we considered proposing to require hospitals to display their standard charge information using only the JSON format, we concluded that some flexibility remains necessary given the variability in hospital sophistication and technical expertise, and the fact that these two proposed non-proprietary formats (CSV and JSON) appear to be the most frequently used by hospitals for displaying standard charges. We sought comment on this issue, and on whether we should instead require use of a single format (such as JSON).

Further, we noted that technical guidance, to which the hospital must conform for purposes of encoding the standard charge information, would be made available through, for example, a data dictionary and within the CMS template. The data dictionary would be similar to the data dictionary that CMS has developed for the 'sample templates,'[797] but would be updated to include any new policies that we finalize in this final rule with comment period. We indicated our belief that this technical instruction would ensure consistent implementation and machine-readability of hospital MRFs across all hospitals. For example, CMS would provide guidance on how to conform to the CMS template layout and encode the data items for the required data elements; that guidance would also consist of the set of rules for the header and attribute naming and rules for allowed values for encoding standard charge information, including the data type (for example, enum, numeric, alphanumeric), data format (for example, string, float), and, in some cases, specific (''enum'') valid values (for example, ''inpatient,'' ''outpatient,'' ''both''). The data dictionary could also include a section on 'how to use the data dictionary' which would provide educational information about the encoding instructions for those with low technology expertise. We stated that we believed that providing such direction via separate technical instructions was reasonable because such direction does not rise to the meaningful substance that is subject to notice-and-comment rulemaking, and it would enable CMS to update such technical specifications to keep pace with and respond to technical developments and inquiries.

We stated that hospitals that did not conform to the CMS template layout, data specifications, and data dictionary would be determined to be noncompliant with 42 CFR 180.50(c) and could be subject to a compliance action. In addition to providing a data dictionary, to further aid hospitals, we considered whether we should develop an MRF validator tool, similar to the validator tool provided by TIC on the CMS GitHub website.[798] The validator tool could be used by hospitals as a check for compliance with the formatting requirements of § 180.50(c), thereby providing some additional

[796] *https://www.cms.gov/hospital-price-transparency/resources.*

[797] *https://www.cms.gov/hospital-price-transparency/resources.*

[798] *https://github.com/CMSgov/price-transparency-guide-validator.*

technical instruction and assurance that the formatting requirements have been met prior to posting the MRF online. We sought comment on whether hospitals would find a validator tool helpful and, if so, what technical specifications such a validator ought to assess.

Additionally, we continued to encourage hospitals to provide any additional information they deem necessary to further explain or contextualize their standard charges, and indicated that we would provide technical instructions and specifications for hospitals to do so. For example, the data dictionary could include one or more optional data elements for inserting additional explanatory notes (similar to the ''additional generic notes'' data element included in the sample formats data dictionary), and could also permit hospitals to add other optional data elements such as 'average reimbursement amounts' derived from past claims, LAN designations, quality information, or the hospital's financial aid policy, or any other categories of information the hospital wishes to convey to the public related to hospital's standard charges.

Consistent with our proposal that hospitals must use a CSV or JSON format, we proposed to remove the examples of specific types of machine-readable formats from the definition of ''machine-readable format'' at § 180.20. Similarly, we proposed a technical edit to the naming convention at § 180.50(d)(5) to remove ''[json|xml|csv]'' and in its place add ''[json|csv].''

We stated that if the proposals related to these formatting requirements were finalized, CMS would provide additional technical instructions for how a hospital should indicate non-applicability, when necessary. As explained more fully in section XVIII.B.3.b of the CY 2024 OPPS/ASC proposed rule, we proposed to apply the term 'as applicable' to the standard charge information that the hospital encodes in the MRF, and not to the data elements themselves. We continued to recognize that a hospital may have no applicable standard charge information to encode in some fields within a CMS template (this is particularly true for CSV formats, which can be opened in a human-readable spreadsheet format that forces column/row cross relationships between data elements which are not always applicable). We therefore reiterated that the absence of encoded information does not necessarily mean that the MRF is incomplete. To illustrate using a specific example, a hospital may have established a gross charge for operating room time described as 'OR time, first 15 minutes' but may not have established any payer-specific negotiated charges that correspond to the same item or service. If the hospital has chosen to use the CMS CSV ''wide'' template (which can also be opened and viewed as a human-readable spreadsheet), a person may see that the cell at the intersection of the column 'gross charge' and row of 'OR time, first 15 minutes' would be encoded with the applicable standard charge amount but the cell at the intersection of any payer and plan's 'payer-specific negotiated charge' column(s) and the row of 'OR time, first 15 minutes' would be empty. In this example, the absence of encoded data would be a result of non-applicability, not non-compliance, because the hospital has not established a standard charge with the payers for a 15-minute increment of OR time.

We cautioned users of the files who choose to view MRFs in human-readable formats from concluding that a hospital is noncompliant solely based on blanks or the hospital's use of ''N/A'' (or other indicator(s) specified by CMS in prior guidance). To help mitigate ongoing misunderstandings by users of hospital MRF data, we noted that CMS intends to continue to educate the public on the standard charge information displayed by hospitals and proper interpretation of the information they contain. Additionally, as discussed in the CY 2024 OPPS/ASC proposed rule, we proposed that hospitals include an affirmation of accuracy and completeness within the CMS template (see proposal in section XVIII.B.2.b of the CY 2024 OPPS/ASC proposed rule), which we believed would provide some assurance to users of hospital MRFs that the data is accurate and complete to the best of the hospital's knowledge and belief. We stated that such an affirmation may also mitigate the need for a hospital to insert any indicator of non-applicability into its MRF. We therefore did not propose to require insertion of such an indicator, however, we sought comment on this issue. We sought comment on whether an indicator of non-applicability is necessary, whether such an indicator should be required or just be recommended, and how CMS can best educate the public on the nature of standard charge information display, and, in particular, the potential for non-applicability in certain MRF formats.

Comment: Many commenters, including hospitals, IT developers, and consumer advocates expressed broad support and appreciation for the proposals for requiring hospitals to conform to a standard CMS template layout and encode their data in a standardized way. Commenters indicated that such standardization is both critical and urgent and would support both macroeconomics (business-to-business competition) as well as microeconomic (consumer) applications. Others indicated their belief that such standardization benefits both users (the public) and producers (hospitals) of the files. Others agreed that the proposal has the potential to facilitate standardization and add clarity for hospitals in meeting requirements and would remove administrative burden from hospitals, particularly for urban or well-resourced hospitals.

Some commenters expressed understanding and appreciation of CMS' willingness to address issues raised by hospitals related to the current format but had concerns with the proposed formatting requirements. Specifically, a few hospitals expressed concern related to additional burden the new requirements would place on hospital staff to adopt a CMS template layout and the short timeline for implementation. One commenter urged CMS to consider retaining flexibility to accommodate diverse hospital contracting methodologies to mitigate implementation challenges and burden while enhancing transparency and standardization. One commenter indicated their belief that rural hospitals would likely see little benefit from using a CMS template because they would still need staff and resources to understand how to meet the new requirements.

Response: We appreciate the general support for requiring hospitals to conform to a standard CMS template layout and encode its data in a standardized way. We believe this policy will improve hospital standard charge information use and ease hospital administrative burden for complying with the requirements. Additionally, we believe that use of a standardized format will improve the public's understanding of the standard charges hospitals have established. We recognize that hospitals have diverse contracting methodologies and believe the CMS template layouts and technical specifications retain sufficient flexibility.

Comment: Several commenters offered specific support for the proposal to allow hospitals to choose between a JSON schema and two CSV templates, stating that this policy would allow hospitals some flexibility to choose a method appropriate for them and align with varying levels of expertise. A few, however, disagreed with permitting hospitals to use JSON indicating that this format is more difficult for

consumers, researchers, and employers to use, and urged CMS to require hospitals to use only a CSV format to ensure the hospital's standard charge information would be easily accessed by both machines and humans alike. These commenters suggested that hospitals might use JSON to circumvent the regulatory requirements. A few commenters expressed support for requiring hospitals to make their standard charge information public in a spreadsheet format (such as Microsoft Excel). These commenters explained that requiring hospitals to encode their standard charge information in a human-readable spreadsheet format would make the information more accessible to consumers of the data. One commenter indicated their belief that the voluntary sample JSON schema currently available is 'flat' and inefficient and provides no advantage over the CSV formats.

Other commenters indicated that different organizations have taken different approaches for making public their standard charge information, and that switching formats now would be very costly. Another requested that CMS provide more description and specific examples of both formats in the final rule and/or as later guidance. One commenter expressed interest in using a validator tool, indicating their belief it would increase compliance with formatting requirements.

Response: We appreciate the comments related to specific formats and CMS templates. We agree that hospitals should have some choice, given varying levels of expertise and formats that are widely used by hospitals to date. The JSON schema was developed for those hospitals that wish to take advantage of a format that is more efficient in disclosing the structured data elements and allows for hospitals to represent their data in a hierarchical structure which can reduce the file sizes significantly. Additionally, the JSON schema is intended to reduce burden for hospitals that have already expressed a preference for making public their standard charge information in a JSON schema. Further, there are free, open source JSON viewers available online for noncommercial use. By contrast, the CSV template was developed for those hospitals that are already using this format or who may not be comfortable encoding data in a JSON schema. CSV is a nonproprietary and common flat-file format that uses commas as a delimiter between values and is easily downloadable into a variety of spreadsheet software packages and applications, including Excel, Access, R, Python, Tableau, and others. The flexibility of this format to be opened by many different applications provides an advantage over requiring hospitals to adopt a single application that may be proprietary or not accessible to all members of the public. This practice is consistent with the Federal Government's general open source principles for data access which provides that: data should be made available in convenient, modifiable, and open formats that can be retrieved, downloaded, indexed, and searched; formats should be machine-readable (that is, data are reasonably structured to allow automated processing); open data structures do not discriminate against any person or group of persons and should be made available to the widest range of users for the widest range of purposes, often by providing the data in multiple formats for consumption; and, to the extent permitted by law, formats should be non-proprietary, publicly available, and no restrictions should be placed upon their use.[799]

For these reasons, we decline to limit options to a single format at this time, or to require hospitals to make public their standard charge information in a human-readable format, however, we will continue to monitor and may revisit this policy in the future.

We also appreciate comments from consumers and consumer advocates and will consider them in the future rulemaking that addresses the consumer-friendly display requirements at § 180.60. We note that we provided detailed examples of both the CSV formats and JSON schema, as well as the technical directions found in the data dictionary. These are currently offered to hospitals on a voluntary basis and can be viewed on the HPT website. We intend to timely update these resources to align with the policies finalized in this final rule with comment period. Finally, we appreciate the input on the value a validator may bring for hospitals that are developing their MRFs and will consider making one available.

Comment: A few commenters commented on the use of an indicator when there is no applicable standard charge information to encode. One commenter suggested specific technical specifications and suggested that the process of manually adding indicators would aid in the hospital validation of the file. One stated that requiring hospitals to insert indicators, rather than leaving blanks, would complicate hospital validation efforts and add to the administrative burden. A few commenters questioned the need for such identifiers and suggested there should be no situations in which there is no applicable data.

Response: We appreciate the input on use of indicators. As described in the CY 2024 OPPS/ASC proposed rule, we believe that there are situations in which there is no applicable standard charge information to encode. We also indicated our belief that if we require a hospital to include a statement affirming the accuracy and completeness of the data it has encoded in the file, then the hospital would not have to fill in 'blanks' because the affirmation would signal the blanks are intentional and not missing data. In order to reduce hospital burden, we will not require encoding of an indicator at this time. We may revisit this policy in future rulemaking.

Finally, we proposed a 60-day enforcement grace period for adoption and conformation to the new CMS template layout and encoding of standard charge information of the newly proposed data elements. To be clear, we stated that the grace period would apply solely with respect to enforcement actions based on the new CMS template display requirements at revised § 180.50(b) and (c); it would in no way affect already-initiated compliance actions or actions for noncompliance with other requirements under 45 CFR part 180 as they are currently being implemented. Additionally, we stated that the grace period would not apply to other proposals which would become effective and enforced on January 1, 2024. We stated we understood that some hospitals may have already adopted the sample format that CMS made available in November 2022, however, we proposed to implement an enforcement grace period to accommodate hospitals that have adopted formats that vary significantly from the sample format. We sought comment on the proposal. In particular, we sought comment on whether and why an enforcement grace period should or should not be applied.

Comment: We received many comments related to the effective date of the proposed requirements. Nearly all of those who commented on the effective date indicated their belief that the proposed timeline is aggressive and it would be unreasonable to require hospitals to adopt the proposed CMS template and encode new data elements into it by the March 1, 2024 enforcement date, although one commenter applauded CMS for its dedication to urgency.

The primary reason for requests in a delay was the need to collect and encode data for newly proposed data

[799] *https://resources.data.gov/PoD/principles/.*

elements, as well as the need to ensure the data presented are accurate and complete. One commenter noted that when TIC was finalized, CMS provided payers an extended timeline for implementation and expressed their belief that it would be unfair if CMS failed to do so for providers. Another indicated that the proposed timeline would be especially challenging for smaller hospitals. A few commenters indicated that their vendors would not begin making any changes to accommodate the new formats and data requirements until CMS finalizes the rules. Others expressed concern related to the timing of planned annual updates and indicated it would be burdensome for a hospital to have to produce two files in a single 12-month period.

Commenters recommended alternative dates for enforcement that they considered to be more reasonable. These alternative dates ranged from as early as April 1, 2024, to 18 or 24 months after any finalized changes. Some commenters suggested CMS permit hospitals to adopt the new format on a rolling basis to align with the hospital's planned annual update, while others suggested a phased-in approach, noting that some new data elements may take additional time to collect and encode accurately and completely, at least initially. Commenters noted that the delay would not be harmful to patients because individuals seeking estimates for healthcare services could continue to use already established price estimator tools, patient portals, and existing machine-readable files.

Additionally, commenters requested that CMS use the time between finalization and enforcement to provide assistance to providers as they seek to comply, for example, hosting nationwide calls with provider technical teams to work through their formatting issues.

Response: We believe that hospitals should adopt a CMS template layout and encode the required data elements as soon as possible to improve public use of hospital standard charge information. However, in light of the comments and as explained below, we are finalizing a phased implementation schedule for the new requirements that we are finalizing in this final rule with comment period. We believe that this step-wise approach will provide hospitals sufficient time to implement all of the new requirements accurately and completely, which we believe will enhance transparency overall. We do not believe it is necessary to mirror the timeline for implementation with the timeline CMS provided to payers under TIC because the requirements are different and at this time, hospitals are already collecting and displaying many of the required data elements in a machine-readable format.

Finally, we thank commenters for their suggestions regarding education and outreach activities and will consider how best to engage hospitals as they seek to meet the requirements established in this final rule with comment period.

Final action: We are finalizing as proposed the revision to the formatting requirements at § 180.50(c). In so doing, we are making a technical revision to existing § 180.50(c), specifically, redesignating the introductory paragraph as paragraph (c)(1) and revising the paragraph to apply to dates prior to July 1, 2024. At new § 180.50(c)(2), we will require that, beginning July 1, 2024, the hospital's machine-readable file must conform to a CMS template layout, data specifications, and data dictionary for purposes of making public the standard charge information required under paragraph (b)(2) of this section. CMS will update the existing sample formats (CSV ''tall'', CSV ''wide'', and JSON schema) and data dictionary found on the CMS website to align with the new regulatory requirements.

In response to comments regarding our proposed 60-day enforcement grace period with respect to adoption of a CMS template format and encoding new data elements, we are not finalizing that proposal. We agree with commenters that the encoding already required data elements in a standardized format is an adjustment and that the new data elements we are finalizing may initially take hospitals some time to collect and encode in a CMS template layout completely and accurately. We believe that complete and accurately encoding standard charge information in a CMS template will improve CMS' ability to assess hospital compliance and take necessary enforcement action for hospitals that are determined to be out of compliance. We are therefore finalizing a phased implementation timeline with respect to the changes we are finalizing in this final rule with comment period. Specifically, we are finalizing that the effective date of all of the changes to the hospital price transparency regulations at 45 CFR part 180 will be January 1, 2024. However, the regulation text will specify later dates by which hospitals must be in compliance with some of these new requirements, and we will begin enforcing hospital compliance with those new requirements on the applicable later compliance date. The date by which hospitals must comply with each of the new requirements in section XVIII.B of this final rule with comment period are described in Tables 151A and 151B.

Table 151A describes the implementation timeline for adoption of a CMS template layout and encoding of the required data elements. The implementation date for all other requirements referenced in section XVIII.B of this final rule with comment period are indicated in Table 151B.

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TABLE 151A: Implementation Timeline for CMS Template Adoption and Encoding Data Elements

Requirement	Regulation cite	Implementation (Compliance) Date
MRF INFORMATION		
MRF Date	45 CFR 180.50(b)(2)(i)(B)	July 1, 2024
CMS Template Version	45 CFR 180.50(b)(2)(i)(B)	July 1, 2024
HOSPITAL INFORMATION		
Hospital Name	45 CFR 180.50(b)(2)(i)(A)	July 1, 2024
Hospital Location(s)	45 CFR 180.50(b)(2)(i)(A)	July 1, 2024
Hospital Address(es)	45 CFR 180.50(b)(2)(i)(A)	July 1, 2024
Hospital Licensure Information	45 CFR 180.50(b)(2)(i)(A)	July 1, 2024
STANDARD CHARGES		
Gross Charge	45 CFR 180.50(b)(2)(ii)	July 1, 2024
Discounted Cash	45 CFR 180.50(b)(2)(ii)	July 1, 2024
Payer Name	45 CFR 180.50(b)(2)(ii)(A)	July 1, 2024
Plan Name	45 CFR 180.50(b)(2)(ii)(A)	July 1, 2024
Standard Charge Method	45 CFR 180.50(b)(2)(ii)(B)	July 1, 2024
Payer-Specific Negotiated Charge –Dollar Amount	45 CFR 180.50(b)(2)(ii)(C)	July 1, 2024
Payer-Specific Negotiated Charge – Percentage	45 CFR 180.50(b)(2)(ii)(C)	July 1, 2024
Payer-Specific Negotiated Charge – Algorithm	45 CFR 180.50(b)(2)(ii)(C)	July 1, 2024
Estimated Allowed Amount	45 CFR 180.50(b)(2)(ii)(C)	January 1, 2025
De-identified Minimum Negotiated Charge	45 CFR 180.50(b)(2)(ii)	July 1, 2024
De-identified Maximum Negotiated Charge	45 CFR 180.50(b)(2)(ii)	July 1, 2024
ITEM & SERVICE INFORMATION		
General Description	45 CFR 180.50(b)(2)(iii)(A)	July 1, 2024
Setting	45 CFR 180.50(b)(2)(iii)(B)	July 1, 2024
Drug Unit of Measurement	45 CFR 180.50(b)(2)(iii)(C)	January 1, 2025
Drug Type of Measurement	45 CFR 180.50 (b)(2)(iii)(C)	January 1, 2025
CODING INFORMATION		
Billing/Accounting Code	45 CFR 180.50(b)(2)(iv)(A)	July 1, 2024
Code Type	45 CFR 180.50(b)(2)(iv)(B)	July 1, 2024
Modifiers	45 CFR 180.50(b)(2)(iv)(C)	January 1, 2025

TABLE 151B: Implementation Timeline for Other New Hospital Price Transparency Requirements

Requirement	Regulation Cite	Implementation (Compliance) Date
Good faith effort	45 CFR 180.50(a)(3)(i)	January 1, 2024
Affirmation in the MRF	45 CFR 180.50(a)(3)(ii)	July 1, 2024
Txt file	45 CFR 180.50(d)(6)(i)	January 1, 2024
Footer link	45 CFR 180.50(d)(6)(ii)	January 1, 2024

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4. Requirements to Improve the Access to Hospital MRFs

Currently, the HPT regulations at § 180.50(d) describe our requirements for the location and accessibility of the hospital's MRF. Specifically, the regulations require a hospital to select a publicly available website for purposes of making public its standard charges (§ 180.50(d)(1)) and displaying the standard charge information in a prominent manner and clearly identified with the hospital location with which the standard charge information is associated (§ 180.50(d)(2)). Additionally, at § 180.50(d)(3), the hospital must ensure that the standard charge information is easily accessible, without barriers, including, but not limited to, ensuring the information is accessible: free of charge; without having to establish a user account or password; without having to submit personal identifying information (PII); and to automated searches and direct file downloads through a link posted on a publicly available website. At § 180.50(d)(4), the digital file and the standard charge information contained within that file must be digitally searchable and, at § 180.50(d)(5), the file must use a naming convention specified by CMS.

As we explained in the CY 2020 HPT final rule, because of the flexibility we allowed to hospitals to choose the internet location, we recognized and expected that there would be some variability in how hospitals would choose to publicly display their MRFs and how quickly the file could be found by the public. However, we indicated our belief that standardizing a file name or website location information could provide consumers with a standard pathway to find the information and would provide some uniformity, making it easier for potential software to review information on each website. We expressed our belief that specific requirements for file naming conventions and locations for posting on websites could also facilitate the monitoring and enforcement of the requirements.

We believe our current policies are sufficient for purposes of manual searches, but may not be sufficient for automated searches. As we noted in the CY 2022 OPPS/ASC proposed rule, in our experience, many publicly available web pages that hospitals select to host the MRF (or a link to the MRF) are discoverable using simple manual internet searches (using key words such as the hospital name plus 'standard charges,' 'price,' or 'machine-readable file') or, for example, by navigating to the hospital's home page and clicking and searching through pages related to patient billing and financing. However, despite the requirement for the MRF and the standard charge information contained in that file to be digitally searchable and the required naming convention, various MRF users, including IT developers and technology innovators, continue to express concerns that they can't efficiently, via automated techniques, aggregate the files. We therefore indicated our belief that these challenges should be addressed because we believe that ensuring that the MRFs and their data contents are easily accessible, including by members of the public who develop tools that improve the public's overall understanding and ability to use the information in meaningful ways, aligns with the MRFs' intended use. As we indicated in the CY 2020 HPT final rule, we believe that ''[b]y ensuring accessibility to all hospital standard charge data for all items and services, these data will be available for use by the public in price transparency tools, to be integrated into EHRs for purposes of clinical decision-making and referrals, or to be used by researchers and policy officials to help bring more value to healthcare.''

As a result, we considered methods that would specifically improve the automated accessibility of MRFs. Thus, at proposed new § 180.50(d)(6), we proposed to require that a hospital ensure that the public website it chooses to host the MRF establishes and maintains automated access to the MRF in two specific ways.

First, we proposed, at new § 180.50(d)(6)(i), that the hospital ensure the public website includes a .txt file in the root folder that includes a standardized set of fields including the hospital location name that corresponds to the MRF, the source page URL that hosts the MRF, a direct link to the MRF (the MRF URL), and hospital point of contact information. We stated that CMS would make available the technical specifications for implementing this file in technical instructions and could also consider creating a simple .txt generator tool to assist non-technical hospital personnel in generating a .txt file as well as plain-language instructions for complying with the requirement to post a .txt file to the root folder of the public website.

In considering the proposed approach to automating access to hospital MRFs, we identified several benefits, including: a standardized text file at a consistent location (for example, the root folder of the website) would provide automated tools a direct link to the MRF as opposed to the current approach of having to locate the correct web page within the website; technical experts suggest this is a relatively simple, low burden method that could be applied by maintainers of any public website that hosts the MRF; and information included in the .txt file could include information necessary to validate the contents of the file, for example, by including hospital point-of-contact information. We also considered potential drawbacks of this approach, including that any standardization of this nature is subject to errors in formatting which could negate the benefit to automated access and generate a compliance action. We believe the benefits outweigh the drawbacks for having a hospital ensure that the public website it chooses to host the MRF includes a .txt file in the root folder that includes a direct link to

the MRF to establish and maintain automated access.

Second, we proposed, at new § 180.50(d)(6)(ii), that the hospital ensure the public website includes a link in the footer on its website, including but not limited to the homepage, that is labeled ''Hospital Price Transparency'' and links directly to the publicly available web page that hosts the link to the MRF. We proposed this requirement because we believe the addition of standardized hyperlinks in the footer of hospital websites would aid in the automation of MRF data retrieval by creating a predictable navigation path to internal web pages that describe the HPT program and providing direct links to the MRF location. Once a human or web crawler arrives at the web page on which the MRF is located, it would be able to identify the specific location of the file(s) containing the pricing data. We believe that by making this information more easily accessible to automated searches and data aggregation, it would help third parties develop tools that further assist the public in understanding this information and capturing it in a meaningful way for making informed health care decisions. Moreover, we believe this requirement would be simple for hospitals to understand and implement, due to the website footer being a common place for hospitals to link to other information. In addition, using a standardized label for the link in the footer may make the location of the MRFs more visible to individual consumers manually searching for such files.

We sought comment on the proposed approach to improving accessibility of MRFs to automated searches. We particularly sought comment on whether there: may be better or more efficient ways of improving access to MRFs or the direct links to the MRFs; are additional benefits or challenges that we should alternatively consider; might be any challenges for automation tools to find MRFs when they are hosted by a publicly available website other than a website hosted by the hospital, and ways that would make those automated searches more easily accessible; and, might be any challenges for hospitals to meet the proposed requirements when the publicly available website hosting the MRF is not under direct control of the hospital. We also sought comment on whether the proposals to require use of a footer and .txt file are complementary to, or duplicative of, the requirements at § 180.50(d)(4) and (5), which, respectively, require that the digital file and standard charge information contained in that file must be digitally searchable; and that the file must use the naming convention specified by CMS at § 180.50(d)(5). We also sought comment on whether there is a better or more efficient standardized label for the link in the footer on the website, including but not limited to the homepage, that links directly to the publicly available website that hosts the link to the MRF.

Comment: Several commenters expressed general support for the proposals to improve automated accessibility of hospital MRFs, noting these proposals will aid in the automation of MRF data retrieval, enhance transparency, make the MRFs more visible to individual consumers, and reduce the effort of aggregating the data. One commenter, while supportive of these proposals, requested that CMS delay enforcement to July 1, 2024, to give hospitals sufficient time to operationalize the changes, while another commenter did not see substantial technical difficulty with implementing either the .txt file or including a link in the footer. One commenter indicated that they did not believe the naming convention would be useful for identifying the location of the MRF, but that the .txt file would help. One commenter suggested adding the file date of the naming convention. Another commenter agreed with CMS that the data should be accessible but believed the proposed requirement for a link in the footer should be optional.

Response: We appreciate the support for this policy and agree that including both a .txt file in the root folder and a link in the footer with a standardized label that links directly to the web page that hosts the link to the MRF will aid in the automated accessibility of MRFs and ultimately enhance transparency. We disagree with the commenter who believes the proposal for a link in the footer should be optional. We believe the addition of standardized hyperlinks in the footer of hospital websites would aid in the automation of MRF data retrieval by creating a predictable navigation path to internal web pages that describe the HPT program and providing direct links to the MRF location. We believe that by making this information more easily accessible to automated searches and data aggregation, it would help third parties develop tools that further assist the public in understanding this information and capturing it in a meaningful way for making informed health care decisions. Further, we agree with the commenter who stated that implementation of these proposals would not pose substantial technical difficulty. We believe that the benefit of automating the identification of the MRF location would outweigh the minimal burden to maintainers of the public web page that hosts the MRF. Therefore, we believe it is important for hospitals to include the .txt file and link in the footer as soon as possible.

Comment: Several commenters opposed the proposals to improve automated accessibility of hospital MRFs, stating they did not believe the proposed changes would improve consumer friendliness or accessibility, expressing concern over not having flexibility in placement of the footer link and saying it would detract from other pertinent hospital information, and finding the proposals to be unnecessarily technical and excessive. A few commenters found the .txt file to be duplicative, stating the proposed MRF template fields would contain hospital location information. One commenter stated that websites do not have root folders, but instead have URLs, and that this would be an issue with the .txt file. One commenter appeared to object to the .txt file requirement stating that anyone using a .txt file could also find the file through the footer link. One commenter noted that the proposal to include a link in the footer would not satisfy at least one State requirement to have the link be immediately visible on the homepage without scrolling. One commenter found the proposal to include a link in the footer to be burdensome, citing a situation where the hospital website hosts an MRF for more than one hospital location and the link bringing the user to a page with multiple links to the various MRFs. By contrast, one commenter recommended the .txt file and footer link be extended to support multiple MRFs and transparency web pages on a website.

A few commenters recommended various alternative approaches, including placing the link to the MRF directly on the hospital's homepage, having CMS maintain a repository of MRF links, and having CMS ingest, host, and directly make available the data required under the regulations. One commenter sought clarification on whether CMS intends for the footer link to appear on every single web page on the hospital's website. One commenter suggested limiting the text of the footer label to ''Price Transparency'' instead of ''Hospital Price Transparency.''

Response: We appreciate the commenters' concerns and recommendations. We disagree that the proposed changes would not improve consumer friendliness or accessibility. We believe that standardizing website location information could provide

consumers with a standard pathway to find the information and would provide some uniformity, making it easier for potential software to review information on each website. We remain committed to ensuring that the MRFs and their data contents are easily 1467cessible, and do not believe that offering flexibility on placement of the proposed footer link anywhere on a hospitals' homepage would achieve a predictable navigation path to internal web pages because link placement could vary from one hospital website to another. We believe the addition of standardized hyperlinks in the footer of hospital websites would aid in the automation of MRF data retrieval by creating a predictable navigation path to internal web pages that describe the HPT program and providing direct links to the MRF location. We further note that nothing would preclude a hospital from additionally providing such a link elsewhere on its homepage if the hospital believes it would be necessary for other reasons.

Despite the requirement for the MRF and the standard charge information contained in that file to be digitally searchable and use the required naming convention, various MRF users, including IT developers and technology innovators, continue to express concerns that they can't efficiently, via automated techniques, aggregate the files. We believe these challenges should be addressed because we believe that ensuring that the MRFs and their data contents are easily accessible, including by members of the public who develop tools that improve the public's overall understanding and ability to use the information in meaningful ways, aligns with the MRFs' intended use.

We appreciate the concern of not detracting from other pertinent information on a hospital's website. Due to the website footer being a common place for hospitals to link to other information, we believe this requirement would be simple for hospitals to understand and implement without taking away from other information on a hospital's website.

We do not agree that the .txt file is duplicative because it's a separate file with different information that serves the purpose of helping machines automatically locate the hospital's MRF. We appreciate the comment noting websites have URLs. We use 'root folder' here to refer to the base URL of the website. We also appreciate the comment noting that the MRF can be found via the footer link and recommending the .txt file requirement be deleted. We believe the .txt file is necessary to help streamline the automation of MRF data retrieval. Having the .txt file would achieve having a predictable URL that could be used to successfully aggregate the files.

We understand the concern regarding potential inconsistency with recently enacted state legislation. While developing this rule, we attempted to balance the States' interests in regulating hospitals with the need to ensure access to uniform hospital pricing data. We further note that nothing would preclude a hospital from additionally providing such a link elsewhere on its homepage if the hospital believes it would be necessary for other reasons.

We appreciate one commenter's concern that the proposal to include a link in the footer would be burdensome. We believe having a footer link to a page with multiple links to the various MRFs would help consolidate and aggregate the information, provide consumers with a standard pathway to find the information, provide some uniformity, and ensure that the MRFs and their data contents are easily accessible. In other words, we believe the burden of providing a link in the footer is outweighed by the benefits to the public. Further, we agree with the commenter who stated that the .txt file and footer link be extended to support multiple MRFs and transparency web pages on a website. The .txt file can have the ability to support multiple MRFs and a footer link can go to a page that contains links to multiple MRFs.

We appreciate the various alternative approaches commenters recommended and may take them into consideration in future rulemaking. We appreciate the commenter seeking clarification on the footer link placement. At minimum, the link in the footer must by on the homepage. We agree with the commenter who suggested limiting the text of the footer label to ''Price Transparency'' instead of ''Hospital Price Transparency.''

Final action: At new § 180.50(d)(6)(i), we are finalizing as proposed the requirement that the hospital ensure the public website includes a .txt file in the root folder that includes a standardized set of fields including the hospital location name that corresponds to the MRF, the source page URL that hosts the MRF, a direct link to the MRF (the MRF URL), and hospital point of contact information. At new § 180.50(d)(6)(ii), we are finalizing the requirement that the hospital ensure the public website includes a link includen the footer on its website, including but not limited to the homepage, that is labeled ''Price Transparency'' (instead of ''Hospital Price Transparency'') and links directly to the publicly available web page that hosts the link to the MRF.

C. Requirements To Improve and Enhance Enforcement

Section 2718(b)(3) of the PHS Act requires the Secretary to promulgate regulations to enforce the provisions of section 2718 of the PHS Act, and, in so doing, the Secretary may provide for appropriate penalties. Our current monitoring and enforcement scheme is codified in our regulations at 45 CFR part 180, subpart C.

Section 180.70(a) states that CMS may monitor and assess hospital compliance with section 2718(e) of the PHS Act via methods including, but not limited to, evaluating complaints made by individuals or entities to CMS, reviewing individuals' or entities' analysis of noncompliance, and auditing hospitals' websites. Should CMS conclude that a hospital is noncompliant with one or more of the requirements to make public standard charges, CMS may take any of the following actions described at § 180.70(b), which generally, but not necessarily, will occur in the following order:

- Provide a written warning notice to the hospital of the specific violation(s).
- Request a corrective action plan (CAP) from the hospital if its noncompliance constitutes a material violation of one or more requirements.
- Impose a CMP on the hospital and publicize the penalty on a CMS website if the hospital fails to respond to CMS' request to submit a CAP or comply with the requirements of a corrective action plan.

To better understand hospitals' HPT compliance and the impact of our implementation efforts, CMS conducted website assessments in 2021 and in 2022. CMS evaluated fourteen criteria for the MRF, and either eleven criteria for the shoppable services display or two criteria for the price estimator tool, depending upon which the hospital chose to offer. In the first 2 years of program implementation, our website assessments demonstrated a substantial increase in hospitals meeting website assessment criteria, increasing from 27 percent to 70 percent between 2021 and 2022.[800] Of the remainder of the 30 percent that failed to meet the criteria, 3 percent fully failed to meet website assessment criteria and 27 percent partially met website assessment criteria. Although these website assessments were not formal

[800] *https://www.healthaffairs.org/content/forefront/hospital-price-transparency-progress-and-commitment-achieving-its-potential.*

compliance reviews (which often require additional information from the hospital to make a final determination of compliance), we believe this demonstrates that hospitals are making improvements to come into compliance and that the increase is largely attributable to the increase in compliance penalties that went into effect in CY 2022, and our significant education, monitoring, and enforcement activities. We remain committed to ensuring compliance with our requirements and taking enforcement actions in areas of noncompliance.

Recently, we announced updates to our enforcement process [801] that are intended to increase the rates of HPT compliance. In this section, we made proposals that would further improve the efficiency, timeliness, and transparency of the compliance process.

Comment: We received several comments related to CMS' general approach to enforcement and the proposals to improve monitoring, assessing, and enforcing the requirements of §§ 180.40, 180.50, and 180.60.

Some commenters expressed appreciation for the general enforcement approach taken by CMS, including CMS' previous work to advance hospital price transparency by increasing the penalties for noncompliance with the transparency requirements and using its enforcement power to work with hospitals and, when necessary, issue warnings, require CAPs, and impose civil monetary penalties on noncompliant hospitals.

One commenter expressed concern related to external reports of high noncompliance rates while a few commenters believed that CMS should refute third-party assessment of HPT compliance. These commenters agreed that only a formal CMS assessment can determine a hospital's compliance with the HPT requirements, and thanked CMS for performing and publishing its own assessment of hospital compliance.

Some commenters expressed support for the proposals to improve CMS enforcement capabilities, and urged CMS to go further by, for example, increasing and promptly assessing penalties.

Response: We thank commenters for their support. We are committed to the monitoring and assessment of hospitals' compliance with the HPT requirements and enforcement of those requirements. We believe that our current compliance actions, culminating in a CMP for those hospitals which CMS determines are out of compliance and that either fail to respond to CMS' request to submit a CAP or comply with the requirements of a CAP, are the appropriate way to address hospital noncompliance with the HPT regulations because the process ensures hospitals have an opportunity to come into compliance before CMS assesses a CMP. We agree that only CMS can make a determination as to a hospital's compliance with the HPT requirements.

Comment: A few commenters were generally opposed to the proposed regulatory changes. One commenter stated the changes would cause hospitals to effectively redo their compliance approach, and instead encouraged CMS to offer incentives to hospitals should the agency aim to promote standardization. One commenter recommended that CMS recognize hospitals making a good faith effort to be in compliance with regulations.

Response: We appreciate the commenters' concerns and recommendations. We remain committed to enforcing the HPT regulations, and do not believe that offering incentives would achieve the goal of compliance. We expect hospitals to fully comply with the HPT regulations.

1. Requirements for Improving Assessment of Hospital Compliance

At § 180.70(a), we finalized a process for monitoring hospital compliance with section 2718(e) of the PHS Act by which we may use monitoring efforts including, but not limited to, evaluating complaints made by individuals or entities to CMS', reviewing individuals' or entities' analysis of noncompliance, and auditing hospitals' websites. The regulation text at § 180.70(a)(2) indicates that such methods are also used to 'assess' hospital compliance; however, we have found these methods to be more appropriate for monitoring, and not as appropriate or sufficient for assessing hospital compliance.

For example, a review of an MRF (such as is performed in a typical website assessment) may reveal some obvious deficiencies which can trigger a compliance action. Similarly, a complaint made by the public may be helpful in identifying an allegedly noncompliant hospital. While we appreciate and continue to encourage submission of complaints, there are many nuances and complexities associated with the way hospitals establish standard charges that can lead to questions related to, in particular, the accuracy and completeness of the standard charge information that is included in a hospital's MRF. By way of example, if a hospital's MRF does not include any 'discounted cash prices,' it can be difficult to determine whether the hospital is noncompliant with the requirement to disclose established discounted cash prices or whether the hospital has simply not established such charges and therefore has nothing to make public. Often, a hospital will preempt questions by making statements on its website or in the file to indicate when there is no applicable standard charges data to share with the public. But when such a public statement is absent, we find that it may be necessary for us to contact the hospital to assess or determine whether the hospital is complying with the requirements of the regulation. In short, we have found it is necessary to employ methods beyond a simple audit of a hospital's website to definitively assess hospital compliance. We believe this distinction between monitoring and assessment activities is necessary because while monitoring activities can be used (by anyone, including CMS) to evaluate alleged noncompliance, only a formal CMS assessment can determine a hospital's compliance with the HPT requirements. We indicated our expectation that many of these issues would be resolved by finalizing the proposed improvements to standardizing display of hospital standard charges (as discussed in section XVIII.B.3 of this final rule with comment period). However, we noted that there could still be times when CMS would need additional information from the hospital to assess compliance.

We therefore proposed to amend § 180.70(a)(2) to add activities that CMS may use to monitor and assess for compliance. Specifically, we proposed:

- To revise § 180.70(a)(2)(iii) to indicate that CMS may conduct a comprehensive compliance review of a hospital's standard charge information posted on a publicly available website. We stated that we believed the proposal was necessary to clarify the methods we may use to determine a hospital's compliance with HPT requirements.
- At new § 180.70(a)(2)(iv), requiring an authorized hospital official to submit to CMS a certification to the accuracy and completeness of the standard charge information posted in the MRF at any stage of the monitoring, assessment, or compliance phase. We also proposed, at new § 180.50(a)(3), that the hospital affirm within the MRF the accuracy and completeness of the standard charge information. However, we indicated that we believed that this additional authority to require a formal certification by an authorized official

[801] *https://www.cms.gov/newsroom/fact-sheets/hospital-price-transparency-enforcement-updates.*

would be necessary because CMS may need a formal certification to resolve any specific questions related to the standard charges displayed and the items and services for which the hospital has established a standard charge, which might not be answered by the proposed affirmation statement in § 180.50(a)(3). For example, a formal certification may be necessary if a complainant alleges that specific standard charges displayed in the hospital's MRF are incomplete or inaccurate, or if certain items and services were provided by the hospital but are not displayed in the MRF with corresponding standard charges. Formal certification would provide assurance to CMS that the information within the MRF has been verified by the authorized official and was valid.

- At new § 180.70(a)(2)(v), requiring submission to CMS of additional documentation as may be necessary to assess hospital compliance. Such documentation may include contracting documentation to validate the standard charges the hospital displays, and verification of the hospital's licensure status or license number, in the event that information was not provided in the MRF. We stated that we believed that the proposal was necessary to enable CMS to adequately evaluate the hospital's publicly posted information to be able to assess compliance.

Further, we proposed two technical revisions. First, we proposed a technical revision to the heading at § 180.70(a) so that it would read ''Monitoring and assessment.'' Second, we proposed to amend § 180.90 by revising paragraph (b)(2)(ii)(C) to remove the phrase ''resulting from monitoring activities'' and adding in its place the phrase ''resulting from monitoring and assessment activities.''

Comment: Several commenters supported CMS' overall efforts to enhance assessment of noncompliance and its focus on improving enforcement.

Response: We thank commenters for their support.

Comment: Several commenters encouraged CMS to focus and commit to ''enforcement, not simply assessment.'' Similarly, a few commenters asserted that ''real enforcement'' is necessary, not just assessment, and that stringent enforcement is necessary to encourage hospital compliance with the law. A few commenters asked CMS to clarify that the proposed assessment and enforcement measures would supplement, not replace, the enforcement mechanisms currently in place, with one commenter encouraging CMS to say the proposals would supplement enforcement measures by strengthening CMS' capacity to assess compliance and respond to verified cases of noncompliance with enforcement actions. This commenter added that the need for clarification arises from the addition of ''assessment'' in § 180.70(a), and failure to use the word ''enforcement'' throughout this section in the CY 2024 OPPS/ASC proposed rule and recommended revised regulation text. A few commenters stated that any enhanced assessment capability must be paired with corresponding robust enforcement authority to engender compliance.

A few commenters disagreed with the proposed technical revision to the regulatory text change to ''monitoring and assessment,'' and strongly encouraged CMS to use consistent and strong language throughout the regulation and recommended CMS use the word ''enforcement'' to send a strong message to hospitals about the seriousness of enforcement activities.

Response: We appreciate the commenters' concerns and recommendations. CMS is committed to strong enforcement of the HPT regulation. We clarify that the proposed assessment and enforcement measures would not replace, but instead would supplement and enhance, existing enforcement mechanisms. Of note, we did not propose to remove the word ''Enforcement'' from § 180.70, but instead proposed to add the word ''Assessment'' in addition to ''Monitoring'' to § 180.70(a). Monitoring and assessment are activities that must occur prior to an enforcement action. Once CMS has determined (by way of its monitoring and assessment activities) that a hospital is out of compliance, the enforcement procedures continue to be addressed in § 180.70(b) under the actions to address hospital noncompliance.

Therefore, we will finalize the use of the word ''assessment'' and decline to replace this word with ''enforcement,'' given that ''enforcement'' is still included within the regulation text and that in order to complete enforcement activities, we must first complete assessment activities.

Comment: We received some comments related to the proposal to revise § 180.70(a)(2)(iii) to indicate that CMS may conduct a comprehensive compliance review of a hospita''s standard charge information posted on a publicly available website.

A few commenters provided general support for the proposal. One commenter supported additional monitoring and assessment capabilities for CMS in overseeing compliance.

One commenter questioned the scope and timing of a ''comprehensive compliance review'' and suggested that the criteria for a comprehensive compliance review be established and included in the CY 2024 OPPS/ASC proposed rule language before finalized so hospitals can have an opportunity to understand and provide appropriate comment. One commenter requested that CMS regularly release information about how compliance is monitored and assessed, such as the factors examined when compliance reviews are pursued.

Response: We appreciate the commenters' support, concerns, and recommendations. We remain committed to enforcement of the HPT regulation, and we take compliance with the regulation seriously. We believe revising § 180.70(a)(2)(iii) to indicate that CMS may conduct a comprehensive compliance review of a hospita''s standard charge information posted on a publicly available website (in addition to CMS audit which is included at § 180.70(a)(2)(iii) and would be retained) is necessary to clarify and align with the process we have established to determine a hospital's compliance with HPT requirements. This change does not alter our enforcement process, but instead merely clarifies the terminology we use in our current processes, and therefore does not diminish our enforcement capabilities. We will continue to evaluate complaints made by individuals or entities, review individuals' or entities' analysis of noncompliance, and audit hospitals' websites. We clarify that we will continue to comprehensively review hospitals' compliance with all the criteria required in 45 CFR 180.40, 180.50, and 180.60 in order to assess noncompliance and enforce those requirements, including any new criteria added as a result of this final rule with comment period. Additionally, in accordance with the regulation, once we make a determination of noncompliance we will continue to follow our established enforcement process, by which we may take one or more enforcement actions indicated in 45 CFR 180.70(b) such as providing a written warning notice to the hospital of the specific violation(s), requesting a CAP from the hospital if its noncompliance constitutes a material violation of one or more requirements, and imposing a CMP on the hospital if it remains noncompliant.

Comment: We received many comments related to our proposal to add § 180.70(a)(2)(iv) requiring submission of certification by an authorized hospital official as to the accuracy and

completeness of the data in the machine-readable file. Several commenters supported a hospital executive attesting to the accuracy of a hospital's data. One commenter requested that a ''top hospital executive'' sign an attestation assuring that the prices are complete and accurate, stating that this is the case for Medicare reimbursement reports. One commenter provided suggested regulation text to implement its suggestions. One commenter supported the proposal because certification of the accuracy and completeness of the standard charges will encourage hospitals to keep this information as up to date as possible, which will benefit the consumer.

A few commenters suggested that CMS require senior officers from the hospital to make such attestations and encouraged CMS to deem such attestations as material to payment from the Federal Government to incorporate potential liability under the False Claims Act (''FCA'') for hospitals that knowingly violate the rule and falsely attest to the accuracy and completeness of their files. Similarly, one commenter recommended that CMS take actionable steps allowing for applicable individuals to be held accountable for the pricing information provided.

Response: We thank commenters for their support. We indicated in the CY 2024 OPPS/ASC proposed rule that additional authority to require a formal certification by an authorized official would be necessary because we may need a formal certification to resolve any specific questions related to the standard charges displayed and the items and services for which the hospital has established a standard charge. This authority, and the authority requiring submission of additional documentation as may be necessary to assess hospital compliance, bolsters our ability to conduct a full compliance review and is in addition to the hospital's affirmation of the completeness and accuracy of the data. We do not agree that formal certification by an authorized official is required in every case.

We thank commenters for their suggestion to pursue noncompliance with the HPT regulations under the FCA; however, the FCA is outside the scope of this rule, and we believe that our current compliance regimen, as bolstered by the proposals that we finalize here, is the appropriate way to address hospital noncompliance with the HPT regulations. In the CY 2022 OPPS/ASC final rule with comment period (86 FR 63941, 63945), we increased the amount of civil monetary penalty to which a hospital could be subject to a minimum total penalty of $109,500 and a maximum total penalty of $2,007,500, per year. Additionally, we note that in addition to the compliance updates we are finalizing in this final rule with comment period, we are engaged in continued efforts to ensure that every hospital complies with the hospital price transparency requirements such as: requiring CAP completion deadlines; imposing CMPs earlier and automatically; and streamlining the compliance process.

Comment: Several commenters disagreed with the proposal to require an authorized hospital official to submit to CMS a certification to the accuracy and completeness of the standard charge information posted in the MRF. One commenter believed, given the complexity of the file development, no single person could certify all the contents of the MRF, and that the proposal could introduce personal liability. This commenter believes that the request for a primary point of contact for questions contained in the acknowledgement of warning notices language is reasonable and should address this issue. Another commenter stated that it would be unreasonable to require a single hospital official to certify the accuracy and completeness of the file with the magnitude of data it contains, and that any certifications should be limited to a targeted and narrow subset of data that can reasonably be reviewed by the hospital official.

Several commenters felt the proposal was duplicative of the requirements to affirm the accuracy of the MRF within the file itself. A few commenters expressed concern that the requirement would impose excessive burden on providers or create difficulty for hospitals that are part of a health system where MRFs are developed at the system level. One commenter believed that there is not much value in CMS receiving this submission, and that, instead, CMS should consider providers setting forth a good faith effort to be in compliance. One commenter questioned whether the formal certification is necessary because the expectation is that all information posted by a given hospital is in fact accurate and expressed concern about whether a hospital could actually certify completeness if a blank cell is required.

Response: We appreciate the commenters' concerns and recommendations. However, we note that a certification by an authorized official is standard practice in various CMS processes, for example, in such areas as Medicare provider-based attestation and the submission of Medicare cost reports. We also believe it is not unreasonable to expect that an authorized official could certify the contents of the MRF, as the standard charge information displayed is expected to be true, accurate, and complete as of the date indicated in the file. As previously stated, formal certification would provide assurance that the information within the MRF has been verified by the authorized official and is valid. The designation of a primary point of contact does not in itself assure accuracy or completeness of an MRF, and therefore does not address the need for a formal certification.

Further, we do not believe the affirmation statement in the MRF and a formal certification by an authorized official of the hospital are duplicative. The primary purpose of the affirmation statement in the MRF is to alert the public that the hospital has made a good faith effort to ensure the data included in the MRF is true, accurate, and complete, to the best of the hospital's knowledge and belief, as of the date indicated in the file. There may, however, be a need to resolve specific questions related to the standard charges displayed, which might not be answered by the proposed affirmation statement. For example, a formal certification may be necessary to validate information that has no independent source of verification.

By contrast to the affirmation statement that would be included in a hospital's MRF, the intent of the certification is use by CMS during the enforcement process, for example, to aid in assessing whether a hospital has corrected the deficiencies noted in a warning notice or in a request for a CAP. As such, a certification as part of CMS' enforcement process, signed by an authorized official of the hospital, serves a different purpose than the affirmation the hospital will be required to include in the MRF, as discussed in section XVIII.B.2. of this final rule with comment period.

We also anticipate that although this formal certification, signed by an authorized official of the hospital, may be requested at any stage of the monitoring, assessment, or compliance phases, it will not be required in all cases. Instead, it will be a method to monitor and assess hospital compliance as part of the enforcement process and will be submitted only upon CMS' request. The formal certification is not required to be posted publicly by the hospital. Therefore, we will finalize this provision as proposed.

Comment: Several commenters disagreed with the proposal to require

submission of additional documentation as may be necessary to make a determination of hospital compliance. One commenter cited hospital burden to comply and offered a detailed alternative process to validate transparency files using ''exploratory conversations.'' A few commenters believed that ''courts have long held that certain contracting information—especially negotiated rate data—is commercially sensitive information that is shielded from disclosure by numerous legal protections'' and cited court cases in support of this assertion. One commenter believed that the proposal would create a far more burdensome audit and review process and would shift monitoring and assessment to data validation. One commenter urged that if the proposal is finalized, that the contracts are designated as confidential commercial information that is exempt from disclosure under the Freedom of Information Act (FOIA).

A few commenters believed that requiring hospitals to share a broad array of additional information would be burdensome. A few commenters suggested that since CMS has already established transparency standards for payers, these could serve as a validation mechanism by cross-referencing the data. One commenter stated that because CMS is requiring a hospital to attest to the accuracy and completeness of its MRF, such additional contracting documentation is unnecessary. One commenter believed that there is not much value in the additional documentation requirement and that, instead, CMS should consider providers setting forth a good faith effort to be in compliance.

A few commenters requested clarification on this requirement. Specifically, one commenter requested CMS to clarify that the requirement is based on a request from CMS during monitoring and enforcement activities, and additional documents are not required to be included in the MRF, while the other commenter expressed concern that the language is overly broad and asked for greater specificity and clarity.

Response: We appreciate the commenters' concerns and recommendations. We believe that the ability to require hospitals to submit supporting source documents may be necessary, as part of the CMS enforcement process, to ensure compliance in some, but not all, cases. We clarify that we anticipate requiring submission of documentation to validate the standard charge information the hospital has included in its MRF, on a case by case basis, thus reducing burden. The documents themselves are not required to be included in the MRF. For example, if there is concern about the completeness and accuracy of payer-specific negotiated charges included in a hospital's MRF, CMS may use externally available information, such as the MRFs displayed by payers as a result of the TIC requirements, to monitor for hospital compliance; however, these data are not source data and may also contain errors. Accordingly, to make a determination of compliance, source data, such as data specified in a contract between a hospital and a third party payer, may be necessary to validate payer-specific negotiated charge information posted in the hospital's MRF. In this example, if CMS needs to make a determination regarding the accuracy or completeness of a hospital's data, this provision would require the hospital to submit documentation to demonstrate that the data encoded in the MRF is in fact accurate and complete. The hospital would determine the type of source data that would provide sufficient evidence needed for us to determine compliance, which may be the contract between the hospital and payer. Thus, we clarify that we are not explicitly requiring hospitals to submit any or all of their contracts to CMS for review. However, in response to an enforcement action, a hospital would need to supply sufficient source documentation so as to satisfy CMS that the hospital has met the regulatory requirements. As such, depending on the specific type of standard charge information that needs verification, the hospital might determine a contract is the appropriate source documentation. Further, a contract is only one type of source documentation that a hospital might choose to submit in response to a request from CMS in; it is not the only type of source documentation that the hospital may submit.

Additionally, we are not aware of any protections specific to hospital contracts being shielded from disclosure to a government agency for the purposes of determining compliance with regulatory requirements, and the case law cited by commenters did not go to that premise. We also note that hospitals are already required to display and disclose the payer-specific data. *See American Hospital Association* v. *Azar,* 468 F. Supp. 3d. (D.D.C. 2020), aff'd by *American Hospital Association* v. *Azar,* 983 F.3d 528 (D.C. Cir. 2020). We note that any documentation that is submitted by the hospital to CMS would be evaluated in accordance with the regulations at 45 CFR part 5, which addresses the FOIA provisions, prior to release in the event of a FOIA request.

We anticipate that any additional documentation requested will be limited to addressing specific evidence of noncompliance with one or more HPT requirements. For these reasons, we will finalize this provision as proposed.

Final action: After considering public comments, we are finalizing as proposed a revision to § 180.70(a)(2) to add activities that CMS may use to monitor and assess for compliance. Specifically, we will revise § 180.70(a)(2)(iii) to indicate that CMS may conduct a comprehensive compliance review of a hospital's standard charge information posted on a publicly available website, in addition to the use of audits which will be retained. We believe the proposal is necessary to clarify the methods we may use to determine a hospital's compliance with HPT requirements. At new § 180.70(a)(2)(iv), we will require, upon our request, an authorized hospital official to submit to CMS a certification to the accuracy and completeness of the standard charge information posted in the MRF. At new § 180.70(a)(2)(v), we will require submission to us, upon our request, additional documentation as may be necessary to make a determination of hospital compliance.

We are also finalizing as proposed a technical revision to the heading at § 180.70(a) so that it would read ''Monitoring and assessment.'' We are finalizing as proposed § 180.90 by revising paragraph (b)(2)(ii)(C) to remove the phrase ''resulting from monitoring activities'' and adding in its place the phrase ''resulting from monitoring and assessment activities.''

2. Requiring Hospital Acknowledgement of Receipt of Warning Notice

Since the HPT regulations first became effective in January 2021 through September 2023, we have issued approximately 989 warning notices to hospitals. Though we send the compliance actions by tracked mail, a few hospitals have reported they did not receive the compliance action notifications. This causes delays in resolution of the deficiencies and in some cases resulted in additional compliance actions (for example, a request for a CAP) from CMS. Requiring that a hospital respond to CMS upon receipt of a warning notice will confirm receipt to CMS and hopefully prompt hospital personnel to appropriately route the warning notice and initiate prompt action to resolve the

deficiencies specified in the warning notice.

We make clear that hospitals' internal process challenges do *not* (and in enforcement proceedings will not) excuse a hospital's HPT noncompliance. But knowledge of this concern caused CMS to consider modifications to the compliance process for purposes of streamlining compliance activities and avoiding unnecessary re-reviews when a hospital has taken no action in response to a warning notice. Additionally, receiving confirmation of receipt directly from individuals at the organization responsible for resolving the deficiencies would streamline our enforcement by providing an appropriate compliance contact earlier in the enforcement process. We therefore proposed at § 180.70(b)(1) that CMS will require that a hospital submit an acknowledgement of receipt of the warning notice in the form and manner, and by the deadline, specified in the notice of violation issued by CMS to the hospital. As part of the confirmation of receipt, we may request contact information from the hospital to streamline further communications.

Comment: Several commenters supported the proposal. A few commenters suggested that the primary contact on the CMS–855A be copied as they are already an intermediary between CMS and the hospital and could help ensure the communication reached the appropriate individuals in a timely manner. One commenter recommended that CMS require that the acknowledgement include contact information for a primary compliance officer at the hospital to streamline further communication. One commenter requested that the form, manner, and deadline for acknowledgement of receipt should be set as part of this rule. One commenter requested that CMS be detailed and explicit in its communication as to what the notice of deficiency is specifically for. One commenter requested that CMS allow hospitals to designate, or confirm, the appropriate hospital point of contact to receive communications from CMS.

CMS received no comments opposed to the proposal.

Response: We thank commenters for their support and suggestions. We intend to delineate the form, manner, and deadline for acknowledgement of receipt within the notice of violation issued to the hospital. We note that currently the hospital CEO may appoint a designee if he/she will not be the official representative communicating with CMS regarding the HPT program. We will continue to allow hospitals to designate the appropriate hospital point of contact.

Final action: After considering public comments, we are finalizing as proposed § 180.70(b)(1), that CMS will require that a hospital submit an acknowledgement of receipt of the warning notice in the form and manner, and by the deadline, specified in the notice of violation issued by CMS to the hospital.

3. Updated Actions To Address Noncompliance Within Hospital Systems

Section 2718(e) of the PHS Act and the HPT regulations apply to 'each hospital' operating in the U.S. As such, when CMS determines that a hospital is out of compliance with the regulations, CMS takes a compliance action against the individual hospital. Many hospitals, however, are part of a broader health system where common management officials have some degree of oversight and management over multiple hospitals. For example, some health systems have centralized administrative activities that establish standard charges for all the hospitals in the system, or that are responsible for ensuring compliance with Federal requirements. Under our current regulation, as explained in more detail in section XVIII.C.4 of the CY 2024 OPPS/ASC proposed rule, we have authority to disclose information about CMS compliance activity only when CMS issues a CMP, at which time CMS posts the CMP notice on its website. We indicated that we believed that amending the regulation to provide CMS with express authority to notify health system officials of a compliance action that CMS has taken against one or more hospitals within their system, and working directly with them, where appropriate, to educate health system leadership and aid them in bringing all hospitals in the system into compliance, could aid in streamlining hospital compliance and our enforcement process.

Therefore, we proposed to add new § 180.70(c) to state that, in the event CMS takes an action to address hospital noncompliance (as specified in paragraph (b)) and the hospital is determined by CMS to be part of a health system, CMS may notify the health system leadership of the action and may work with hospital system leadership to address similar deficiencies for hospitals across the health system. In determining whether a hospital is part of a health system and health system contact information, we anticipate using data from sources including, but not limited to, internal CMS systems such as the Medicare Provider Enrollment, Chain, and Ownership System (PECOS) or the Chronic Conditions Data Warehouse (CCW). For example, PECOS may be used to identify relationships among organizations including ownership or enrollment associations.[802]

We stated that we believed that notifying health system officials of a compliance action taken against one of the hospitals in the system and working with health system officials and (where different) the hospital's officials to help the hospital to come into compliance would have several benefits. First, it could serve to ensure full and consistent compliance across all hospitals in the health system. Second, we stated we believed the ability to work directly with health system officials, in addition to working with the noncompliant hospital, could reduce the need for compliance actions against other health system hospitals because the health system could more quickly and efficiently implement system-wide changes. For example, in one case multiple hospitals designated the same hospital system official as the point of contact to work with CMS. This allowed the hospital official to effectively correct violations cited across multiple locations and resulted in system-wide changes.

We sought comment on the proposal, including on whether there are additional data sources that CMS could access for purposes of identifying health system affiliation and leadership contact information.

Comment: Several commenters supported the proposal to address noncompliance within hospital systems. Several commenters showed their support for CMS' efforts to streamline hospital compliance and enforcement processes and indicated their belief that the proposal may seamlessly address noncompliance, improve delivery of communications, reduce administrative burden, and provide potential educational engagement and collaboration opportunities. One commenter supported the collaborative nature of the proposal but noted that it may be difficult for a health system to promptly implement a hospital-level corrective action plan with a system-wide change.

One commenter supported the proposal but suggested that CMS work

[802] Cohen GR, Jones DJ, Heeringa J, Barrett K, Furukawa MF, Miller D, Mutti A, Reschovsky JD, Machta R, Shortell SM, Fraze T, Rich E. Leveraging Diverse Data Sources to Identify and Describe U.S. Health Care Delivery Systems. EGEMS (Wash DC). 2017 Dec 15;5(3):9. Doi: 10.5334/egems.200. PMID: 29881758; PMCID: PMC5983023.

with individual hospitals to determine the correct personnel at each location. Further, they requested that CMS offer hospitals an opportunity to regularly update contact information in order to address any notices of noncompliance timely.

One commenter indicated they supported the proposal but would not support using the CMS–855A form that CMS currently uses to gather contact information, instead advocating for less administratively burdensome methods. By contrast, a few commenters recommended that all official communications be sent to PECOS authorized officials and delegated officials, or the hospital contact listed on the provider's CMS–855A form. Another commenter requested the ability to designate official contacts ahead of any compliance activities.

Response: We thank commenters for their support in alerting hospital system leadership when CMS has determined that one or more of the hospitals within the system is noncompliant. As explained in the CY 2024 OPPS/ASC proposed rule, once CMS determines that a hospital is out of compliance with the regulation, it takes a compliance action against an individual hospital. However, we have found that many hospitals are part of a larger health system. We believe the ability notify hospitals within a system and work with these health system officials may allow for consistent and efficient compliance across all hospitals in the health system. We also believe this could reduce instances of noncompliance among hospitals within a health system as they may be positioned to implement more informed system-wide changes. With that, we appreciate the commenter expressing it may be difficult for a health system to promptly implement a hospital-level corrective action plan with a system-wide change. However, we note that the proposal does not require hospitals to implement system-wide changes.

We agree with the commenters that addressing compliance with health systems may streamline hospital compliance and enforcement, improve delivery of communications, reduce administrative burden, and provide potential educational engagement and collaboration opportunities. Additionally, we appreciate the commenters who provided feedback on data sources that CMS may access for purposes of identifying health system affiliation and leadership contact information.

Final action: After consideration of the public comments we received, we are finalizing as proposed § 180.70(c) to state that, in the event CMS takes an action to address hospital noncompliance (as specified in paragraph (b)) and the hospital is determined by CMS to be part of a health system, CMS may notify health system leadership of the action and may work with health system leadership to address similar deficiencies for hospitals across the health system.

We believe these policies will aid in advancing hospital compliance and our enforcement process.

4. Publicizing Compliance Actions and Outcomes

In the CY 2020 HPT final rule, we sought comment related to publicizing complaints and posting results of CMS assessments of hospitals' HPT compliance, including on the most effective way for CMS to publicize information regarding hospitals that fail to comply. Some commenters recommended publicizing noncompliant hospitals, while one commenter expressed the belief that publicizing noncompliance even after imposition of a CMP would amount to ''public shaming,'' which the commenter believed would not be of benefit. We considered these comments and ultimately finalized a policy at § 180.90(e)(1) that, should CMS issue a CMP to a hospital it determines is noncompliant, CMS would post the notice of imposition of the CMP on a CMS website.

In finalizing this policy, we explained that we believed that publicizing a hospital's noncompliance prior to imposing a CMP, for example, could be an effective tool to raise public awareness of, for example, incomplete hospital data, and could encourage hospitals to promptly remedy its violation(s) to avoid being publicly identified as noncompliant. However, we declined at the time to finalize publicizing information beyond publicizing the notice of imposition of a CMP. We indicated that we would consider revisiting through future rulemaking the timing for, and approach by, which CMS publicizes its determination of a hospital's noncompliance with the requirements to make public standard charges.

As of September 2023, CMS had issued approximately 989 warning notices and 631 requests for CAPs since the initial regulation went into effect in January 2021. Approximately 346 hospitals were determined by CMS after a comprehensive compliance review to not require any compliance action and approximately 738 hospitals received a closure notice from CMS after having addressed deficiencies indicated in a prior warning notice or a request for a CAP following an initial comprehensive compliance review. At the time of the publication of the CY 2024 OPPS/ASC proposed rule, we had imposed CMPs on four hospitals and publicized those CMP impositions on our website.[803]

We explained that CMS routinely receives inquiries from the public, including state hospital associations, related to its compliance activities, asking, among other things, whether CMS has reviewed certain hospitals in certain states or other geographic locations. Given this significant public interest, we considered whether publicizing more information about CMS compliance activities and hospital-specific actions would be useful. We reviewed other Federal programs that make public compliance actions for various programs, such as HHS/HRSA's 340B Drug Pricing Program which publicly posts audit results that include the name of the entity and state, audit findings, sanction, and corrective action status,[804] CMS' Part C and D results related to the Medicare Advantage and Prescription Drug Plan program audits[805] and compliance actions,[806] and the FDA which provides the public access to an online, searchable dashboard of compliance actions, including warning letters.[807]

We indicated our belief that such information could improve the public's understanding and transparency of CMS' enforcement process by allowing interested parties to view compliance actions and determinations made by CMS. We further stated that making public compliance information may reduce repetitive complaints to CMS about hospital compliance issues and provide a central source of information for inquirers, including the media and state officials, who have expressed interest in this issue. Additionally, making these enforcement actions transparent may increase the likelihood that hospitals will more quickly come into compliance due to public scrutiny.

As a result, we proposed at § 180.70(d) that CMS may publicize on its website information related to CMS' assessment of a hospital's compliance, any compliance actions taken against a hospital, the status of such compliance

[803] *https://www.cms.gov/hospital-price-transparency/enforcement-actions.*

[804] *https://www.hrsa.gov/opa/program-integrity/fy-22-audit-results.*

[805] *https://www.cms.gov/medicare/compliance-and-audits/part-c-and-part-d-compliance-and-audits/programaudits.*

[806] *https://www.cms.gov/Medicare/Compliance-and-Audits/Part-C-and-Part-D-Compliance-and-Audits/PartCandPartDComplianceActions.*

[807] *https://datadashboard.fda.gov/ora/cd/complianceactions.htm.*

action(s), and the outcome of such compliance action(s). Additionally, we proposed at § 180.70(d) that CMS may publicize on its website information related to notifications that CMS may send to health system leadership, if proposals discussed in section XVIII.C.3 of the CY 2024 OPPS/ASC proposed rule were finalized. We indicated that should CMS decide to publicize this information on its website, it would apply uniformly to all hospitals. We further noted that, similar to other such assessments, the information we would make public would only be relevant as of the date indicated and should not be taken to suggest any ongoing state of compliance or noncompliance.

Comment: A few commenters supported the proposal to publicize information related to CMS' assessment of a hospital's compliance, compliance actions taken against a hospital, and the status and outcome of such compliance actions. A few commenters also supported CMS' proposal to create and publicize compliance information to help refute inaccurately reported third-party information. Taking it further, one commenter provided strong support for the proposal and shared their belief that CMS publicize when assessments of compliance are started, in progress, and completed. Another commenter requested that CMS provide a proactive notification of compliance in situations where CMS conducted a compliance assessment and confirmed no instances of noncompliance.

One commenter supported the proposal and recommended that CMS set up a regular cadence under which they assess hospital compliance and publicize the information associated with the status and outcome of such compliance actions. One commenter suggested that CMS consider delaying its enforcement for the first effective year of the CY 2024 OPPS/ASC proposed rule so hospitals and CMS can collaborate without a publication of noncompliance. Another commenter supported the proposal but requested CMS' commitment to note when an entity fixes its issues and moves into compliance in a timely manner to avoid public scrutiny.

Response: We appreciate the comments regarding the proposal to allow CMS the ability to publicize on its website information related to CMS' assessment of a hospital's compliance, any compliance actions taken against a hospital, the status of such compliance actions, and the outcomes of such compliance actions. We believe that publishing these actions may be an effective tool to raise public awareness and encourage hospitals to more quickly remedy any determinations of noncompliance to avoid public scrutiny. We also appreciate commenters who provided CMS with recommendations for displaying such information or suggestions for what we may include in our publication, or when CMS may post these actions.

Comment: One commenter supported CMS' efforts to be more transparent about how the agency assesses hospitals for compliance and list hospitals that have had compliance actions taken against them, while another commenter believed that may be helpful in encouraging improved compliance by hospitals, and yet another believed it will raise public awareness and encourage timely remediation of hospital violations.

A few commenters noted the proposal has the potential to reduce the collaboration between hospitals and CMS in resolving any assessment of noncompliance which may be remedied by a hospital conferring with CMS prior to a publication of a compliance action taken against them. Additionally, a few commenters recommended a process to be used to engage hospitals outside of a compliance action when CMS has questions about the file.

Response: We agree with the commenters that the proposal will assist in providing more transparency into CMS enforcement activities and, in addition to the requirements we are finalizing related to standardization in section XVIII.B.3. in this final rule with comment period, the criteria used for assessing hospitals for compliance. We believe the proposal will minimize frequent and often repetitive complaints made to CMS regarding a hospital's ongoing compliance status. Moreover, we believe the proposal allows for the public to view compliance determinations made by CMS on an ad hoc basis, increasing awareness and access to information previously not provided.

As noted by a commenter, there have been many productive conversations between hospitals and CMS during the compliance process that have involved education on both sides. CMS intends to continue conversations with hospitals, providing clarity and assistance when possible. Further, we intend to broaden our scope of engagement by working with health systems as proposed in § 180.70(c).

Comment: Regarding notification to health system leadership, one commenter suggested that CMS consider allowing publication of the responses of [health system] leadership to a compliance action if hospitals wish to have such responses published. Another commenter did not support publicly posting collaborative conversations between health system leaders and CMS. One commenter suggested publishing when a hospital utilized any CMS developed validation tool.

Response: As discussed in more detail in section XVIII.C.3 of this final rule with comment, we believe that the ability to work with health system leadership will benefit CMS in ensuring that hospitals across large health systems comply with the HPT requirements. As finalized, we intend to work with health system leadership on a collaborative and voluntary basis. Therefore, at this time, we decline to post communications received from health system leadership as they are not part of the formal compliance process and posting this information could have a chilling effect on the willingness of health system leadership to voluntarily work with CMS.

Similarly, we do not intend to publish details regarding a hospital's use of a CMS developed validation tool. The validator tool is intended as an aid to be used voluntarily by hospitals as they are developing their MRF which may help them format their standard charge information in accordance with the required technical specifications (finalized at new § 180.50(c)(2)); it is not intended as enforcement tool or as a tool to assess overall compliance with the HPT requirements at 45 CFR part 180. As such, as we want to encourage hospitals to use the validator tool to aid them while they are in the process of developing their MRFs, and not create any unintended chilling effect by tracking hospital use of the validator tool for enforcement purposes.

Comment: Several commenters did not support publicizing CMS assessments, compliance actions, and outcomes because hospitals that quickly come into compliance may receive negative public attention, and the information publicized could be misleading or misconstrued.

A few commenters also opposed publicizing CMS assessments, compliance actions, and outcomes as it may unfairly stigmatize hospitals that make a good-faith effort to comply, but, due to limited resources and capabilities, may require additional time to become fully compliant.

A few commenters urged CMS to make it clear that hospitals are not deemed noncompliant when under review. Another commenter requested that CMS refrain from publishing enforcement actions while hospitals work towards complying with the rule's requirements.

Comment: Several commenters expressed their belief that publishing this information may beget unjustified or negative feedback or unfairly stigmatize a hospital that is working to come into compliance.

Response: In contrast, we believe that publishing this information may work to bring hospitals into compliance more quickly to avoid public scrutiny. A few commenters concurred with CMS' belief. We believe that such information could improve the public's understanding and transparency of CMS' enforcement process by allowing interested parties to view compliance actions and determinations made by CMS.

Comment: One commenter voiced concern about a hospital being mistakenly listed as noncompliant and requested that CMS publicly retract assessments of noncompliance that have been incorrectly published. The same commenter suggested a delay of publication until CMS has taken steps to correct the contact information needed for the letters of noncompliance. One commenter acknowledged CMS' need to release this information and suggested data fields be released with corresponding disclaimer language. Another commenter believed that CMS does not publicize detailed information for any other types of enforcement and that HPT should be treated similarly. A few commenters suggested that CMS only publicize outcomes of compliance activities such as closure notices or CMPs to avoid unintended consequences or confusion and cautioned against publicizing information before compliance activities have closed. Another commenter requested that when a hospital receives a request for a CAP that is posted publicly in accordance with the proposal, that CMS removes the hospital as soon as they have satisfied the conditions of the CAP. Commenters expressed concern about CMS' publishing data preemptively and making unsubstantiated determinations of noncompliance, suggesting a warning notice is not a true compliance action. A few other commenters reiterated that CMS is the arbiter of compliance.

Response: We note that § 180.70(a) states that CMS may monitor and assess hospital compliance with section 2718(e) of the PHS Act and, should CMS conclude that a hospital is noncompliant with one or more of the requirements to make public standard charges, may take actions described at § 180.70(b) that include issuing a written warning notice. We believe the proposal may provide a single source of truth for hospitals, interested parties, or other inquirers.

We note that there are other Federal programs that make public compliance actions for various programs, including CMS' Part C and D results related to the Medicare Advantage and Prescription Drug Plan program audits [808] and compliance actions.[809]

We believe that making public compliance information may reduce repetitive complaints to CMS about hospital compliance issues and provide a central source of information.

However, we appreciate the commenters' concerns and recommendations, and we will continue to monitor and assess the impact of the proposal.

Final action: After consideration of the public comments we received, we are finalizing as proposed at § 180.70(d), that CMS may publicize on its website information related to the following:

(1) CMS' assessment of a hospital's compliance.

(2) Any compliance action taken against a hospital, the status of such compliance action, or the outcome of such compliance action.

(3) Notifications sent to health system leadership.

We believe that such information will improve the public's understanding of CMS' enforcement process by allowing interested parties to view compliance actions and determinations made by CMS, increasing transparency. We further believe that making public compliance information may reduce repetitive complaints to CMS regarding a hospital's compliance assessment. Further, making these enforcement actions transparent may increase the likelihood that hospitals will more quickly come into compliance due to public scrutiny.

D. Comments on CMS' Request for Information Related to Consumer-Friendly Displays and Alignment With Transparency in Coverage and No Surprises Act (NSA)

In the CY 2024 OPPS/ASC proposed rule, we included a Request for Information (RFI) related to consumer-friendly displays and alignment with TIC and the NSA. We received approximately 71 timely pieces of correspondence that were submitted in response to the RFI questions. We thank all interested parties for their comments and will take them into consideration in the future.

XIX. Changes to the Inpatient Prospective Payment System Medicare Code Editor

As discussed in the FY 2024 Inpatient Prospective Payment System (IPPS)/Long-Term Care Hospital (LTCH) Prospective Payment System (PPS) proposed rule (88 FR 26752), the Medicare Code Editor (MCE) is a software program that detects and reports errors in the coding of Medicare claims data. Patient diagnoses, procedure(s), and demographic information are entered into the Medicare claims processing systems and are subjected to a series of automated screens. The MCE screens are designed to identify cases that require further review before classification into a Medicare Severity Diagnosis Related Group (MS–DRG). If any of the MCE claim edits are triggered, the claim is returned to the provider to correct any issues related to the coded claims data and resubmit the claim for processing by the MAC.

After patient information is screened through the MCE and further development of the claim is conducted, the cases are classified into the appropriate MS–DRG by the Medicare GROUPER software program. The GROUPER program was developed as a means of classifying each case into an MS–DRG. The GROUPER software used under the LTCH PPS is the same GROUPER software program used under the IPPS and therefore, also utilizes the MCE to identify cases that require further review before assignment into a Medicare Severity Long-Term Care Diagnosis Related Group (MS–LTC–DRG) can be made.

As discussed in the FY 2023 IPPS/LTCH PPS final rule (87 FR 48874), we made available the FY 2023 ICD–10 MCE Version 40 manual file. The manual contains the definitions of the Medicare code edits, including a description of each coding edit with the corresponding diagnosis and procedure code edit lists. The link to this MCE manual file, along with the link to the mainframe and computer software for the MCE Version 40 (and ICD–10 MS–DRGs) are posted on the CMS website at: *https://www.cms.gov/medicare/medicare-fee-for-service-payment/acuteinpatientpps/ms-drg-classifications-and-software.* The MCE manual is currently comprised of two chapters: *Chapter 1: Edit code lists* provides a listing of each edit, an explanation of each edit, and as applicable, the diagnosis and/or procedure codes for each edit, and

[808] *https://www.cms.gov/medicare/compliance-and-audits/part-c-and-part-d-compliance-and-audits/programaudits.*

[809] *https://www.cms.gov/Medicare/Compliance-and-Audits/Part-C-and-Part-D-Compliance-and-Audits/PartCandPartDComplianceActions.*

Chapter 2: Code list changes summarizes the changes in the edit code lists (for example, additions and deletions) from the prior release of the MCE software.

As discussed in the FY 2024 IPPS/LTCH PPS proposed rule (88 FR 26758) and prior rulemaking, as we continue to evaluate the purpose and function of the MCE with respect to ICD–10, we encourage public input for future discussion, including with respect to whether there are concerns with the current edits, including specific edits or language that should be removed or revised, edits that should be combined, or new edits that should be added to assist in detecting errors or inaccuracies in the coded data. We note that historically, CMS has typically addressed the addition or deletion of MCE edits in its annual IPPS rulemakings, as well as the addition or deletion of ICD–10 diagnosis and procedure codes for the applicable MCE edit code lists effective October 1, consistent with the October 1 updates to the ICD–10 code set. We also note that currently, any changes applicable to the MCE edit code list in connection with the April 1 updates to the ICD–10 code set are made available on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/MS-DRG-Classifications-and-Software.*

As we have continued to evaluate the purpose and function of the MCE with respect to ICD–10, we recognize a need to further examine the operability of the MCE software program, including the current list of edits and the definitions of those edits. We have also considered the operation of the MCE as compared to the claims editing programs used for other Medicare payment systems, including how those edits are defined and applied, as well as how they are updated and maintained. For example, the Outpatient Prospective Payment System (OPPS) ''Integrated'' Outpatient Code Editor (I/OCE) is a software program that combines editing logic with an ambulatory payment classification (APC) assignment program. Similar to the IPPS MCE, the I/OCE edits the claims data to identify errors and ensure accuracy of submitted data. The I/OCE also serves additional claims editing functions as compared to the IPPS MCE. CMS makes updates to the I/OCE through quarterly releases with effective dates of January 1, April 1, July 1, and October 1 of each year. The updates reflect modifications to the program logic, such as additions and deletions of the ICD–10–CM diagnosis codes and Healthcare Common Procedure Coding System (HCPCS) codes; adding, removing or revising APCs; activating and deactivating edits; and other related actions. Changes and updates to the I/OCE are announced through quarterly I/OCE Change Requests (CRs) that are posted to the CMS website for MACs and public download at: *https://www.cms.gov/Medicare/Coding/OutpatientCodeEdit/OCEQtrReleaseSpecs.* The public may submit any questions or concerns related to the I/OCE through the CMS website at: *https://www.cms.gov/Medicare/Coding/OutpatientCodeEdit/ContactUs.*

Similar to the claims editing programs used for the OPPS and other Medicare payment systems, the claims edits under the MCE serve the operational function of identifying cases that require further review before classification into an MS–DRG. As previously discussed, if an edit is triggered, the claim is returned to the provider to correct any issues related to the coded claims data and to resubmit the claim for processing. Accordingly, consistent with the process that is used for updates to the I/OCE and other Medicare claims editing systems, we proposed to address any future revisions to the MCE, including any additions or deletions of claims edits, as well as the addition or deletion of ICD–10 diagnosis and procedure codes to the applicable MCE edit code lists, outside of the annual IPPS rulemakings. As discussed in the CY 2024 OPPS/ASC proposed rule, we stated that we anticipate generally announcing any such changes or updates to the MCE as part of our instructions issued to the MACs in connection with the April 1 and October 1 ICD–10 code updates.

Under our current process, we announce updates to the MCE in connection with the April 1 and October 1 ICD–10 code updates, as applicable. For example, as discussed in the FY 2024 IPPS/LTCH PPS proposed rule (88 FR 26767), we issued Change Request (CR) 13034, Transmittal 11746, titled ''April 2023 Update to the Medicare Severity—Diagnosis Related Group (MS–DRG) Grouper and Medicare Code Editor (MCE) Version 40.1 for the International Classification of Diseases, Tenth Revision (ICD–10) Diagnosis Codes for Collection of Health-Related Social Needs (HRSNs) and New ICD–10 Procedure Coding System (PCS) Codes'', on December 15, 2022 (available on the CMS website at: *https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Transmittals/r11746cp*), regarding the release of an updated version of the ICD–10 MS–DRG GROUPER and Medicare Code Editor software, Version 40.1, effective with discharges on and after April 1, 2023, reflecting the new diagnosis and procedure codes. We noted in the CR that the updated software, along with the updated ICD–10 MS–DRG V40.1 Definitions Manual and the Definitions of Medicare Code Edits V40.1 manual is available at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/MS-DRG-Classifications-and-Software.* We issued similar instructions with respect to the October 1, 2022 updates to the MCE and related materials, including the release of the updated Version 40 ICD–10 MS–DRG GROUPER and Medicare Code Editor software, effective with discharges on and after October 1, 2022, available at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/MS-DRG-Classifications-and-Software.*

We stated in the proposed rule that under our proposed approach, we would continue to issue instructions to the MACs in connection with any April 1 or October 1 updates to the IPPS MCE, including the effective date for the appropriate version of the MCE software program and the Definitions of Medicare Code Edits manual, and where these resources may be found on the CMS website. We also stated we would be interested in feedback as to whether it would also be helpful to list the specific MCE updates in the CR, including any additions or deletions of diagnosis or procedure codes or any addition or deletion of particular MCE edits. As previously noted, Chapter 2 of the MCE manual currently identifies the changes in the edit code lists (for example, additions and deletions) from the prior release of the MCE software. In the CY 2024 OPPS/ASC proposed rule, we stated that beginning with the FY 2025 rulemaking, we would no longer address the addition or deletion of MCE edits or the addition or deletion of ICD–10 diagnosis and procedure codes for the applicable MCE edit code lists in the annual IPPS rulemakings.

We noted that under this revised approach, we would also continue to welcome input from the public on the current edits, including input from providers and other users on how the MCE may currently be utilized in their respective workflow processes, as well as feedback on users' experience with the MCE, to inform any future revisions to the MCE.

We invited public comments on our proposal to remove discussion of the MCE from the annual IPPS rulemakings, beginning with the FY 2025 rulemaking, and to generally address future changes or updates to the MCE through instruction to the MACs, as previously described.

Comment: A few commenters stated that the opportunity for public comment on proposed changes to the MCE has historically been addressed through IPPS rulemaking. According to the commenters, there are important topics that may warrant additional consideration that hospital coding, clinical, and revenue cycle professionals need to ensure awareness of ahead of implementation to allow opportunity for comment. The commenters strongly recommended that CMS not finalize any changes related to the MCE and suggested the agency include the proposal in the upcoming FY 2025 IPPS/LTCH PPS proposed rulemaking, to help ensure that the appropriate IPPS audience has ample opportunity to review and provide comment.

A commenter specifically urged CMS to maintain discussion of the MCE in IPPS rulemaking. The commenter stated that the annual rulemaking process provides a more formal and publicly visible opportunity to provide comments to CMS on MCE manual changes, including any concerns with current edits, including specific edits or language recommended for removal or revision, edits that could be combined, or new edits to be added, and further stated that discussion of the MCE through multiple MACs would be a more de-centralized and fragmented process, particularly with multiple MACs involved, each of which may have varying processes for interpreting and implementing the MCE manual edits. According to the commenter, hospital systems would have to provide multiple submissions across various MACs and responses from the MACs may be inconsistent, leading to further fragmentation and confusion across hospitals and other providers. The commenter stated their belief that the more systematic annual regulatory process, with opportunity for notice and public comment, will assist in promoting a more seamless process for seeking and responding to public comment while minimizing confusion about MCE edits.

Another commenter expressed its appreciation that CMS indicated it would continue to welcome input from the public on the current MCE edits under the proposed revised approach, however the commenter urged CMS to establish a process that allows the public to continue to provide input on MCE changes if these changes are no longer going to be addressed through IPPS rulemaking. In addition, in response to our request for feedback as to whether it would also be helpful to list the specific MCE updates in a CR, the commenter recommended specific MCE updates be listed in the CR if the revised approach for addressing MCE revisions is adopted.

Response: We appreciate the commenters' feedback. We agree that historically, CMS has typically addressed the addition or deletion of MCE edits in its annual IPPS rulemakings, as well as the addition or deletion of ICD–10 diagnosis and procedure codes for the applicable MCE edit code lists effective October 1. However, we also note that, as discussed in the FY 2024 IPPS/LTCH PPS final rule (88 FR 58764), we historically have not listed the changes we have made to the MCE as a result of the new and modified codes approved after the annual spring ICD–10 Coordination and Maintenance Committee meeting, as these changes are approved too late in the rulemaking schedule for inclusion in the proposed rule. Furthermore, although our MCE policies have been described in our proposed and final rules, we have not provided the detail of each new or modified diagnosis and procedure code edit in the final rule. However, we make available the finalized Definitions of Medicare Code Edits (MCE) file and would continue to do so.

In response to comments recommending that CMS instead include the proposal in the upcoming FY 2025 IPPS/LTCH PPS proposed rulemaking to help ensure that the appropriate IPPS audience has ample opportunity to review and provide comment, we note that in the FY 2024 IPPS/LTCH PPS final rule (88 FR 58764 and 58765) we specifically referred readers to the discussion of the MCE proposal that was included in the CY 2024 OPPS/ASC proposed rule (88 FR 49552). We further believe that parties interested in Medicare payment for IPPS hospitals would regularly review the annual OPPS/ASC proposed rule and note that the proposal was specifically identified in the title to the CY 2024 OPPS/ASC proposed rule, which included ''Proposed Changes to the Inpatient Prospective Payment System Medicare Code Editor'' (88 FR 49552). Accordingly, we believe that the public, including the appropriate IPPS audience, had ample opportunity to review and provide comment on the proposal.

In response to the commenter who expressed concern that discussion of the MCE through multiple MACs would be a more de-centralized and fragmented process, as discussed in the proposed rule and previously in this final rule, we anticipate generally announcing any such changes or updates to the MCE as part of our instructions issued to the MACs in connection with the April 1 and October 1 ICD–10 code updates, as we currently do. This process would be similar to that currently used for changes and updates to the I/OCE that are announced through quarterly I/OCE Change Requests (CRs) that are posted to the CMS website for MACs and public download. We note that CMS maintains a network of MACs to serve as the primary operational contact between the Medicare FFS program and the health care providers enrolled in the program. We refer the reader to the CMS website at: *https://www.cms.gov/medicare/coding-billing/medicare-administrative-contractors-macs/whats-mac* for additional information on the role of the MACs. We also note that currently, there are MACs that provide information on their respective websites to inform providers when CRs have been published and to also provide additional information that may be helpful for providers with respect to the I/OCE and the MCE. For example, Noridian Healthcare Solutions, LLC at *https://med.noridianmedicare.com/web/jea/topics/claim-submission/ioce-mce#mce* and Palmetto GBA at *https://www.palmettogba.com/palmetto/jma.nsf/M/SearchSiteAdd?Open&term=Medicare%20Code%20Editor&fz=true.* We believe that the definition of each edit, as reflected in the Definitions of Medicare Code Edits manual, provides sufficient information on the intent of the edit. We also note that the Grouper software that is made publicly available via the CMS website at *https://www.cms.gov/medicare/payment/prospective-payment-systems/acute-inpatient-pps/ms-drg-classifications-and-software* in connection with the Definitions of Medicare Code Edits manual, reflects updates made to the MCE and that process is not changing.

In response to the commenter who urged CMS to establish a process that allows the public the opportunity to continue to provide input on MCE changes, we believe it is important to provide the public with opportunities to provide feedback on the MCE edits and, as discussed in the proposed rule, would continue to welcome public input. The public may submit any questions, comments, concerns, or recommendations regarding the MCE to the CMS mailbox at *MSDRGClassificationChange@cms.hhs.gov* for our review and consideration. We will also consider the recommendation to list specific MCE updates in a CR.

In summary, we believe that the proposal will allow for consistency in making updates and modifications to

claims edits under the MCE and other Medicare claims editing systems.

Final action: For the reasons discussed, and after consideration of the public comments we received, we are finalizing the proposal to remove discussion of the MCE from the annual IPPS rulemakings, beginning with FY 2025 rulemaking, and to generally address future changes or updates to the MCE through instruction to the MACs. We will also continue to analyze data on the current edits to determine utility and whether any edits should be modified or removed from the FFS claims processing systems in the future.

XX. Technical Edits for REH Conditions of Participation and Critical Access Hospital (CAH) CoP Updates

On November 23, 2022, we published a final rule for the Rural Emergency Hospital health and safety standards (or the Conditions of Participation), which was included in the ''Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Organ Acquisition; Rural Emergency Hospitals: Payment Policies, Conditions of Participation, Provider Enrollment, Physician Self-Referral; New Service Category for Hospital Outpatient Department Prior Authorization Process; Overall Hospital Quality Star Rating; COVID–19'' final rule with comment period (87 FR 71748). In that rule, we finalized a designation and certification process for Rural Emergency Hospitals at 42 CFR 485.506. In section XVIII.A.2 of the final rule, entitled ''Statutory Authority and Establishment of Rural Emergency Hospitals as a Medicare Provider Type,'' (87 FR 72160) we noted that in order to become an REH, section 1861(kkk)(3) of the Act requires that the facility, on the date of enactment of the CAA, 2021 (December 27, 2020), was a CAH or a rural hospital with not more than 50 beds. For the purpose of REH designation, section 1861(kkk)(3)(B) defines rural hospital as a subsection (d) hospital (as defined in section 1886(d)(1)(B) with not more than 50 beds located in a county (or equivalent unit of local government) in a rural area (as defined in section 1886(d)(2)(D) of the Act)), or treated as being located in a rural area pursuant to section 1886(d)(8)(E) of the Act. (87 FR 72161).

We reiterated these requirements in the discussion of the Designation and Certification of REHs (§ 485.506) and finalized the regulatory text for the requirement at 42 CFR 485.506; however, we inadvertently cited the incorrect statutory references in one paragraph of the preamble. We proposed to correct these statutory citations from ''1881(d)(2)(D)'' to ''1886(d)(2)(D)'' and from ''1881(d)(1)(B)'' to ''1886(d)(1)(B)'' at § 485.506(b) and (c) (87 FR 72294).

We did not receive any public comments on our proposal and therefore, we are finalizing our proposal.

XXI. Rural Emergency Hospitals (REHs): Payment for Rural Emergency Hospitals (REHs)

A. Background on Rural Emergency Hospitals (REHs)

The Consolidated Appropriations Act (CAA), 2021 (Pub. L. 116–260), was signed into law on December 27, 2020. In this legislation, Congress established Rural Emergency Hospitals (REHs), a new rural Medicare provider type, to help maintain access to rural outpatient hospital services and prevent rural hospital closures. These providers furnish emergency department and observation care, and other specified outpatient medical and health services, if elected by the REH, that do not exceed an annual per patient average of 24 hours. Hospitals are eligible to convert to REHs if they were CAHs or rural hospitals with not more than 50 beds participating in Medicare as of the date of enactment of the CAA. For more information on the statutory authority for and the regulations implementing this new Medicare provider type, please refer to the CY 2023 OPPS/ASC final rule with comment period (87 FR 72160 through 72161).

B. REH Payment Methodology

Pursuant to section 1834(x)(1) of the Act and CMS's implementing regulations at 42 CFR 419.91 and 419.92(a)(1), payment for REH services is defined in terms of the amount of payment ''that would otherwise apply under section 1833(t),'' for covered outpatient department (OPD) services, increased by 5 percent. As discussed in the CY 2023 OPPS/ASC final rule with comment period, CMS interprets ''rural emergency hospital services,'' as defined by section 1861(kkk)(1) of the Act, to include the scope of covered OPD services as defined in 1833(t)(1)(B) of the Act (excluding 1833(t)(1)(B)(ii) of the Act) (87 FR 72162). In the CY 2023 OPPS/ASC final rule with comment period, CMS also finalized regulations at 42 CFR 419.92(c) which address payment for services furnished by an REH that fall outside the scope of the covered OPD services under section 1833(t)(1)(B) of the Act. In addition, pursuant to section 1834(x)(2) of the Act, CMS codified at § 419.92(b) that REHs will be paid an additional monthly facility payment, which was calculated for CY 2023 pursuant to the methodology described in the CY 2023 OPPS/ASC final rule with comment period and will be updated in subsequent years by the hospital market basket percentage increase as described in section 1886(b)(3)(B)(iii) of the Act.

C. Background on the IHS Outpatient All-Inclusive Rate (AIR) for Tribal and IHS Hospitals

For many years, tribal and IHS hospitals have been paid for hospital outpatient services furnished to Medicare beneficiaries based upon an outpatient per visit rate (the All-Inclusive Rate or ''AIR''), which is published annually by the IHS in the **Federal Register**. For additional information about the annual all-inclusive rates that IHS sets for inpatient and outpatient medical care provided by IHS facilities, please refer to IHS's CY 2023 Reimbursement Rate Notice which appeared in the **Federal Register** on February 27, 2023 (88 FR 12387).

In the CY 2002 OPPS final rule, CMS explicitly excluded IHS hospitals from the OPPS (66 FR 59893) and codified that exclusion at § 419.20(b)(4), explaining that these facilities would continue to be paid under the separately established rate (the AIR) that is published annually in the **Federal Register**.

D. Paying Indian Health Service (IHS) and Tribal Hospitals That Convert to an REH Under the AIR

While some tribal and IHS hospitals have expressed interest in converting to an REH, they have expressed significant reservations about doing so due to having to transition from their existing payment methodology under the AIR to the REH payment methodology. As discussed above, in accordance with § 419.20(b)(4) and CMS's longstanding policy, tribal and IHS hospitals are excluded from payment under the OPPS and instead are paid for hospital outpatient services under the AIR. In contrast, payment for REH services is defined in section 1834(x)(1) of the Act and under § 419.92(a)(1) as ''the amount of payment that would otherwise apply under section 1833(t) of the Act for the equivalent covered OPD service.'' Because there is no amount that would otherwise apply under section 1833(t) of the Act for hospital outpatient services furnished by tribal and IHS hospitals (because these hospitals have always been excluded from the OPPS for payment for hospital outpatient services), such services, when furnished by IHS or tribally operated REHs

(hereinafter referred to as ''IHS–REHs''), do not fall within the scope of ''REH services''. Under § 419.92(c), ''a service furnished by an REH that does not meet the definition of an REH service under § 419.91 is paid for under the payment system applicable to the service, provided the requirements for payment under that system are met.'' Consequently, we proposed that IHS–REHs be paid for hospital outpatient services under the same rate (the applicable AIR that is established and published annually by the IHS) that would otherwise apply if these services were performed by an IHS or tribal hospital, consistent with the requirements of § 419.92(c). Under the proposal, the AIR would serve as payment for services furnished by IHS–REHs as part of an outpatient hospital encounter in the same manner as the AIR currently applies to IHS operated hospitals. Accordingly, to the extent that IHS hospitals are currently compensated via the AIR, rather than other Medicare payment mechanisms, for services other than hospital outpatient services that are furnished as part of an outpatient hospital encounter, we proposed that an IHS–REH would also be paid via the AIR when furnishing such services as part of an outpatient hospital encounter. Further, we note that existing beneficiary coinsurance policies applicable to such services under the AIR would remain unchanged by our proposal.

We proposed that IHS–REHs would receive the REH monthly facility payment consistent with how this payment is made to REHs that are not tribal or IHS facilities. CMS pays the monthly facility payment, pursuant to section 1834(x)(2) of the Act, as a separate payment to the REH that is not tied to specific services. Likewise, there is nothing in the statute and CMS's implementing regulations (§ 419.92(b)) that would preclude REHs, including tribal or IHS–REHs, from receiving this payment, even if they are paid under a separate payment framework for hospital outpatient services provided to beneficiaries (87 FR 72167 through 72181). Therefore, we proposed that IHS–REHs would receive the monthly facility payment, consistent with § 419.92(b).

We also believe that for IHS–REHs it would be most efficient from a claims processing perspective for the IHS–REHs to process their claims separately from other REHs. Therefore, we proposed to update the OPPS claims processing logic to include an IHS–REH specific payment flag, which an IHS–REH provider would utilize to indicate that the provider is an IHS–REH and should be paid the AIR.

Allowing tribal and IHS hospitals to continue receiving payment for hospital outpatient services through the AIR would remove several barriers to these hospitals converting to REHs. The proposal would provide tribal and IHS hospitals that convert to REHs greater predictability by allowing these facilities to continue to be paid via a familiar payment mechanism (the AIR), that will enable payment at the same rate that these hospitals are currently paid for outpatient hospital encounters. The proposal would also reduce the administrative burden for tribal and IHS hospitals to convert to an REH since they would already be familiar with reporting services and receiving payment using the AIR and would not need to invest in new software and additional staff training to receive payment for individual REH services at the REH payment rate. The continued use of the AIR would also make it easier for tribal and IHS providers that convert to an REH, but later determine it was the wrong decision for their facility, to convert back to a CAH or an inpatient hospital. Finally, CMS anticipates that the proposal would enable an increased number of rural tribal and IHS hospitals to attain an REH designation in a manner that would allow them to maintain their outpatient services, which may have a positive impact on health equity for Native Americans and people adversely affected by persistent poverty or inequality by facilitating access to health care in rural tribal communities.

We proposed to add a new paragraph (d) to § 419.92 to codify that, beginning in CY 2024, IHS and tribally operated REHs, as defined in a proposed new paragraph (e) in § 419.92 as discussed below, will be paid under the outpatient hospital AIR that is established and published annually by the IHS instead of being paid the rates for REH services described in § 419.92(a)(1).

We also proposed to amend § 419.93(a)(2), relating to services furnished by an off-campus provider-based department of an REH, to add a reference to the proposed new provision at § 419.92(d) for purposes of payment for services furnished by off-campus provider-based departments of IHS and tribally operated REHs.

Finally, we proposed to establish a definition for IHS or tribally operated REHs, to identify the REHs that will be eligible to receive payment under the proposed new policy in § 419.92(d). Accordingly, we proposed to add paragraph (e) to § 419.92 to codify that for purposes of § 419.92, an IHS or tribally operated REH means an REH, as defined in § 485.502, that is operated by the IHS or by a tribe or tribal organization with funding authorized by Title I or III of the Indian Self-Determination and Education Assistance Act (Pub. L. 93–638).

Comment: Two commenters requested a technical change to the proposed regulation text in § 419.92(e) to state that ''. . . an Indian Health Service (IHS) or tribal REH is an REH, as defined in 42 CFR 485.502 of this chapter, that is operated by the IHS or by a tribe or tribal organization with funding authorized by Title I or V of the Indian Self-Determination and Education Assistance Act (Pub. L. 93–638)'' instead of by Title I or III of the Indian Self-Determination and Education Assistance Act (Pub. L. 93–638).

Response: We agree with the commenters that the correct statutory reference for the funding authorization described in this context is to Titles I and V of the Indian Self-Determination and Education Assistance Act (Pub. L. 93–638), and so we will be adopting this correction when finalizing § 419.92(f) as part of this final rule with comment period. Consistent with the commenters' suggested technical change to the proposed regulation text, we are also updating the term ''Indian Health Service (IHS) or tribally operated REH'' to ''Indian Health Service (IHS) or tribal REH'' in the regulation text at § 419.92(e) and (f) that we are finalizing as part of this final rule with comment period. As previously discussed, CMS proposed to allow Indian Health Service (IHS) or tribal facilities that become REHs to continue to receive the AIR in order to build on the longstanding policy and allow for continuity for eligible IHS and tribal hospitals that currently receive the AIR, and who might be interested in converting to the REH provider type. Providers that currently receive the outpatient AIR in the OPPS context are referred to as ''IHS or tribal hospitals,'' and thus for clarity and consistency we are finalizing § 419.92(e) and (f) with updated language that refers to ''Indian Health Service (IHS) or tribal REHs.''

Comment: One commenter asked that IHS and tribal REHs have the option to choose whether they can receive payment for services performed by an IHS–REH through either the AIR or the standard REH service payment methodology of paying the OPPS rate for a service plus an additional 5 percent payment.

Response: We thank the commenter but respectfully disagree with the suggestion to give IHS–REHs the option

to choose between whether their facility will receive payment for services provided through the AIR or the standard REH service payment methodology. As stated earlier in this section and in the CY 2024 OPPS/ASC proposed rule, CMS's proposal that IHS and tribal facilities that become REHs be paid for hospital outpatient services via the AIR, rather than the standard REH services payment methodology, is based on CMS's longstanding policy, in accordance with § 419.20(b)(4), that IHS and tribal facilities are excluded from payment under the OPPS and instead are paid for hospital outpatient services under the AIR. Section 1834(x)(1) of the Act and § 419.92(a)(1) define payment for REH services as ''the amount of payment that would otherwise apply under section 1833(t) of the Act for the equivalent covered OPD service.'' Because there is no amount that would otherwise apply under section 1833(t) of the Act for hospital outpatient services furnished by tribal and IHS hospitals, such services, when furnished by IHS or tribal REHs do not fall within the scope of REH services. Based on this, CMS has proposed that hospital outpatient services furnished by IHS or tribal REHs be paid via the AIR consistent with § 419.92(c), which provides that ''a service furnished by an REH that does not meet the definition of an REH service under § 419.91 is paid for under the payment system applicable to the service, provided the requirements for payment under that system are met.'' However, because paying IHS–REHs for hospital outpatient services under an alternative payment mechanism (the AIR) would be premised on hospital outpatient services furnished IHS–REHs not meeting the definition of ''REH services,'' it would be contradictory to also allow IHS–REHs the option of being paid under the standard payment mechanism for ''REH services'' when furnishing those same services.

Comment: Multiple commenters supported our proposals to allow IHS–REHs to receive service payments through the AIR instead of through the standard REH service payment methodology of the OPPS rate for a service plus an additional 5 percent payment.

Response: We thank the commenters for their support of our proposals.

After consideration of the public comments we received, and for the reasons discussed above and in the proposed rule, we are finalizing our proposals to allow IHS and tribal hospitals that become REHs to receive payment for services using the IHS outpatient hospital AIR with two minor modifications. First, we are correcting the statutory reference to the Indian Self Determination and Education Act (Pub. L. 93–638) which appears in § 419.92(f). Second, we are updating the term ''Indian Health Service (IHS) or tribally operated REH'' to be ''Indian Health Service (IHS) or tribal REH'' in § 419.92(e) and (f).

E. Exclusion of REHs From the OPPS

Hospitals that are excluded from payment under the OPPS are specified under § 419.20(b) of the regulations. Because, as described above, REHs are paid outside of the OPPS, we intended to revise § 419.20(b) during the CY 2023 rulemaking cycle to exclude REHs from payment under the OPPS. However, this intended revision was inadvertently omitted. Consequently, we proposed to codify the exclusion of REHs from the OPPS by adding new paragraph (b)(5) to § 419.20.

Comment: One commenter expressed their support for the corrections to the REH statutory references.

Response: We appreciate the support of the commenter.

After consideration of the public comments we received, we are implementing our proposal without modification.

XXII. Request for Public Comments on Potential Payment Under the IPPS and OPPS for Establishing and Maintaining Access to Essential Medicines

A. Overview

On January 26, 2021, President Biden issued Executive Order (E.O.) 14001, ''A Sustainable Public Health Supply Chain'' (86 FR 7219), which launched a whole-of-government effort to strengthen the resilience of medical supply chains, especially for pharmaceuticals and simple medical devices. This effort was bolstered subsequently by E.O.s 14005, 14017, and 14081 (86 FR 7475, 11849, and 25711, respectively). In June 2021, as tasked in E.O. 14017 on ''America's Supply Chains,'' the Department of Health and Human Services released a review of pharmaceuticals and active pharmaceutical ingredients, analyzing risks in these supply chains and recommending solutions to increase their reliability.[810] In July 2022, as tasked in E.O. 14001, the Biden–Harris Administration also released the *National Strategy for a Resilient Public Health Supply Chain,* which laid out a roadmap to support reliable access to products for public health in the future, including through prevention and mitigation of medical product shortages.[811]

Over the last few years, shortages for critical medical products have persisted and continued to increase.[812] For pharmaceuticals, even before the COVID–19 pandemic, nearly two-thirds of hospitals reported more than 20 drug shortages at any one time—from antibiotics used to treat severe bacterial infections to crash cart drugs necessary to stabilize and resuscitate critically ill adults.[813] The frequency and severity of these supply disruptions has only been exacerbated over the last few years.

Recent data supports that hospitals are estimated to spend more than 8.6 million personnel hours and $360 million per year to address drug shortages, which will likely further result in treatment delays and denials, changes in treatment regimens, medication errors,[814] [815] [816] as well as higher rates of hospital-acquired infections and in-hospital mortality.[817] [818] The additional time, labor, and resources required to navigate drug shortages also increase health care costs.[819]

[810] Department of Health and Human Services, *Review of Pharmaceuticals and Active* Pharmaceutical Ingredients (pp. 207–250), June 2021: *https://www.whitehouse.gov/wp-content/uploads/2021/06/100-day-supply-chain-review-report.pdf.*

[811] Department of Health and Human Services, *National Strategy for a Resilient Public Health Supply Chain,* July 2021: *https://www.phe.gov/Preparedness/legal/Documents/National-Strategy-for-Resilient-Public-Health-Supply-Chain.pdf.*

[812] Senate Committee on Homeland Security & Governmental Affairs, *Short Supply: The Health and National Security Risks of Drug Shortages,* March 2023: *https://www.hsgac.senate.gov/wp-content/uploads/2023-06-06-HSGAC-Majority-Draft-Drug-Shortages-Report.-FINAL-CORRECTED.pdf.*

[813] Vizient, *Drug Shortages and Labor Costs: Measuring the Hidden Costs of Drug Shortages on U.S. Hospitals,* June 2019: *https://wieck-vizient-production.s3.us-west-1.amazonaws.com/page-Brum/attachment/c9dba646f40b9b5def8032480ea51e1e85194129.*

[814] American Journal of Health System Pharmacology, *National Survey on the Effect of Oncology* Drug Shortages on Cancer Care, 2013: *https://pubmed.ncbi.nlm.nih.gov/23515514/.*

[815] JCO Oncology Practice, *National Survey on the Effect of Oncology Drug Shortages in Clinical Practice,* 2022: *https://pubmed.ncbi.nlm.nih.gov/35544740/.*

[816] Journal of the American Medical Association, *Association between U.S. Norepinephrine Shortage and Mortality Among Patients with Septic Shock,* 2017: *https://pubmed.ncbi.nlm.nih.gov/28322415/.*

[817] Clinical Infectious Diseases, *The Effect of a Piperacillin/Tazobactam Shortage on Antimicrobial Prescribing and Clostridium difficile Risk in 88 US Medical Centers,* 2017: *https://pubmed.ncbi.nlm.nih.gov/28444166/.*

[818] New England Journal of Medicine, *The Impact of Drug Shortages on Children with Cancer: The Example of Mechlorethamine,* 2012: *https://pubmed.ncbi.nlm.nih.gov/23268661/.*

[819] Department of Health and Human Services, *ASPE Report to Congress: Impact of Drug Shortages on Consumer Costs,* May 2023: *https://aspe.hhs.gov/reports/drug-shortages-impacts-consumer-costs.*

Hospitals' procurement preferences directly influence upstream intermediary and manufacturer behavior and can be leveraged to help foster a more resilient supply chain for lifesaving drugs and biologicals. With respect to shortages, supply chain resiliency includes having sufficient inventory that can be leveraged in the event of a supply disruption or demand increase—as opposed to ''just-in-time'' inventory-management efficiency that can leave supply chains vulnerable to shortage.[820] [821] This concept is especially true for essential medicines, which generally comprise of products that are medically necessary to have available at all times in an amount adequate to serve patient needs and in the appropriate dosage forms. A resilient supply can also include essential medicines from multiple manufacturers, including the availability of domestic pharmaceutical manufacturing capacity, to diversify the sourcing of essential medicines. We believe it is necessary to support practices that can curtail pharmaceutical shortages of essential medicines and promote resiliency in order to safeguard and improve the care hospitals are able to provide to beneficiaries.

As discussed below in sections XXII.B, XXII.C, and XXII.D of this final rule with comment period, we sought comment on separate payment under the IPPS, and potentially the OPPS, for establishing and maintaining access to a buffer stock of essential medicines to foster a more reliable, resilient supply of these medicines. We provide an overview of comments received and next steps in sections XXII.E and XXII.F of this final rule with comment period.

B. Establishing and Maintaining a Buffer Stock of Essential Medicines

The report *Essential Medicines Supply Chain and Manufacturing Resilience Assessment,* as developed by the U.S. Department of Health and Human Services (HHS) Office of the Assistant Secretary for Preparedness and Response (ASPR) prioritized 86 essential medicines (hereinafter referred to as, the ''essential medicines'') identified as either critical for minimum patient care in acute settings or important for acute care or important for acute care of respiratory illnesses/conditions, with no comparable alternative available.[822] [823] When hospitals have insufficient supply of these essential medicines, such as during a shortage, care for Medicare beneficiaries can be negatively impacted. To mitigate negative care outcomes in the event of insufficient supply, hospitals can adopt procurement strategies that foster a consistent, safe, stable, and resilient supply of these essential medicines. Such procurement strategies can include provisions to maintain or otherwise provide for extra stock of product (for example, either to maintain or to hold directly at the hospital, arrange contractually for a distributor to hold, or arrange contractually with a wholesaler for a manufacturer to hold), which can act as a buffer in the event of an unexpected increase in product use or disruption to supply. We expect that the resources required to establish and maintain access to a minimal ''buffer stock'' of essential medicines, such as a 3-month supply, will generally be greater than the resources required to establish and maintain access to these medicines through alternative means that are more susceptible to supply chain disruptions (for example, through so-called ''just-in-time'' inventory practices). Given these additional resource costs, we stated in the CY 2024 OPPS/ASC proposed rule we were considering separate payment under the IPPS and the OPPS for the costs of establishing and maintaining access to a buffer stock of essential medicines.

For the IPPS, we indicated that the Secretary could potentially make this separate payment for the additional resource costs of establishing and maintaining access to a buffer stock of essential medicines under section 1886(d)(5)(I) of the Act, which authorizes the Secretary to provide by regulation for such other exceptions and adjustments to the payment amounts under section 1886(d) of the Act as the Secretary deems appropriate.

For the OPPS, we indicated that the Secretary could potentially make this separate payment for the additional resource costs under section 1833(t)(2)(E) of the Act. Section 1833(t)(2)(E) of the Act provides that the Secretary shall establish, in a budget neutral manner, other adjustments (in addition to outlier and transitional pass-through payments and payments for non-opioid treatments for pain relief) necessary to ensure equitable payments, such as adjustments for certain classes of hospitals.

Additionally, we stated that sustaining sources of domestically sourced medical supplies can also help support continued availability in the event of public health emergencies and other disruptions.[824] [825] We indicated this concept was consistent with our current policy for domestic National Institute for Occupational Safety and Health (NIOSH) approved surgical N95 respirators (87 FR 72037). Hospitals, as major purchasers and users in the U.S. of essential medicines, can support the existence of domestic sources by sourcing domestically made essential medicines. However, we indicated that we expect that domestically manufactured essential medicines may be more expensive than those sourced from some other countries that may have lower manufacturing costs.[826] Given these additional resource costs, we took into account the increased costs to establish and maintain access to a buffer stock of domestically manufactured essential medicines when developing the potential payment policy discussed in the CY 2024 OPPS/ASC proposed rule.

In addition to essential medicines, we indicated that we may consider expanding a potential Medicare payment policy in future years to include critical medical devices once the HHS Critical Medical Device List (CMDL) becomes available. In accordance with implementation of Executive Order 14001 on a Sustainable Public Health Supply Chain, the FDA is leading an effort to develop this list of recommended medical devices that are critical to have on hand, at all times for patients, healthcare workers, and the U.S. public because of their clinical need. We stated that HHS' list was expected to be available by the end of 2023.

[820] Department of Health and Human Services, Review of Pharmaceuticals and Active Pharmaceutical Ingredients (pp. 207–250), June 2021: *https://www.whitehouse.gov/wp-content/uploads/2021/06/100-day-supply-chain-review-report.pdf.*

[821] Department of Health and Human Services, National Strategy for a Resilient Public Health Supply Chain, July 2021: *https://www.phe.gov/Preparedness/legal/Documents/National-Strategy-for-Resilient-Public-Health-Supply-Chain.pdf.*

[822] *https://www.armiusa.org/wp-content/uploads/2022/07/ARMI_Essential-Medicines_Supply-Chain-Report_508.pdf.*

[823] *https://aspr.hhs.gov/newsroom/Pages/Essential-Medicines-May22.aspx.*

[824] Department of Health and Human Services, *Review of Pharmaceuticals and Active Pharmaceutical Ingredients* (pp. 207–250), June 2021: *https://www.whitehouse.gov/wp-content/uploads/2021/06/100-day-supply-chain-review-report.pdf.*

[825] Department of Health and Human Services, *National Strategy for a Resilient Public Health Supply Chain,* July 2021: *https://www.phe.gov/Preparedness/legal/Documents/National-Strategy-for-Resilient-Public-Health-Supply-Chain.pdf.*

[826] Department of Health and Human Services, *Review of Pharmaceuticals and Active Pharmaceutical Ingredients* (pp. 207–250), June 2021: *https://www.whitehouse.gov/wp-content/uploads/2021/06/100-day-supply-chain-review-report.pdf.*

C. Potential Separate Payment Under IPPS and OPPS for Establishing and Maintaining Access to a Buffer Stock of Essential Medicines

Currently, payment for the resources required to establish and maintain access to medically reasonable and necessary drugs and biologicals is generally part of the IPPS or OPPS payment. As noted in section XXII.B of the CY 2024 OPPS/ASC proposed rule, we expect that the resources required to establish and maintain access to a buffer stock of essential medicines will generally be greater than the resources required to establish and maintain access to these medicines without such a buffer stock. Additionally, the resources required to establish and maintain access to a buffer stock of domestically manufactured essential medicines may generally be greater than the resources required to establish and maintain access to a buffer stock of these medicines from non-domestic sources. Given the policy goals we discussed in sections XXII.A and XXII.B of the CY 2024 OPPS/ASC proposed rule, we stated we believe it may be appropriate to pay separately for the additional resource costs associated with establishing and maintaining access, including through contractual arrangement, to a buffer stock of essential medicines. We indicated that these potential separate payments would be in addition to payment for the essential medicines themselves, whether that payment is bundled with other items or services or the essential medicines are separately paid, and would help account for the additional resource costs associated with establishing and maintaining access, including through contractual arrangements, to a buffer stock of these essential medicines.

We noted it is challenging to quantify these additional resource costs precisely based on currently available information. As noted in section XXII.B of the CY 2024 OPPS/ASC proposed rule, hospitals could establish and maintain access to a buffer stock in a variety of ways, including, but not limited to, through contractual arrangements with distributors and wholesalers. Given the current challenge in precisely quantifying these additional resource costs, we indicated in the CY 2024 OPPS/ASC proposed rule that CMS could initially base the IPPS payment on the IPPS shares of the additional reasonable costs of a hospital to establish and maintain access to its buffer stock. The use of IPPS shares in this payment adjustment would be consistent with the use of these shares for the payment adjustment for domestic NIOSH approved surgical N95 respirators (87 FR 72037). These costs, which could include costs to hold essential medicines directly at the hospital, arrange contractually for a distributor to hold, or arrange contractually with a wholesaler for a manufacturer to hold, could be reported to CMS by a hospital in aggregate on its cost report. These costs would not include the costs of the essential medicine itself. This reported information, along with existing information already collected on the cost report, could be used to calculate a Medicare payment for the estimated cost, specific to each hospital, incurred to establish and maintain access to its buffer stock of these essential medicines. In accordance with the principles of reasonable cost as set forth in section 1861(v)(1)(A) of the Act and in 42 CFR 413.1 and 413.9, we indicated that Medicare could make a lump-sum payment for Medicare's share of these additional inpatient costs at cost report settlement.

In the CY 2024 OPPS/ASC proposed rule, we indicated these payments for the IPPS shares of establishing and maintaining access to a buffer stock of essential medicines could be provided biweekly as interim lump-sum payments to the hospital and would be reconciled at cost report settlement. A provider could make a request for these biweekly interim lump sum payments for an applicable cost reporting period, as provided under 42 CFR 413.64 (Payments to providers: Specific rules) and 412.116(c) (Special interim payments for certain costs). These payment amounts would be determined by the Medicare Administrative Contractor (MAC), consistent with existing policies and procedures. In general, interim payments are determined by estimating the reimbursable amount for the year using Medicare principles of cost reimbursement and dividing it into 26 equal biweekly payments. The estimated amount is based on the most current cost data available, which will be reviewed and, if necessary, adjusted at least twice during the reporting period. (See CMS Pub 15–1 2405.2 for additional information.) The MACs could determine the interim lump-sum payments based on the data the hospital may provide that reflects the information that could be included on a supplemental cost reporting form. (In the CY 2024 OPPS/ASC proposed rule we indicated that CMS would separately seek comment through the PRA process on a potential supplemental cost reporting form that could be used for this purpose.) In future years, the MACs could determine the interim biweekly lump-sum payments utilizing information from the prior year's cost report, which may be adjusted based on the most current data available. This would be consistent with the current policies for medical education costs, and bad debts for uncollectible deductibles and coinsurance paid on interim biweekly basis as noted in CMS Pub 15–1 2405.2. It is also consistent with the payment adjustment for domestically sourced NIOSH approved surgical N95 respirators (87 FR 72037).

We sought comment on separate payment under IPPS for the IPPS share of the reasonable costs of establishing and maintaining access to a 3-month buffer stock of one or more essential medicine(s). We indicated that essential medicines for a potential IPPS separate payment would be the 86 essential medicines prioritized in the report *Essential Medicines Supply Chain and Manufacturing Resilience Assessment.* We indicated that an adjustment under OPPS could be considered for future years. We sought comment on all aspects of this potential payment policy.

We indicated that to reflect any such separate payment under the IPPS, we were considering amending our regulations at 42 CFR 412.1 by revising paragraph (a)(1)(iv) to read as follows: ''Additional payments are made for outlier cases, bad debts, indirect medical education costs, for serving a disproportionate share of low-income patients, for the additional resource costs of domestic National Institute for Occupational Safety and Health approved surgical N95 respirators, and for the additional resource costs of establishing and maintaining access to a buffer stock of essential medicines.''

We stated that we were also considering amending our regulations, and sought comment on these potential revisions, at 42 CFR 412.2 by adding paragraph (f)(11) to read as follows: ''A payment adjustment for the additional resource costs of establishing and maintaining access to a buffer stock of essential medicines as specified in § 412.113.''

We stated that we were also considering amending our regulations, and sought comment on these potential revisions at § 412.113 by adding a paragraph (g) providing that additional resource costs of establishing and maintaining access to a buffer stock of essential medicines:

- Essential medicines are the 86 medicines prioritized in the report *Essential Medicines Supply Chain and Manufacturing Resilience Assessment*

developed by the U.S. Department of Health and Human Services Office of the Assistant Secretary for Preparedness and Response and published in May of 2022. A buffer stock of essential medicines for a hospital is a 3-month supply of one or more essential medicines;

- The additional resource costs of establishing and maintaining access to a buffer stock of essential medicines for a hospital are the additional resource costs incurred by the hospital to directly hold a buffer stock of essential medicines for its patients, or arrange contractually for such a buffer stock to be held for use by the hospital for its patients. The additional resource costs of establishing and maintaining access to a buffer stock of essential medicines does not include the resource costs of the essential medicines themselves;
- For cost reporting periods beginning on or after January 1, 2024, a payment adjustment to a hospital for the additional resource costs of establishing and maintaining access to a buffer stock of essential medicines is made as described in § 412.113(g)(4); and
- The payment adjustment is based on the reasonable cost incurred by the hospital for establishing and maintaining access to a buffer stock of essential medicines during the cost reporting period.

D. Comment Solicitation on Additional Considerations

In addition to the potential payment policy described in section XXII.C of the CY 2024 OPPS/ASC proposed rule, we sought comment on additional considerations in section XXII.D of the CY 2024 OPPS/ASC proposed rule. These additional considerations are summarized below, but we refer the public to section XXII. D of the CY 2024 OPPS/ASC proposed rule for the complete discussion. We sought comment on the following:

- How effective the potential payment policy would be at improving the resiliency of the supply chain for essential medicines and the care delivery system.
- A number of issues related to establishing and maintaining access to a buffer stock of more expensive domestically manufactured essential medicines compared to non-domestically manufactured ones.
- The list of essential medicines, including expanding the list to include essential medicines used in the treatment of cancer.
- Whether a 3-month supply is the appropriate amount of supply for the buffer stock or whether an alternative duration should be used.
- The resources involved in establishing and maintaining access to a buffer stock of essential medicines.
- Current practices regarding buffer stocks, including the use of contractual arrangements.
- The unique circumstances of safety net hospitals or other types of hospitals.
- Flexibilities that should exist for implementing buffer stock practices.
- The immediate impacts on the supply of essential medicines that could be expected upon implementation of the potential policy, including what steps, if any, would need to be taken to mitigate risks of possible demand-driven shortages as a result of implementation of such a policy.
- A separate payment adjustment to more acutely address supply issues that emerge specific to a pandemic or other public health emergency.
- Essential medicines that are currently in shortage, and thus potentially not appropriate for arranging to have buffer stock.
- A number of issues related to critical medical devices.

E. Overview of Comments Received

All commenters acknowledged the importance of addressing domestic drug shortages and medical supply chain disruptions. Many thanked HHS for drawing attention to the issue and considering actions aimed at reducing the many negative repercussions to hospitals and patients caused by drug shortages. However, there was a lack of consensus among commenters about a potential Medicare payment policy. As described further below, CMS is not finalizing any changes at this time, but intends to propose future policy addressing aspects of hospital practices with respect to pharmaceutical supply, including in future payment rules and through Conditions of Participation.

Some commenters, including a limited number of pharmaceutical manufacturers, some smaller hospital associations, hospital pharmacist and other health care provider associations and hospital systems were supportive of the potential separate payment. Some of these commenters stated that a potential payment could foster a more resilient and reliable supply of essential medicines, and would help hospitals mitigate negative impacts to drug supply and patient care during emergencies. Some of these commenters suggested that CMS clarify whether hospitals could—or should—arrange for these buffer stocks to be maintained by other parties ''upstream,'' such as manufacturers and wholesalers, rather than maintain buffer stocks themselves as individual hospitals. Some of these commenters noted the importance of implementing a policy in a way that mitigates potential for demand-driven shortages.

The majority of commenters, including MedPAC, stated they did not support the specific potential payment policy as described and discussed in the request for comment. Most hospitals, hospital associations, pharmaceutical manufacturers, academic researchers, and patient organizations who commented were concerned that design changes would be necessary to avoid exacerbating existing drug shortages or causing demand-driven shortages. Some commenters were concerned about a potential policy inducing hoarding behaviors and fragmenting the available stock of the 86 essential medicines. Several commenters suggested that CMS phase in (for example, by region or length of time covered by the buffer stock) or stagger implementation of any potential policy over time to mitigate the risk of demand shocks (including impacts to care settings outside of hospitals), remove drugs from the essential medicines list if they are currently in shortage, and, to help inform policy approaches, first work with hospitals and manufacturers to better understand current practices and patterns. Commenters stated we should either implement flexibilities for drugs in shortage or at risk of shortage or exclude them from eligibility under any potential policy.

Commenters were generally supportive of a 3-month length of time for the buffer stock, with some advocating a smaller stock to maximize adoption of the policy. Others advocated for a 6-month buffer stock, either initially or transitioning to that length, to better improve supply chain resiliency. Several commenters stated that no length of time was uniformly appropriate for all the 86 essential medicines, suggesting that HHS tailor the size of the buffer stock to each drug.

Some commenters raised equity concerns regarding the impact of this policy on small, rural providers and safety net hospitals. They indicated that these providers tend to have less surplus funding on hand and may not be able to afford the upfront costs of establishing a buffer stock of one or more of the 86 essential medicines. Commenters stated that if only large, urban hospitals can afford to opt into the policy and thereby fragment the existing supply of essential medicines, rural and safety net hospitals may experience reduced access to these essential medicines. Because the cost of the medicines themselves would not be included under the potential payment

policy as described, commenters suggested that CMS provide incentive payments or direct financial support to hospitals unable to opt into the policy due to financial obstacles. Several commenters expressed concern that such a policy may exclusively benefit large urban hospitals, as they claimed only these hospitals could afford the upfront costs of establishing a buffer stock. Commenters indicated that hospital participation in such policy as described in the comment solicitation should be voluntary.

We received many comments about the appropriate list of essential medicines considered for inclusion in a potential policy. Many commenters agreed with the use of the 86 essential medicines prioritized in the report *Essential Medicines Supply Chain and Manufacturing Resilience Assessment* (also referred to as ''ASPR's list'' by commenters). Other commenters proposed other lists, including the list FDA was directed to issue under E.O. 13944 (referred to as the ''FDA list'' by many commenters), the World Health Organization's Essential Medicines List, Vizient's Essential Medications For High-Quality Patient Care, a list of drugs developed by the National Association of EMS Physicians, and a Pediatric Drug List. Many commenters stated the E.O. 13944 list is more inclusive (including blood products) than ASPR's list and some stated that health care workers are most familiar with it. Several commenters suggested creating a new list organized by disease states, such that any medication approved for treating a given disease on the list would be approved for inclusion under the policy. Other commenters suggested that CMS convene a panel of experts to create a tailored list, stating that some critical medicines are missing from the existing ASPR list and some medicines on the list are unnecessary to include (for example, oral olanzapine). Other commenters proposed the expansion of existing lists or creation of new lists of essential medicines for the outpatient setting including outpatient cancer care and physicians' offices. Commenters stated that an expanded list would enable the program to adapt quickly to changes in manufacturing supply and demand and address the specific needs of individual hospitals.

Several commenters expressed interest in a broader policy targeting effective quality management practices among pharmaceutical manufacturers, which they stated remains the leading driver of supply-driven drug shortages, and requested that HHS adopt policies to address this issue. Some advised instituting payment incentives for, or limiting eligibility to, those providers that contracted with manufacturers with strong quality management maturity practices when establishing their respective buffer stock of one or more of the 86 essential medicines. Another commenter stated that, to reduce reliance on companies likely to have quality failures, drugs from manufacturers with a recent history of FDA warning letters should be excluded. Other commenters suggested that CMS focus higher payments on the purchase of domestically made essential medicines. Some commenters stated that an operational definition of domestic would be difficult for the essential medicines, and suggested that CMS consider definitions of domestic other than the definition noted in the CY 2024 OPPS/ASC proposed rule.

Many commenters were concerned about the added administrative burden associated with tracking and calculating the additional costs associated with establishing and maintaining a buffer stock of essential medicines, either directly or through contractual arrangements with pharmaceutical intermediaries or manufacturers. They stated that the administrative burden of collecting and reporting this information through a supplemental cost reporting worksheet would be sufficiently costly or onerous to prevent hospitals from seeking separate payment. Some commenters expressed concern about the administrative complexity of directly maintaining a buffer stock of essential medicines if they wished to do so rather than maintaining the buffer stock through a contract with a pharmaceutical manufacturer or distributor. These commenters stated concerns about having adequate storage space and inventory management capability for 3 months of product. Commenters stated that such hospitals would likely have to maintain separate records for buffer stock essential medicines, depending on the scope of the policy, as well as potentially for domestically versus non-domestically manufactured medicines within those buffer stocks. One commenter suggested episodically surveying hospitals on their storage costs and making payment based on a national average (excluding outliers) so providers are not subject to as many reporting requirements.

Several commenters expressed concern that providers may not receive separate payment for the IPPS share of establishing and maintaining a buffer stock upon audit. For example, as indicated earlier, in accordance with the principles of reasonable cost as set forth in section 1861(v)(1)(A) of the Act and in 42 CFR 413.1 and 413.9, Medicare could make a lump-sum payment for Medicare's share of the additional inpatient costs at cost report settlement. As with other separate Medicare payments based on reasonable costs, an audit of the cost report submitted by the hospital might determine the costs submitted by the hospital not to be reasonable. Some commenters stated this may make providers hesitant or unwilling to opt into a potential essential medicines policy.

F. Next Steps

We appreciate the broad consensus regarding the need to curtail pharmaceutical shortages of essential medicines and promote resiliency in order to safeguard and improve the care hospitals are able to provide to beneficiaries. We agree with commenters that a multifaceted approach is likely necessary. As part of our initial efforts, we intend to propose new Conditions of Participation in forthcoming notice and comment rulemaking addressing hospital processes for pharmaceutical supply. Although in this final rule with comment period we are not adopting a policy regarding payment under the IPPS or OPPS for establishing and maintaining access to essential medicines, in response to the comments received, we continue to seek feedback from interested parties on ways to address the additional costs hospitals face to address pharmaceutical shortages and prepare for future emergencies. We will consider this feedback in future payment policy. We look forward to continuing to engage with the public on this critical issue in future rulemaking.

XXIII. Files Available to the Public Via the Internet

The Addenda to the OPPS/ASC proposed rules and 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 titled ''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). In the CY 2022 OPPS/ASC final rule

with comment period (85 FR 86266), we updated the format of the OPPS Addenda A, B, and C by adding a column titled ''Drug Pass-Through Expiration during Calendar Year'' where we flagged, through the use of an asterisk, each drug for which pass-through payment was expiring during the calendar year on a date other than December 31. For CY 2024 and subsequent years, we proposed to retain these columns that are updated to reflect the drug codes for which pass-through payment is expiring in the applicable year.

In the CY 2023 OPPS/ASC final rule with comment period (87 FR 72250) for CY 2023, we changed the format of the OPPS Addenda A, B, and C by adding a column titled ''Drug Pass-Through Expiration during Calendar Year'' to include devices, so that the column reads: ''Drug and Device Pass-Through Expiration during Calendar Year'' where we flagged, through the use of an asterisk, each drug and device for which pass-through payment was expiring during the calendar year on a date other than December 31. For CY 2024 and subsequent years, we proposed to retain these columns that are updated to reflect the devices for which pass-through payment is expiring in the applicable year.

In addition, we proposed to delete the column titled ''Copayment Capped at the Inpatient Deductible'' and instead to add a new column for ''Adjusted Beneficiary Copayment'' to identify any copayment adjustment due to either the inpatient deductible amount copayment cap or the inflation-adjusted copayment of a Part B rebatable drug per section 1833(t)(8)(F) and section 1833(i)(9) of the Act, as added by section 11101 of the Inflation Reduction Act (IRA). We also proposed to add another column for notes. We proposed that the ''Note'' column would contain multiple messages including, but not limited to, inflation-adjusted copayment of a Part B rebatable drug, the copayment for a code capped at the inpatient deductible, or 8 percent of the reference product add-on applied for a biosimilar.

For CY 2024, we did not receive any public comments and are finalizing our proposal to update the addenda format by deleting the column titled ''Copayment Capped at the Inpatient Deductible'' and instead to add two new columns for ''Adjusted Beneficiary Copayment'' and ''Note.''

In addition, for CY 2024, we are updating the format of the OPPS Addenda A, B, and C by adding another column for ''IRA Coinsurance Percentage'' to identify the percentage for the inflation-adjusted copayment of a Part B rebatable drug per section 1833(t)(8)(F) and section 1833(i)(9) of the Act, as added by section 11101 of the Inflation Reduction Act (IRA). To view the Addenda to this final rule pertaining to CY 2024 payments under the OPPS, we refer readers to the CMS website at: *https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient/regulations-notices;* select ''CMS–1786–FC'' from the list of regulations. All OPPS Addenda to this final rule with comment period are contained in the zipped folder titled ''2024 NFRM OPPS Addenda'' in the related links section at the bottom of the page. To view the Addenda to this CY 2024 OPPS/ASC final rule with comment period pertaining to CY 2024 payments under the ASC payment system, we refer readers to the CMS website at: *https://www.cms.gov/medicare/payment/prospective-payment-systems/ambulatory-surgical-center-asc/asc-regulations-and-notices;* select ''CMS–1786–FC'' from the list of regulations. The ASC Addenda to the CY 2024 OPPS/ASC proposed rule are contained in a zipped folder titled ''2024 NFRM Addendum AA, BB, DD1, DD2, EE, and FF''.

XXIV. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995, we are required to provide 30-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. 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 solicited public comment on each of these issues for the following sections of this document that contain information collection requirements (ICRs):

A. ICRs Related to Proposed Intensive Outpatient Physician Certification Requirements

As discussed in the CY 2024 OPPS/ASC proposed rule (88 FR 49702), we proposed to codify the content of certification and plan of treatment requirements for intensive outpatient services at § 424.24(d). Specifically, we proposed to mirror the PHP content of certification and plan of care treatment requirements at § 424.24(e), with the following exceptions: require the content of certification to include documentation that the individual requires such services for a minimum of 9 hours per week (with no requirement for a need for inpatient psychiatric care if the IOP services were not provided).

We stated that the proposed ICRs at § 424.24(d) are subject to the Act. However, we stated that we believe the burden associated with these ICRs are exempt, as defined by 5 CFR 1320.3(b)(2), because the time, effort, and financial resources necessary to comply with these requirements would be incurred by persons in the normal course of their activities. We stated that we believe the record keeping requirements described in section VIII.B.3 of the CY2024 OPPS/ASC proposed rule are a usual and customary part of physicians' activities in developing the plan of treatment for existing patients in intensive outpatient programs, and that the requirements are similar to existing ICRs under Medicare for partial hospitalization patients.

We did not receive any comments on the burden estimate in the CY 2024 OPP/ASC proposed rule.

B. ICRs Related to the Hospital OQR Program

1. Background

The Hospital Outpatient Quality Reporting (OQR) Program is generally aligned with the CMS quality reporting program for hospital inpatient services known as the Hospital Inpatient Quality Reporting (IQR) Program. We refer readers to the CY 2011 through CY 2023 OPPS/ASC final rules (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 and 79863; 82 FR 59476 through 59479; 83 FR 59155 and 59156; 84 FR 61468 through 61469; 85 FR 86266 through 86267; 86 FR 63961 through 63968, and 87 FR 72250 through 72252, respectively) for detailed discussions of the previously finalized Hospital OQR Program ICRs.

The ICRs associated with the Hospital OQR Program are currently approved

under OMB control number 0938–1109, which expires on February 28, 2025. In the CY 2023 OPPS/ASC final rule, our burden estimates were based on an assumption that approximately 3,350 hospitals would report data to the Hospital OQR Program. For this final rule, based on data from the CY 2023 Hospital OQR Program payment determination, which supports this assumption, we will continue to estimate that 3,350 hospitals will report data to the Hospital OQR Program, unless otherwise noted. While the exact number of hospitals required to submit data annually may vary, we use this estimate to be consistent with previous rules and for ease of calculation across reporting periods.

In the CY 2018 OPPS/ASC final rule with comment period (82 FR 52617), we finalized a policy 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. We note that since the CY 2023 OPPS/ASC final rule with comment period, BLS removed this labor category and added a new labor category titled ''Medical Records Specialists.'' While the most recent data from the BLS reflects a median hourly wage of $24.56 per hour for all medical records specialists, $26.06 is the hourly mean wage for ''general medical and surgical hospitals,'' [827] which is an industry within medical records specialists. We believe the industry of ''general medical and surgical hospitals'' is more specific to our settings for use in our calculations than other industries that fall under medical records specialists, such as ''office of physicians'' or ''nursing care facilities.'' We have finalized a policy to calculate the cost of overhead, including fringe benefits, at 100 percent of the mean hourly wage (82 FR 52617). 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 ($26.06 × 2 = $52.12) to estimate the total cost is a reasonably accurate estimation method and allows for a conservative estimate of hourly costs.

In section XIV.B.2 of this final rule with comment period, we finalized our proposals to modify three previously adopted measures: (1) the COVID–19 Vaccination Coverage Among Healthcare Personnel measure, beginning with the CY 2024 reporting period/CY 2026 payment determination; (2) the Cataracts: Improvement in Patient's Visual Function Within 90 Days Following Cataract Surgery measure survey instrument usage, beginning with the voluntary CY 2024 reporting period; and (3) the Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients measure, beginning with the CY 2024 reporting period/CY 2026 payment determination. We finalized with modification, our proposals to adopt two new measures: (1) Risk Standardized Patient-Reported Outcome-Based Performance Measure (PRO–PM) Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA) in the HOPD Setting, with voluntary reporting beginning with the CY 2025 reporting period followed by mandatory reporting beginning one year later than proposed with the CY 2028 reporting period/CY 2031 payment determination; and (2) the Excessive Radiation Dose or Inadequate Image Quality for Diagnostic Computed Tomography (CT) in Adults (Hospital Level—Outpatient) electronic clinical quality measure (eCQM), with voluntary reporting beginning with the CY 2025 reporting period followed by mandatory reporting beginning one year later than proposed with the CY 2027 reporting period/CY 2029 payment determination.

We did not finalize our proposals to: (1) remove the Left Without Being Seen measure; or (2) re-adopt the Hospital Outpatient Volume on Selected Outpatient Surgical Procedures measure with modification.

2. Information Collection Burden To Modify the COVID–19 Vaccination Coverage Among Healthcare Personnel (HCP) Measure Beginning With the CY 2024 Reporting Period/CY 2026 Payment Determination

In the CY 2022 OPPS/ASC final rule with comment period, we finalized adoption of the COVID–19 Vaccination Coverage Among Healthcare Personnel (HCP) measure for the Hospital OQR Program (87 FR 71748 through 72310). In section XIV.B.2.a of this final rule with comment period, we finalized our proposal to modify the COVID–19 Vaccination Coverage Among HCP measure to utilize the term ''up to date'' in the HCP vaccination definition and update the numerator to specify the timeframes within which an HCP is considered up to date with recommended COVID–19 vaccines, including booster doses, beginning with the CY 2024 reporting period/CY 2026 payment determination for the Hospital OQR Program. We previously discussed information collection burden associated with this measure in the CY 2022 OPPS/ASC final rule with comment period (86 FR 63962).

We do not believe that the use of the term ''up to date'' or the update to the numerator will impact information collection or reporting burden because the modification changes neither the amount of data being submitted to CMS nor the frequency of data submission. Additionally, because we did not finalize any updates to the form, manner, and timing of data submission for this measure, we do not anticipate any increase in burden associated with this policy. The modified COVID–19 Vaccination Coverage Among HCP measure will continue to be calculated using data submitted to the CDC under a separate OMB control number (0920–1317; expiration date January 31, 2024). However, the CDC currently has a PRA waiver for the collection and reporting of vaccination data under section 321 of the National Childhood Vaccine Injury Act of 1986 (enacted on November 14, 1986) (NCVIA) (Pub. L. 99–660).

3. Information Collection Burden To Modify the Cataracts: Improvement in Patient's Visual Function Within 90 Days Following Cataract Surgery Measure Survey Instrument Use Beginning With the CY 2024 Reporting Period

In the CY 2014 OPPS/ASC final rule with comment period (78 FR 75102 through 75104), we finalized the adoption of the Cataracts: Improvement in Patient's Visual Function Within 90 Days Following Cataract Surgery beginning with the CY 2016 payment determination; this measure currently is voluntary. In section XIV.B.2.b of this final rule with comment period, we finalized our proposal to limit the survey instruments that can be used to administer this measure to three assessment tools: NEI VFQ–25, VF–14, and VF–8R, beginning with the CY 2024 reporting period.

Because the three assessment tools being finalized are currently allowable for collecting data for this measure, we do not believe limiting use to these three surveys would result in a change in burden. As a result, we did not propose any changes in burden per response associated with this policy to finalize. Additionally, as currently stated in the Hospital OQR Program Specifications Manual, the maximum annual sample case size for chart abstraction for this measure is 63 cases

[827] U.S. Bureau of Labor Statistics. Occupational Outlook Handbook, Medical Records Specialists. Accessed on March 6, 2023. Available at: *https://www.bls.gov/oes/current/oes292072.htm.*

for hospitals with an outpatient population size of between 0 and 900 and 96 cases for hospitals with an outpatient population size of greater than 900.[828] We did not propose an increase in the required sample size for chart abstraction; therefore we do not believe there is any increase in burden associated with this policy.

4. Information Collection Burden To Modify the Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients Measure Beginning With the CY 2024 Reporting Period/CY 2026 Payment Determination

In the CY 2014 OPPS/ASC final rule with comment period, we finalized the Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients measure (78 FR 75101 and 75102). In section XIV.B.2.c of this final rule with comment period, we finalized our proposal to amend the measure denominator language by removing the phrase ''aged 50 years'' and adding in its place the phrase ''aged 45 years.''

As currently stated in the Hospital OQR Program Specifications Manual, the maximum annual sample case size for chart abstraction for this measure is 63 cases for hospitals with an outpatient population size of between 0 and 900 and 96 cases for hospitals with an outpatient population size of greater than 900. We did not propose an increase in the required sample size for chart abstraction; therefore, we do not believe there is any increase in burden associated with this policy.

5. Information Collection Burden To Adopt the Risk Standardized Patient-Reported Outcome-Based Performance Measure (PRO–PM) Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA) in the HOPD Setting With Voluntary Reporting Beginning With the CY 2025 Reporting Period Followed by Mandatory Reporting Beginning With the CY 2028 Reporting Period/CY 2031 Payment Determination

In section XIV.B.3.b of this final rule with comment period, we finalized our proposal to adopt the THA/TKA PRO–PM with voluntary reporting beginning with the CY 2025 reporting period, followed by mandatory reporting beginning one year later than proposed with the CY 2028 reporting period/CY 2031 payment determination. This measure was previously adopted for the Hospital IQR Program in the FY 2023 IPPS/LTCH PPS final rule with an estimated burden of 7.25 minutes (0.120833 hours) per patient to complete both the pre-operative and post-operative surveys and 10 minutes (0.167 hours) per hospital per response to collect and submit the measure data via the Hospital Quality Reporting (HQR) system (87 FR 49386 and 49387). We believe the estimated burden for both patient surveys and data submission would be the same for the Hospital OQR Program.

The THA/TKA PRO–PM uses four sources of data for the calculation of the measure: (1) patient-reported outcome (PRO) data; (2) claims data; (3) Medicare enrollment and beneficiary data; and (4) U.S. Census Bureau survey data. We estimate no additional burden associated with claims data, Medicare enrollment and beneficiary data, and U.S. Census Bureau survey data as these data are already collected via other mechanisms such as Medicare enrollment forms, CMS Form 1500, and U.S. Census Informational Questionnaires. While we did not propose to require how hospitals collect PRO data for this measure, hospitals collecting PRO data would have multiple options for when and how they would collect these data so they can best determine the mode and timing of collection that works best for their patient population.

The possible patient touchpoints for pre-operative PRO data collection include the doctor's office, pre-surgical steps such as education classes, or medical evaluations that can occur in an office or at the hospital. The modes of PRO data collection can include completion of the pre-operative surveys using electronic devices (such as an iPad or tablet), pen and paper, mail, telephone, or through a patient portal. Post-operative PRO data collection modes are similar to pre-operative modes. The possible patient touchpoints for post-operative data collection can occur before the follow-up appointment, at the doctor's office, or after the follow-up appointment. The potential modes of PRO data collection for post-operative data are the same as for pre-operative data. If the patient does not or cannot attend a follow-up appointment, the modes of collection can include completion of the post-operative survey using email, mail, telephone, or through a patient portal. Similar to other surveys, like the Outpatient and Ambulatory Surgery Consumer Assessment of Healthcare Providers and Systems (OAS CAHPS) survey, we believe the use of multiple modes would maximize response rates as it allows for different patient preferences.

For the THA/TKA PRO–PM data, hospitals would be able to submit data during three voluntary periods. The first voluntary reporting period would begin in CY 2025 for eligible procedures occurring between January 1, 2025, through December 31, 2025; the second voluntary reporting period would begin in CY 2026 for eligible procedures occurring between January 1, 2026, through December 31, 2026; and the third voluntary reporting period would begin in CY 2027 for eligible procedures occurring between January 1, 2027, through December 31, 2027. Voluntary reporting would be followed by mandatory reporting beginning with the CY 2028 reporting period for eligible elective procedures occurring between January 1, 2028, and December 31, 2028, impacting the CY 2031 payment determination. Hospitals would need to submit data twice (pre-operative data and post-operative data).

For the purposes of calculating burden, similar to assumptions used for the Hospital IQR Program in the FY 2023 IPPS/LTCH PPS final rule (87 FR 49386 and 49387), we estimate that during the voluntary periods, 50 percent of hospitals that perform at least one THA/TKA procedure would submit data for 50 percent of THA/TKA patients. For purposes of calculating burden, we estimate that, during the mandatory period, hospitals would submit for 100 percent of patients. While we finalized the requirement that hospitals submit, at minimum, 50 percent of eligible, complete pre-operative data with matching eligible, complete post-operative data, we are conservative in our estimate for the mandatory period in case hospitals exceed this threshold.

To estimate the cost burden for patients completing the surveys for this finalized measure, we refer to the ''Valuing Time in U.S. Department of Health and Human Services Regulatory Impact Analyses: Conceptual Framework and Best Practices,'' as it identifies the approach for valuing time when individuals undertake activities on their own time.[829] Therefore, we estimate that the cost for beneficiaries undertaking administrative and other tasks on their own time is a post-tax wage of $20.71/hour. To derive the costs for beneficiaries, a measurement of the usual weekly earnings of wage and salary workers of $998, divided by 40 hours to calculate an hourly pre-tax wage rate of $24.95/hour. This rate is adjusted downwards by an estimate of the effective tax rate for median income

[828] *https://qualitynet.cms.gov/files/63c8361058e56000179b310e?filename=OQR_v16.0a_SpecsManual_011723.pdf.*

[829] *https://aspe.hhs.gov/reports/valuing-time-us-department-health-human-services-regulatory-impact-analyses-conceptual-framework.*

households of about 17 percent, resulting in the post-tax hourly wage rate of $20.71/hour. Unlike our State and private sector wage adjustments, we are not adjusting beneficiary wages for fringe benefits and other indirect costs since the individuals' activities, if any, would occur outside the scope of their employment.

For burden estimating purposes for this measure, we assume that most hospitals would likely undertake PRO data collection through a screening tool incorporated into their electronic health record (EHR) or other patient intake process. We estimate that approximately 526,793 THA/TKA procedures occur in the outpatient setting each year, and that many patients could complete both the pre-operative and post-operative questionnaires. However, from our experience with using this measure in the Comprehensive Joint Replacement model, we are also aware that not all patients who complete the pre-operative questionnaire would complete the post-operative questionnaire. For the CYs 2025, 2026, and 2027 reporting periods, we assume 131,698 patients would complete the survey (526,793 patients × 0.50 × 0.50 of hospitals) for a total of 15,914 hours annually (131,698 respondents × 0.120833 hours) at a cost of $329,579 (15,914 hours × $20.71) across all hospitals. Beginning with mandatory reporting in the CY 2028 reporting period, we estimate a total of 63,654 hours (526,793 patients × 0.120833 hours) at a cost of $1,318,274 (63,654 hours × $20.71) across all hospitals.

Regarding hospitals' burden related to submitting data for this finalized measure, which would be reported via the HQR System, we estimate a burden of 10 minutes per response. Hospitals would submit data associated with pre-operative surveys by March 31 of the CY following the CY in which the eligible procedures took place and would submit data associated with post-operative surveys by March 31 of the CY following the CY in which pre-operative data was submitted. Therefore, for the initial voluntary reporting period for eligible procedures occurring in CY 2025, pre-operative survey data submission would occur in the first quarter of the CY 2026 reporting period and post-operative survey data submission would occur in the first quarter of the CY 2027 reporting period. For each reporting period, we estimate that each hospital would spend 20 minutes (0.33 hours) annually (10 minutes × 2 surveys) to collect and submit the data. For the CY 2026 reporting period, we estimate a burden for all participating hospitals of 279.2 hours (0.167 hours × 3,350 hospitals × 50 percent) at a cost of $14,552 (279.2 hours × $52.12). For the CYs 2027 and 2028 reporting periods, we estimate a burden for all participating hospitals of 558.3 hours (0.33 hours × 3,350 hospitals × 50 percent) at a cost of $29,099 (558.3 hours × $52.12). For the CY 2029 reporting period, we estimate a burden for all participating hospitals of 837.5 hours [(0.167 hours × 3,350 hospitals × 50 percent) + (0.167 hours x 3,350 hospitals)] at a cost of $43,651 (837.5 hours × $52.12). For the CY 2030 reporting period and subsequent years, we estimate a total of 1,116.7 hours (0.33 hours × 3,350 hospitals) at a cost of $58,202 (1,116.7 hours × $52.12).

With respect to any costs/burdens unrelated to data submission, we refer readers to section XXVI.C.3.b ''Regulatory Impact Analysis'' of this final rule with comment period.

6. Information Collection Burden To Adopt the Excessive Radiation Dose or Inadequate Image Quality for Diagnostic Computed Tomography (CT) in Adults (Hospital Level—Outpatient) eCQM, With Voluntary Reporting Beginning With the CY 2025 Reporting Period, Followed by Mandatory Reporting Beginning With the CY 2027 Reporting Period/CY 2029 Payment Determination

In section XIV.B.3.c of this final rule with comment period, we finalized our proposal to adopt the Excessive Radiation Dose or Inadequate Image Quality for Diagnostic CT in Adults (Hospital Level—Outpatient) eCQM, with voluntary reporting beginning with the CY 2025 reporting period, followed by mandatory reporting beginning one year later than proposed with the CY 2027 reporting period/CY 2029 payment determination. For the CYs 2025 and 2026 voluntary reporting periods, hospitals would be able to voluntarily report the measure for one or more quarters during the year. For subsequent years, as described in section XIV.E.6.b of this final rule with comment period, we finalized our proposal to gradually increase the number of quarters of data hospitals would be required to report on the measure starting with two self-selected quarters for the CY 2027 reporting period/CY 2029 payment determination, and all four quarters for the CY 2028 reporting period/CY 2030 payment determination.

For the voluntary reporting periods in CYs 2025 and 2026, we estimate 20 percent of hospitals would voluntarily report one quarter of data for the measure with 100 percent of hospitals reporting the measure as finalized to be required in subsequent years. Similar to the ST-elevation myocardial infarction (STEMI) eCQM for which adoption was finalized in the CY 2022 OPPS/ASC final rule with comment period for the Hospital OQR Program, we assume a Medical Records Specialist would require 10 minutes to submit the data required per quarter for each hospital (86 FR 63962 through 63963). For the CYs 2025 and 2026 voluntary reporting periods, we estimate an annual burden for all participating hospitals of 111.7 hours (3,350 hospitals × 20 percent × 0.1667 hours × 1 quarter) at a cost of $5,822 (111.7 hours × $52.12). For the CY 2027 reporting period/CY 2029 payment determination, we estimate the annual burden for all participating hospitals to be 1,116.7 hours (3,350 hospitals × .1667 hours × 2 quarters) at a cost of $58,202 (1,116.7 hours × $52.12). For the CY 2028 reporting period/CY 2030 payment determination, we estimate the annual burden for all participating hospitals to be 2,233.3 hours (3,350 hospitals × .1667 hours × 4 quarters) at a cost of $116,400 (2,233.3 hours × $52.12).

For the Excessive Radiation eCQM, hospitals would also be required to log in through the measure developer's secure portal and run the Alara Imaging Software for CMS Measure Compliance inside the firewall. The software runs automatically to create the three intermediate data elements needed for the measure. Once the software finishes creating these intermediate variables, hospitals can either: (1) send the data to a hospital's EHR for reporting; (2) send the data to another vendor for reporting; or (3) have the measure developer submit the data on behalf of and at the behest of hospitals to CMS. No manual data entry is required. Similar to our assumptions for the Hospital IQR Program in the FY 2024 IPPS/LTCH PPS final rule (88 FR 59313), we estimate that each hospital would spend approximately 15 minutes (0.25 hours) annually to conduct these activities prior to data submission. For the CYs 2025 and 2026 voluntary reporting periods, we estimate a per reporting period burden of 167.5 hours (0.25 hours × 670 hospitals) at a cost of $8,730 (167.5 hours × $52.12/hour). Beginning with the CY 2027 mandatory reporting period, we estimate a total annual burden of 837.5 hours (0.25 hours × 3,350 hospitals) at a cost of $43,651 (837.5 hours × $52.12/hour).

7. Summary of Information Collection Burden Estimates for the Hospital OQR Program

In summary, under OMB control number 0938–1109 (expiration date February 28, 2025), we estimate that the finalized proposals in this final rule

with comment period will result in an increase of 67,842 hours at a cost of $1,536,526 for 3,350 OPPS hospitals across a 6-year period from the CY 2025 reporting period/CY 2027 payment determination through the CY 2030 reporting period/CY 2032 payment determination. The following Tables 152 through 157 summarize the total burden changes for each respective CY payment determination compared to our currently approved information collection burden estimates (the table for the CY 2032 payment determination reflects the cumulative burden changes). We will submit the revised information collection estimates to OMB for approval under OMB control number 0938–1109.

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TABLE 152: SUMMARY OF HOSPITAL OQR PROGRAM INFORMATION COLLECTION BURDEN CHANGE FOR THE CY 2025 REPORTING PERIOD/CY 2027 PAYMENT DETERMINATION

	Annual Recordkeeping and Reporting Requirements Under OMB Control Number 0938-1109 for the CY 2027 Payment Determination							
Activity	**Estimated time per record (minutes)**	**Number reporting quarters per year**	**Number of hospitals reporting**	**Average number records per hospital per quarter**	**Annual burden (hours) per hospital**	**Finalized annual burden (hours) across OPPS hospitals**	**Previously finalized annual burden (hours) across OPPS hospitals**	**Net difference in annual burden hours**
Add THA/TKA PRO-PM (Survey Completion)	3.625	2	1,675	78.6	9.5	15,914	N/A	+15,914
Report Excessive Radiation eCQM	10	1	670	1	0.167	111.7	N/A	+111.7
Run Software for Excessive Radiation eCQM	15	1	670	1	0.25	167.5	N/A	+167.5
	Total Change in Information Collection Burden Hours: +16,193							
	Total Cost Estimate: Updated Hourly Wage (Varies) x Change in Burden Hours (+16,193) = **$344,131**							

TABLE 153: SUMMARY OF HOSPITAL OQR PROGRAM INFORMATION COLLECTION BURDEN CHANGE FOR THE CY 2026 REPORTING PERIOD/CY 2028 PAYMENT DETERMINATION

	Annual Recordkeeping and Reporting Requirements Under OMB Control Number 0938-1109 for the CY 2028 Payment Determinations							
Activity	**Estimated time per record (minutes)**	**Number reporting quarters per year**	**Number of OPPS hospitals reporting**	**Average number records per hospital per quarter**	**Annual burden (hours) per hospital**	**Finalized annual burden (hours) across OPPS hospitals**	**Previously finalized annual burden (hours) across OPPS hospitals**	**Net difference in annual burden hours**
Add THA/TKA PRO-PM (Survey Completion)	3.625	2	1,675	78.6	9.5	15,914	N/A	+15,914
Add THA/TKA PRO-PM (Data Submission)	10	1	1,675	1	0.167	279.2	N/A	+279.2
Report Excessive Radiation eCQM	10	1	670	1	0.167	111.7	N/A	+111.7
Run Software for Excessive Radiation eCQM	15	1	670	1	0.25	167.5	N/A	+167.5
	Total Change in Information Collection Burden Hours: +16,472							
	Total Cost Estimate: Updated Hourly Wage (Varies) x Change in Burden Hours (+16,472) = **$358,683**							

TABLE 154: SUMMARY OF HOSPITAL OQR PROGRAM INFORMATION COLLECTION BURDEN CHANGE FOR THE CY 2027 REPORTING PERIOD/CY 2029 PAYMENT DETERMINATION

	Annual Recordkeeping and Reporting Requirements Under OMB Control Number 0938-1109 for the CY 2029 Payment Determination							
Activity	**Estimated time per record (minutes)**	**Number reporting quarters per year**	**Number of OPPS hospitals reporting**	**Average number records per hospital per quarter**	**Annual burden (hours) per hospital**	**Finalized annual burden (hours) across OPPS hospitals**	**Previously finalized annual burden (hours) across OPPS hospitals**	**Net difference in annual burden hours**
Add THA/TKA PRO-PM (Survey Completion)	3.625	2	1,675	78.6	9.5	15,914	N/A	+15,914
Add THA/TKA PRO-PM (Data Submission)	10	2	1,675	1	0.33	558.3	N/A	+558.3
Report Excessive Radiation eCQM	10	2	3,350	1	0.33	1,116.7	N/A	+1,116.7
Run Software for Excessive Radiation eCQM	15	1	3,350	1	0.25	837.5	N/A	+837.5
	Total Change in Information Collection Burden Hours: +18,427							
	Total Cost Estimate: Updated Hourly Wage (Varies) x Change in Burden Hours (+18,427) = **$460,531**							

TABLE 155: SUMMARY OF HOSPITAL OQR PROGRAM INFORMATION COLLECTION BURDEN CHANGE FOR THE CY 2028 REPORTING PERIOD/CY 2030 PAYMENT DETERMINATION

	Annual Recordkeeping and Reporting Requirements Under OMB Control Number 0938-1109 for the CY 2030 Payment Determination							
Activity	**Estimated time per record (minutes)**	**Number reporting quarters per year**	**Number of OPPS hospitals reporting**	**Average number records per hospital per quarter**	**Annual burden (hours) per hospital**	**Finalized annual burden (hours) across OPPS hospitals**	**Previously finalized annual burden (hours) across OPPS hospitals**	**Net difference in annual burden hours**
Add THA/TKA PRO-PM (Survey Completion)	3.625	2	3,350	157.3	19	63,654	N/A	+63,654
Add THA/TKA PRO-PM (Data Submission)	10	2	1,675	1	0.33	558.3	N/A	+558.3
Report Excessive Radiation eCQM	10	4	3,350	1	0.67	2,233.3	N/A	+2,233.3
Run Software for Excessive Radiation eCQM	15	1	3,350	1	0.25	837.5	N/A	+837.5
	Total Change in Information Collection Burden Hours: +67,283							
	Total Cost Estimate: Updated Hourly Wage (Varies) x Change in Burden Hours (+67,283) = **$1,507,424**							

TABLE 156: SUMMARY OF HOSPITAL OQR PROGRAM INFORMATION COLLECTION BURDEN CHANGE FOR THE CY 2029 REPORTING PERIOD/CY 2031 PAYMENT DETERMINATION

	Annual Recordkeeping and Reporting Requirements Under OMB Control Number 0938-1109 for the CY 2031 Payment Determination							
Activity	**Estimated time per record (minutes)**	**Number reporting quarters per year**	**Number of OPPS hospitals reporting**	**Average number records per hospital per quarter**	**Annual burden (hours) per hospital**	**Finalized annual burden (hours) across OPPS hospitals**	**Previously finalized annual burden (hours) across OPPS hospitals**	**Net difference in annual burden hours**
Add THA/TKA PRO-PM (Survey Completion)	3.625	2	3,350	157.3	19	63,654	N/A	+63,654
Add THA/TKA PRO-PM (Voluntary Data Submission)	10	1	1,675	1	0.167	279.2	N/A	+279.2
Add THA/TKA PRO-PM (Mandatory Data Submission)	10	1	3,350	1	0.167	558.3	N/A	+558.3
Report Excessive Radiation eCQM	10	4	3,350	1	0.67	2,233.3	N/A	+2,233.3
Run Software for Excessive Radiation eCQM	15	1	3,350	1	0.25	837.5	N/A	+837.5
	Total Change in Information Collection Burden Hours: +67,562							
	Total Cost Estimate: Updated Hourly Wage (Varies) x Change in Burden Hours (+67,562) = **$1,521,976**							

TABLE 157: SUMMARY OF HOSPITAL OQR PROGRAM INFORMATION COLLECTION BURDEN CHANGE FOR THE CY 2030 REPORTING PERIOD/CY 2032 PAYMENT DETERMINATION

	Annual Recordkeeping and Reporting Requirements Under OMB Control Number 0938-1109 for the CY 2032 Payment Determination							
Activity	**Estimated time per record (minutes)**	**Number reporting quarters per year**	**Number of OPPS hospitals reporting**	**Average number records per hospital per quarter**	**Annual burden (hours) per hospital**	**Finalized annual burden (hours) across OPPS hospitals**	**Previously finalized annual burden (hours) across OPPS hospitals**	**Net difference in annual burden hours**
Add THA/TKA PRO-PM (Survey Completion)	3.625	2	3,350	157.3	19	63,654	N/A	+63,654
Add THA/TKA PRO-PM (Data Submission)	10	2	3,350	1	0.33	1,116.7	N/A	+1,116.7
Report Excessive Radiation eCQM	10	4	3,350	1	0.67	2,233.3	N/A	+2,233.3
Run Software for Excessive Radiation eCQM	15	1	3,350	1	0.25	837.5	N/A	+837.5
	Total Change in Information Collection Burden Hours: +67,842							
	Total Cost Estimate: Updated Hourly Wage (Varies) x Change in Burden Hours (+67,842) = **$1,536,526**							

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C. ICRs Related to 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 through CY 2023 OPPS/ASC final rules with comment period (77 FR 68532 and 68533; 78 FR 75172 through 75174; 79 FR 67015 and 67016; 80 FR 70582 through 70584; 81 FR 79863 through 79865; 82 FR 59479 through 59481; 83 FR 59156 and 59157; 84 FR 61469; 85 FR 86267; 86 FR 63968 through 63971; and 87 FR 72252 and 72253 respectively) for detailed discussions of the ASCQR Program ICRs we have previously finalized. The ICRs associated with the ASCQR Program for the CY 2014 through CY 2027 payment determinations are currently approved under OMB control number 0938–1270, which expires on August 31, 2025.

While the most recent data from the BLS reflects a median hourly wage of $24.56 per hour for medical records specialists generally, $26.06 is the hourly mean wage for medical records specialists in ''general medical and surgical hospitals,'' [830] which we believe is more specific to our settings for use in our calculations than a position that may be found in other settings, such as ''office of physicians'' or ''nursing care facilities.'' We have finalized a policy to calculate the cost of overhead, including fringe benefits, at 100 percent of the mean hourly wage (81 FR 79863 and 79864). 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 ($26.06 × 2 = $52.12) to estimate the total cost is a reasonably accurate estimation method and allows for a conservative estimate of hourly costs.

Based on the most recent analysis of the CY 2023 payment determination data, we found that, of the 5,375 ambulatory surgical centers (ASCs) that were actively billing Medicare, 3,733 were required to participate in the ASCQR Program and met all reporting requirements, whereas 194 did not. Of the 1,448 ASCs not required to participate in the program, 687 ASCs

[830] U.S. Bureau of Labor Statistics. Occupational Outlook Handbook, Medical Records Specialists. Accessed on March 6, 2023. Available at: *https://www.bls.gov/oes/current/oes292072.htm.*

did so. In addition, 195 Hospitals Without Walls have returned to active ASC billing and will be eligible to participate toward CY 2024 payment determinations. On this basis, we estimate that 4,809 ASCs (3,733 + 194 + 687 + 195) will submit data for the ASCQR Program for the CY 2026 payment determination unless otherwise noted. We note that this estimate is a decrease of 248 ASCs from our estimate of 5,057 provided in the CY 2024 OPPS/ASC proposed rule (88 FR 49881) due to results from more recent data analysis regarding numbers of eligible ASCs. In section XV.B.4 of this final rule with comment period, we finalized our proposals to modify three previously adopted measures: (1) the COVID–19 Vaccination Coverage Among Healthcare Personnel measure, beginning with the CY 2024 reporting period/CY 2026 payment determination; (2) the Cataracts: Improvement in Patient's Visual Function Within 90 Days Following Cataract Surgery measure survey instrument usage, beginning with the voluntary CY 2024 reporting period; and (3) Endoscopy/ Polyp Surveillance: Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients measure, beginning with the CY 2024 reporting period/CY 2026 payment determination. We also finalized with modification, our proposal to adopt the Risk Standardized Patient-Reported Outcome-Based Performance Measure (PRO–PM) Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA) in the ASC Setting, with voluntary reporting beginning with the CY 2025 reporting period, followed by mandatory reporting beginning 1 year later than proposed with the CY 2028 reporting period/CY 2031 payment determination.

We are not finalizing our proposal to re-adopt with modification the ASC Facility Volume on Selected ASC Surgical Procedures measure.

2. Information Collection Burden To Modify the COVID–19 Vaccination Coverage Among Healthcare Personnel (HCP) Measure Beginning With the CY 2024 Reporting Period/CY 2026 Payment Determination

In the CY 2022 OPPS/ASC final rule with comment period, we finalized adoption of the COVID–19 Vaccination Coverage Among Healthcare Personnel (HCP) measure for the ASCQR Program (86 FR 63875 through 63883). In section XV.B.4.a of this final rule with comment period, we finalized our proposal to modify the COVID–19 Vaccination Coverage Among HCP measure to utilize the term ''up to date'' in the HCP vaccination definition and update the numerator to specify the time frames within which an HCP is considered up to date with recommended COVID–19 vaccines, including booster doses, beginning with the CY 2024 reporting period/CY 2026 payment determination for the ASCQR Program. We previously discussed information collection burden associated with this measure in the CY 2022 OPPS/ASC final rule with comment period (86 FR 63969).

We do not believe that the use of the term ''up to date'' or the update to the numerator will impact information collection or reporting burden because the modification changes neither the amount of data being submitted to CMS nor the frequency of data submission. Additionally, because we did not propose any updates to the form, manner, and timing of data submission for this measure, we do not anticipate any increase in burden associated with this policy. Furthermore, the modified COVID–19 Vaccination Coverage Among HCP measure will continue to be calculated using data submitted to the CDC under a separate OMB control number (0920–1317; expiration date January 31, 2024). However, the CDC currently has a PRA waiver for the collection and reporting of vaccination data under section 321 of the National Childhood Vaccine Injury Act of 1986 (enacted on November 14, 1986) (NCVIA).[831]

3. Information Collection Burden To Modify the Cataracts: Improvement in Patient's Visual Function Within 90 Days Following Cataract Surgery Measure Survey Instrument Use Beginning With the CY 2024 Reporting Period

In the CY 2014 OPPS/ASC final rule with comment period (78 FR 75126 and 75127), we finalized the adoption of the Cataracts: Improvement in Patient's Visual Function Within 90 Days Following Cataract Surgery measure beginning with the CY 2016 payment determination. In section XV.B.4.b of this final rule with comment period, we finalized our proposal to limit the survey instruments that can be used to administer this measure to three assessment tools: NEI VFQ–25, VF–14, and VF–8R, beginning with the CY 2024 reporting period.

Because the three assessment tools being finalized are currently allowable for administering this measure, we do not believe limiting use to these three surveys will result in a change in burden. As a result, we did not propose any changes in burden per response associated with this policy. Additionally, as currently stated in the ASCQR Program Specifications Manual, the maximum annual sample case size for chart abstraction for this measure is 63 cases for ASCs with an outpatient population size of between 0 and 900 and 96 cases for ASCs with an outpatient population size of greater than 900.[832] We did not propose an increase in the required sample size for chart abstraction; therefore we do not believe there is any increase in burden associated with this policy.

4. Information Collection Burden To Modify the Endoscopy/Polyp Surveillance: Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients Measure, Beginning With the CY 2024 Reporting Period/CY 2026 Payment Determination

In the CY 2014 OPPS/ASC final rule with comment period, we finalized the Endoscopy/Polyp Surveillance: Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients measure (78 FR 75127 through 75128). In section XV.B.4.c of this final rule comment period, we finalized our proposal to amend the measure denominator language by removing the phrase ''aged 50 years'' and adding in its place the phrase ''aged 45 years.''

As currently stated in the ASCQR Program Specifications Manual, the maximum annual sample case size for chart abstraction for this measure is 63 cases for ASCs with an outpatient population size of between 0 and 900 and 96 cases for ASCs with an outpatient population size of greater than 900. We did not propose an increase in the required sample size for chart abstraction; therefore, we do not believe there is any increase in burden associated with this policy.

5. Information Collection Burden To Adopt the Risk Standardized Patient-Reported Outcome-Based Performance Measure (PRO–PM) Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA) in the ASC Setting, With Voluntary Reporting Beginning With the CY 2025 Reporting Period Followed by Mandatory Reporting Beginning With the CY 2028 Reporting Period/CY 2031 Payment Determination

In section XV.B.5.b of this final rule with comment period, we finalized our proposal to adopt the THA/TKA PRO–PM, with voluntary reporting beginning with the CY 2025 reporting period,

[831] Public Law 99–660.

[832] *https://qualitynet.cms.gov/files/62900933404aa300169072f1?filename=12.0_ASC_Full_Specs_Mnl.pdf.*

followed by mandatory reporting beginning one year later than proposed with the CY 2028 reporting period/CY 2031 payment determination. This measure was previously adopted for the Hospital IQR Program in the FY 2023 IPPS/LTCH PPS final rule with an estimated burden of 7.25 minutes (0.120833 hours) per patient to complete both the pre-operative and post-operative surveys and 10 minutes (0.167 hours) per hospital per response to collect and submit the measure data via the HQR system (87 FR 49386 through 49387). We believe the estimated burden for both patient surveys and data submission will be the same for the ASCQR Program.

The THA/TKA PRO–PM uses four sources of data for the calculation of the measure: (1) patient-reported outcome (PRO) data; (2) claims data; (3) Medicare enrollment and beneficiary data; and (4) U.S. Census Bureau survey data. We estimate no additional burden associated with claims data, Medicare enrollment and beneficiary data, and U.S. Census Bureau survey data as these data are already collected via other mechanisms such as Medicare enrollment forms, CMS Form 1500, and U.S. Census Informational Questionnaires. While we did not propose to require how ASCs collect PRO data for this measure, ASCs collecting PRO data will have multiple options for when and how they will collect these PRO data so they can best determine the mode and timing of collection that works best for their patient population.

The possible patient touchpoints for pre-operative PRO data collection include the doctor's office, pre-surgical steps such as education classes, or medical evaluations that can occur in an office or at the ASC. The modes of PRO data collection can include completion of the pre-operative surveys using electronic devices (such as an iPad or tablet), pen and paper, mail, telephone, or through a patient portal. Post-operative PRO data collection modes are similar to pre-operative modes. The possible patient touchpoints for post-operative data collection can occur before the follow-up appointment, at the doctor's office, or after the follow-up appointment. The potential modes of PRO data collection for post-operative data are the same as for pre-operative data. If the patient does not or cannot attend a follow-up appointment, the modes of collection can include completion of the post-operative survey using email, mail, telephone, or through a patient portal.

Similar to other surveys like the Outpatient and Ambulatory Surgery Consumer Assessment of Healthcare Providers and Systems (OAS CAHPS) survey, we believe the use of multiple modes will maximize response rates as it allows for different patient preferences. For the THA/TKA PRO–PM data, ASCs will be able to submit data during three voluntary periods. The first voluntary reporting period will begin in CY 2025 for eligible procedures occurring between January 1, 2025, through December 31, 2025; the second voluntary reporting period will begin with CY 2026 for eligible procedures occurring between January 1, 2026, through December 31, 2026; and the third voluntary reporting period will begin with CY 2027 for eligible procedures occurring between January 1, 2027, through December 31, 2027. Voluntary reporting will be followed by mandatory reporting beginning with the CY 2028 reporting period for eligible elective procedures occurring between January 1, 2028, and December 31, 2028, impacting the CY 2031 payment determination.

Whether participating in the voluntary reporting periods or during subsequent mandatory reporting, ASCs will need to submit data twice (pre-operative data and post-operative data). For the purposes of calculating burden. Specifically, we estimate that, during the voluntary periods, 50 percent of ASCs that perform at least one THA/TKA procedure will submit data and will do so for 50 percent of THA/TKA patients. For purposes of calculating burden for the mandatory period, we estimate that ASCs will submit for 100 percent of patients. While we finalized to require ASCs to submit, at minimum, 50 percent of eligible, complete pre-operative data with matching eligible, complete post-operative data, we are conservative in our estimate for the mandatory period in case ASCs exceed this threshold.

To estimate the cost burden for patients completing the surveys for this measure, we believe that the cost for beneficiaries undertaking administrative and other tasks on their own time is a post-tax wage of $20.71/hour. We base this estimate on the ''Valuing Time in U.S. Department of Health and Human Services Regulatory Impact Analyses: Conceptual Framework and Best Practices,'' which identifies the approach for valuing time when individuals undertake activities on their own time.[833] To derive the costs for beneficiaries, a measurement of the usual weekly earnings of wage and salary workers of $998, divided by 40 hours to calculate an hourly pre-tax wage rate of $24.95/hour. This rate is adjusted downwards by an estimate of the effective tax rate for median income households of about 17 percent, resulting in the post-tax hourly wage rate of $20.71/hour. Unlike our state and private sector wage adjustments, we are not adjusting beneficiary wages for fringe benefits and other indirect costs since the individuals' activities, if any, would occur outside the scope of their employment.

To estimate the burden of information collection for patients completing surveys for this measure, we assume that most ASCs will likely undertake PRO data collection through a screening tool incorporated into their electronic health record (EHR) or other patient intake process. We utilized recently analyzed Medicare claims information, which was unavailable for the CY 2024 OPPS/ASC proposed rule, to estimate the number of ASCs performing these procedures. We believe this data is more appropriate as ASCs specialize and these procedures are recently added to the ASC covered procedures list. We found that there were 2,381 THA/TKA ASC claims in CY 2022 with an average of 58 Medicare claims per ASC for 41 ASCs. Thus, we estimate that approximately 58 THA/TKA procedures will occur in each ASC each year, and that many patients could complete both the pre-operative and post-operative questionnaires. However, from our experience with using this measure in the Comprehensive Joint Replacement model, we are also aware that not all patients who complete the pre-operative questionnaire will complete the post-operative questionnaire. For the voluntary CYs 2025, 2026, and 2027 reporting periods, we assume 609 patients will complete the survey (58 patients × 0.50 × 21 ASCs) for a total of 74 hours annually (609 respondents × 0.120833 hours) at a cost of $1,524 (74 hours × $20.71) across all ASCs that perform these procedures. Beginning with mandatory reporting in the CY 2028 reporting period/CY 2031 payment determination, we estimate a total of 288 hours (2,381 patients × 0.120833 hours) at a cost of $5,958 (288 hours × $20.71) across all ASCs performing these procedures.

Regarding ASCs' burden related to submitting data for this measure, which will be reported via the HQR System, we estimate a burden of 10 minutes per response. ASCs will submit data associated with pre-operative surveys by March 31 of the CY following the CY in which the eligible procedures took place and will submit data associated with

[833] *https://aspe.hhs.gov/reports/valuing-time-us-department-health-human-services-regulatory-impact-analyses-conceptual-framework.*

post-operative surveys by March 31 of the CY following the CY in which pre-operative data was submitted. Therefore, for the first voluntary reporting period for eligible procedures occurring in CY 2025, pre-operative survey data submission will occur in the first quarter of the CY 2026 reporting period and post-operative survey data submission will occur in the first quarter of the CY 2027 reporting period. For each of the three voluntary reporting periods, we estimate that each ASC will spend 20 minutes (0.33 hours) annually (10 minutes × 2 surveys) to collect and submit the data. For the CY 2026 reporting period, we estimate a burden for all participating ASCs of 4 hours (0.167 hours × 21 ASCs) at a cost of $182 (4 hours × $52.12). For the CYs 2027 and 2028 reporting periods, we estimate a burden for all participating ASCs of 7 hours (0.33 hours × 21 ASCs) at a cost of $365 (7 hours × $52.12). For the CY 2029 reporting period, we estimate a burden for all participating ASCs of 10 hours [(0.167 hours × 21 ASCs) + (0.167 hours x 41 ASCs)] at a cost of $539 (10 hours × $52.12). For the CY 2030 reporting period and subsequent years, we estimate a total of 14 hours (0.33 hours × 41 ASCs) at a cost of $712 (14 hours × $52.12).

With respect to any costs or burdens unrelated to data submission, we refer readers to section XXVI.C.4.b ''Regulatory Impact Analysis'' of this final rule with comment period.

6. Summary of Information Collection Burden Estimates for the ASCQR Program.

In summary, under OMB control number 0938–1270 (expiration date August 31, 2025), we estimate that the finalized proposals in this final rule with comment period will result in an increase of 302 hours at a cost of $6,670 for 4,089 ASCs across a 6-year period from the CY 2025 reporting period/CY 2027 payment determination through the CY 2030 reporting period/CY 2032 payment determination. The following Tables 158 through 163 summarize the total burden changes for each respective CY payment determination compared to our currently approved information collection burden estimates (the table for the CY 2030 payment determination reflects the cumulative burden changes). We will submit the revised information collection estimates to OMB for approval under OMB control number 0938–1270.[834]

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TABLE 158: SUMMARY OF ASCQR PROGRAM INFORMATION COLLECTION BURDEN CHANGE FOR THE CY 2025 REPORTING PERIOD/CY 2027 PAYMENT DETERMINATION

	Annual Recordkeeping and Reporting Requirements Under OMB Control Number 0938-1270 for the CY 2027 Payment Determination							
Activity	**Estimated time per record (minutes)**	**Number reporting quarters per year**	**Number of ASCs reporting**	**Average number records per ASC per quarter**	**Annual burden (hours) per ASC**	**Finalized annual burden (hours) across ASCs**	**Previously finalized annual burden (hours) across ASCs**	**Net difference in annual burden hours**
Add THA/TKA PRO-PM Measure (Survey Completion)	3.625	2	21	29	3.5	74	N/A	+74
	Total Change in Information Collection Burden Hours: +74							
	Total Cost Estimate: Updated Hourly Wage (Varies) x Change in Burden Hours (+74) = **$1,524**							

[834] CY 2023 Final Rule ASCQR Program ''Supporting Statement-A''. Available at: *https://www.reginfo.gov/public/do/PRAViewDocument?ref_nbr=201911-0938-015.*

TABLE 159: SUMMARY OF ASCQR PROGRAM INFORMATION COLLECTION BURDEN CHANGE FOR THE CY 2026 REPORTING PERIOD/CY 2028 PAYMENT DETERMINATION

	Annual Recordkeeping and Reporting Requirements Under OMB Control Number 0938-1270 for the CY 2028 Payment Determinations							
Activity	**Estimated time per record (minutes)**	**Number reporting quarters per year**	**Number of OPPS ASCs reporting**	**Average number records per ASC per quarter**	**Annual burden (hours) per ASC**	**Finalized annual burden (hours) across ASCs**	**Previously finalized annual burden (hours) across ASCs**	**Net difference in annual burden hours**
Add THA/TKA PRO-PM Measure (Survey Completion)	3.625	2	21	29	3.5	74	N/A	+74
Add THA/TKA PRO-PM Measure (Data Submission)	10	2	21	1	0.167	4	N/A	+4
	Total Change in Information Collection Burden Hours*: +77							
	Total Cost Estimate: Updated Hourly Wage (Varies) x Change in Burden Hours (+77) = **$1,706**							

*Total varies from sum of individual information collections due to rounding

TABLE 160: SUMMARY OF ASCQR PROGRAM INFORMATION COLLECTION BURDEN CHANGE FOR THE CY 2027 REPORTING PERIOD/CY 2029 PAYMENT DETERMINATION

	Annual Recordkeeping and Reporting Requirements Under OMB Control Number 0938-1270 for the CY 2029 Payment Determination							
Activity	**Estimated time per record (minutes)**	**Number reporting quarters per year**	**Number of OPPS ASCs reporting**	**Average number records per ASC per quarter**	**Annual burden (hours) per ASC**	**Finalized annual burden (hours) across ASCs**	**Previously finalized annual burden (hours) across ASCs**	**Net difference in annual burden hours**
Add THA/TKA PRO-PM Measure (Survey Completion)	3.625	2	21	29	3.5	74	N/A	+74
Add THA/TKA PRO-PM Measure (Data Submission)	10	2	21	1	0.33	7	N/A	+7
	Total Change in Information Collection Burden Hours: +81							
	Total Cost Estimate: Updated Hourly Wage (Varies) x Change in Burden Hours (+81) = **$1,889**							

TABLE 161: SUMMARY OF ASCQR PROGRAM INFORMATION COLLECTION BURDEN CHANGE FOR THE CY 2028 REPORTING PERIOD/CY 2030 PAYMENT DETERMINATION

	Annual Recordkeeping and Reporting Requirements Under OMB Control Number 0938-1270 for the CY 2030 Payment Determination							
Activity	**Estimated time per record (minutes)**	**Number reporting quarters per year**	**Number of OPPS ASCs reporting**	**Average number records per ASC per quarter**	**Annual burden (hours) per ASC**	**Finalized annual burden (hours) across ASCs**	**Previously finalized annual burden (hours) across ASCs**	**Net difference in annual burden hours**
Add THA/TKA PRO-PM Measure (Survey Completion)	3.625	2	41	58	7	288	N/A	+288
Add THA/TKA PRO-PM Measure (Data Submission)	10	1	21	1	0.33	7	N/A	+7
	Total Change in Information Collection Burden Hours: +295							
	Total Cost Estimate: Updated Hourly Wage (Varies) x Change in Burden Hours (+295) = **$6,323**							

TABLE 162: SUMMARY OF ASCQR PROGRAM INFORMATION COLLECTION BURDEN CHANGE FOR THE CY 2029 REPORTING PERIOD/CY 2031 PAYMENT DETERMINATION

	Annual Recordkeeping and Reporting Requirements Under OMB Control Number 0938-1270 for the CY 2031 Payment Determination							
Activity	**Estimated time per record (minutes)**	**Number reporting quarters per year**	**Number of OPPS ASCs reporting**	**Average number records per ASC per quarter**	**Annual burden (hours) per ASC**	**Finalized annual burden (hours) across ASCs**	**Previously finalized annual burden (hours) across ASCs**	**Net difference in annual burden hours**
Add THA/TKA PRO-PM Measure (Survey Completion)	3.625	2	41	58	7	288	N/A	+288
Add THA/TKA PRO-PM Measure (Voluntary Data Submission)	10	1	21	1	0.167	4	N/A	+4
Add THA/TKA PRO-PM Measure (Mandatory Data Submission)	10	1	41	1	0.167	7	N/A	+7
	Total Change in Information Collection Burden Hours*: +298							
	Total Cost Estimate: Updated Hourly Wage (Varies) x Change in Burden Hours (+298) = **$6,497**							

*Total varies from sum of individual information collections due to rounding

TABLE 163: SUMMARY OF ASCQR PROGRAM INFORMATION COLLECTION BURDEN CHANGE FOR THE CY 2030 REPORTING PERIOD/CY 2032 PAYMENT DETERMINATION

	Annual Recordkeeping and Reporting Requirements Under OMB Control Number 0938-1270 for the CY 2032 Payment Determination							
Activity	**Estimated time per record (minutes)**	**Number reporting quarters per year**	**Number of OPPS ASCs reporting**	**Average number records per ASC per quarter**	**Annual burden (hours) per ASC**	**Finalized annual burden (hours) across ASCs**	**Previously finalized annual burden (hours) across ASCs**	**Net difference in annual burden hours**
Add THA/TKA PRO-PM Measure (Survey Completion)	3.625	2	41	58	7	288	N/A	+288
Add THA/TKA PRO-PM Measure (Data Submission)	10	2	41	1	0.33	14	N/A	+14
	Total Change in Information Collection Burden Hours: +302							
	Total Cost Estimate: Updated Hourly Wage (Varies) x Change in Burden Hours (+302) = **$6,670**							

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D. ICRs Related to the REHQR Program

1. Background

In section XVI of this final rule with comment period, we discuss the requirements for the Rural Emergency Hospital Quality Reporting (REHQR) Program. In this final rule with comment period, we finalized the adoption of four new measures, beginning with the CY 2024 reporting period: (1) the Abdomen Computed Tomography (CT)—Use of Contrast Material measure; (2) the Median Time from ED Arrival to ED Departure for Discharged ED Patients measure; (3) the Facility7-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy measure; and (4) the Risk-Standardized Hospital Visits Within 7 Days After Hospital Outpatient Surgery measure. As we are establishing the REHQR Program in this final rule with comment period, the ICRs associated with the REHQR Program will be submitted for OMB approval under a new OMB control number.

While the most recent data from the BLS reflects a median hourly wage of $24.56 per hour for all medical records specialists, $26.06 is the hourly mean wage for medical records specialists in ''general medical and surgical hospitals.'' [835] We believe specialists in ''general medical and surgical hospitals'' is more specific to our settings for use in our calculations than a position that may be found in other medical record specialist settings, such as ''office of physicians'' or ''nursing care facilities.'' We are finalizing to calculate the cost of overhead, including fringe benefits, at 100 percent of the mean hourly wage similar to the policy previously finalized in the CY 2018 OPPS/ASC final rule with comment period for the Hospital OQR Program (82 FR 52617). 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 ($26.06 × 2 = $52.12) to estimate the total cost is a reasonably accurate estimation method and allows for a conservative estimate of hourly costs.

[835] U.S. Bureau of Labor Statistics. Occupational Outlook Handbook, Medical Records Specialists. Accessed on March 6, 2023. Available at: *https://www.bls.gov/oes/current/oes292072.htm.*

Based on our analysis of CAHs and subsection (d) hospitals currently participating in the Hospital OQR Program with 50 beds or less, we have estimated 746 hospitals could transition to REH status assuming that all eligible hospitals in states which have passed or amended necessary legislation enabling transition to occur as of March 2023 choose to do so. We will revise this estimate in future rules when updated data are available.

2. Information Collection Burden To Adopt Three Claims-Based Measures Beginning With the CY 2024 Reporting Period

In sections XVI.B.5.a, XVI.B.5.c, and XVI.B.5.d of this final rule with comment period, we finalized the adoption of the following claims-based measures beginning with the CY 2024 reporting period: (1) the Abdomen Computed Tomography (CT)—Use of Contrast Material measure; (2) the Facility 7-Day Risk-Standardized Hospital Visit Rate After Outpatient Colonoscopy measure; and (3) the Risk-Standardized Hospital Visits Within 7 Days After Hospital Outpatient Surgery measure. Because these measures are calculated using data that are already

reported to the Medicare program for payment purposes, adopting these measures does not result in additional burden for REHs in the REHQR Program.

3. Information Collection Burden To Adopt the Median Time From ED Arrival to ED Departure for Discharged ED Patients Measure Beginning With the CY 2024 Reporting Period

In section XVI.B.5.b of this final rule with comment period, we finalized the adoption of the Median Time from ED Arrival to ED Departure for Discharged ED Patients measure beginning with the CY 2024 reporting period. This chart-abstracted measure was previously adopted as part of the Hospital OQR Program in the CY 2011 OPPS/ASC final rule with comment period (75 FR 72086). Similar to reporting of this measure to the Hospital OQR Program as currently approved under OMB control number 0938–1109 (expiration date February 28, 2025), we estimate that chart-abstracted measures where patient-level data are submitted directly to CMS will take 2.9 minutes, or 0.049 hours. Further, based on sample size requirements for the measure in the Hospital OQR Program, we assume that each REH will similarly abstract and submit data from 63 cases per quarter, for a total of 252 cases per year.[836] We therefore estimate that it will take approximately 12.2 hours (0.049 hours × 252 cases) at a cost of approximately $636 per hospital (12.2 hours × $52.12/hour) to collect and report data for this measure. Therefore, for all participating REHs, we estimate an annual chart-abstraction burden of 9,101 hours (12.2 hours per REH × 746 REHs) at a cost of $474,344 per measure (9,101 hours × $52.12/hour).

4. Summary of Information Collection Burden Estimates for the REHQR Program

In summary, we estimate that the finalized policies in this final rule will result in an initial burden of 9,101 hours at a cost of $474,344 for 746 REHs annually beginning with the CY 2024 reporting period, as reflected in Table 164. We will submit these information collection estimates to OMB for approval as part of a new information collection request.

With respect to any costs/burdens unrelated to data submission, we refer readers to section XXVI.C.5.a of this final rule with comment period.

TABLE 164: SUMMARY OF REHQR PROGRAM INFORMATION COLLECTION BURDEN CHANGE FOR THE CY 2024 REPORTING PERIOD

	Annual Recordkeeping and Reporting Requirements for the CY 2024 Reporting Period							
Activity	**Estimated time per record (minutes)**	**Number reporting quarters per year**	**Number of REHs reporting**	**Average number records per REH per quarter**	**Annual burden (hours) per REH**	**Finalized annual burden (hours) across REHs**	**Previously finalized annual burden (hours) across REHs**	**Net difference in annual burden hours**
Adoption of Median Time from ED Arrival to ED Departure for Discharged ED Patients Measure	2.9	1	746	252	12.2	9,101	0	+9,101
	Total Change in Information Collection Burden Hours: +9,101							
	Total Cost Estimate: Updated Hourly Wage ($52.12) x Change in Burden Hours (9,101) = **$474,344**							

E. ICRs Related to Conditions of Participation (CoPs): Admission, Initial Evaluation, Comprehensive Assessment, and Discharge or Transfer of the Client (§ 485.914)

To implement Division FF, section 4124 of the CAA 2023, we proposed to modify the regulation text at § 485.914(a)(2) to include a cross-reference to § 485.918(g), which are additional requirements CMHCs must meet when assessing and admitting clients into the IOP program. At present, § 485.914(a)(2) solely pertains to PHP services with reference to § 485.918(f), which provides distinct criteria for clients evaluated and accepted for PHP services. We believe the burdens associated with these requirements are usual and customary business practice under 5 CFR 1320.3(b)(2). As such, the burden associated with these requirements is exempt from PRA; therefore, we did not seek PRA approval for any information collection or recordkeeping activities that may be

[836] *https://qualitynet.cms.gov/files/63c8361058e56000179b310e?filename=OQR_v16.0a_SpecsManual_011723.pdf.*

conducted in connection with the proposed revisions to § 485.914(a)(2).

We also proposed to revise § 485.914(d)(2), which sets forth standards for updating a PHP client's comprehensive assessment no less frequently than every 30 days. We proposed to add ''and IOP services,'' which requires the PHP and IOP client's interdisciplinary treatment team to update the assessment no less frequently than every 30 days. We believe that the burden associated with these requirements is the time required to update the comprehensive assessment and that this documentation is usual and customary business practice under 5 CFR 1320.3(b)(2). Therefore, we did not seek PRA approval for any information collection or recordkeeping activities that may be conducted in connection with the proposed revisions to § 485.914(d)(2). We did not receive any public comments on our proposal and therefore, we are finalizing our proposal to add IOP services to the requirement at § 485.914.

F. ICRs Related to Conditions of Participation (CoPs): Treatment Team, Person-Centered Active Treatment Plan, and Coordination of Services (§ 485.916)

We proposed to modify § 485.916(d), which sets forth requirements for reviewing the person-centered active treatment plan. Currently, the interdisciplinary team is required to review, revise, and document the active treatment plan as frequently as the client's condition requires, but no less frequently than every 30 calendar days. A revised active treatment plan must include information from the client's updated comprehensive assessment and must document the client's progress toward the outcomes specified in the active treatment plan. CMHCs must also meet PHP program requirements specified under § 424.24(e) if such services are included in the active treatment plan. As Division FF, section 4124 of the CAA 2023 included coverage of IOP services for CMHCs, we believe it is necessary to add IOP services to this requirement and reference the specific IOP program requirements being proposed in section VIII.C.2 at § 424.24(d) of the CY 2024 OPPS/ASC proposed rule. We proposed to cross-reference additional requirements specified under § 424.24(d) if a client's active treatment plan includes IOP services. The 2013 CMHC CoP final rule (78 FR 64603) included a burden for § 485.916(d) and is collected under OMB control number 0938–1245. The proposed revision to this requirement does not affect the burden. Therefore, we did not propose to seek PRA approval for any information collection or recordkeeping activities that may be conducted in connection with the proposed revisions to § 485.916(d).

Comment: We received several comments requesting we revise the CoPs at § 485.916(a)(1) and (3) to specifically identify MFTs and MHCs as potential members of the CMHC interdisciplinary team. Comments stated that including MFTs and MHCs will clarify that these practitioners may lawfully take their place on the CMHC interdisciplinary teams.

Response: We agree with the commenters suggestions and have modified the language at § 485.916(a)(1) to include the MFT or MHC as providers who can lead the CMHC interdisciplinary team. We believe that the burden associated with adding MFT and MHC to the list of practitioners who can lead the CMHC interdisciplinary team is usual and customary business practice under 5 CFR 1320.3(b)(2). Therefore, we do not propose seeking PRA approval for any information collection or recordkeeping activities that may be conducted in connection with the proposed revisions to § 485.914(d)(2).

After consideration of the public comments we received, we have modified the language at § 485.916(a)(1) to include the MFT or MHC as practitioners who can lead the CMHC interdisciplinary team. This requirement allows CMHCs the flexibility to utilize appropriate counselors that may serve on the client's interdisciplinary team.

G. ICRs Related to Conditions of Participation (CoPs): Organization, Governance, Administration of Services, Partial Hospitalization Services (§ 485.918)

To implement Division FF, section 4124 of the CAA, 2023, which extended coverage of IOP services for CMHCs, we proposed to revise the title of § 485.918 to include IOP services. The overall goal of this section is to ensure that the management structure is organized and accountable for the services furnished. We proposed to add ''and intensive outpatient services'' to the end of the section heading.

The requirement at § 485.918(b), ''Standard: Provision of services'' specifies a comprehensive list of services that a CMHC must furnish. This list of services that CMHCs provide corresponds directly to the statutory requirements in section 1861(ff)(3) of the Act. We proposed to add ''and intensive outpatient services'' to § 485.918(b)(1)(iii), which states where specific services cannot be furnished, such as other than in an individual's home or an inpatient or residential setting, or psychosocial rehabilitation services. We believe that adding IOP services to § 485.918(b)(1)(iii) is a usual and customary business practice under 5 CFR 1320.3(b)(2). Therefore, we did not seek PRA approval for any information collection or recordkeeping activities that may be conducted in connection with the proposed revisions to § 485.918(b)(1)(iii).

We proposed to add a new standard at § 485.918(g), ''Standard: Intensive outpatient services'', which will require all IOP services to meet all applicable requirements of 42 CFR parts 410 and 424. We also believe adding the IOP services requirement in the new requirement at § 485.918(g) is a usual and customary business practice under 5 CFR 1320.3(b)(2). Therefore, we did not seek PRA approval for any information collection or recordkeeping activities that may be conducted in connection with the proposed revisions to § 485.918(g).

We did not receive any public comments on our proposal, therefore, we are finalizing our proposal to add IOP services to the requirements at § 485.918.

H. ICRs Related to Hospital Price Transparency

In a final rule published in November 2019 (84 FR 65524) (herein referred to as the CY 2020 HPT final rule), we adopted requirements for hospitals to make public their standard charges in two ways: (1) as a comprehensive machine-readable file (MRF); and (2) in a consumer-friendly format. We codified these requirements at new 45 CFR 180.50 and 180.60, respectively.

The existing information collection requirement and the associated burden were finalized in the CY 2020 HPT final rule and are currently approved under OMB control number 0938–1369, which expires on December 31, 2023. We originally estimated the number of hospitals to be 6,002. We finalized an initial one-time burden 150 hours and cost of $11,898.60 per hospital, resulting in a total national burden of 900,300 hours (150 hours × 6,002 hospitals) and $71,415,397 ($11,898.60 × 6,002 hospitals) to build processes and make required system updates to make their standard charge data publicly available: (1) as a comprehensive machine-readable file and (2) in a consumer-friendly format. Additionally, we estimated an on-going annual burden of 46 hours per hospital with a cost of $3,610.88 per hospital, resulting in a

total national burden of 276,092 hours (46 hours × 6,002 hospitals) and total cost of $21,672,502 ($3,610.88 × 6,002 hospitals), to make required annual updates to the hospital's standard charge data information. For a detailed discussion of the cost estimates for the requirements related to hospitals making their standard charge data publicly available, we refer readers to our discussion in the collection of information section in the CY 2020 HPT final rule (84 FR 65591 through 65596).

In section XVIII of the CY 2024 OPPS/ASC proposed rule (88 FR 49890 through 49892), we proposed to revise regulations at 45 CFR 180.50 related to making public hospital standard charges in an MRF. First, we proposed to add data elements to be included in the hospital's MRF and to require hospitals to conform to a CMS template layout. Second, to enhance automated access to the MRF, we proposed that hospitals include a .txt file in the root folder of the public website it selects to host its MRF in the form and manner specified by CMS that includes a standardized set of fields, and a link in the footer on its website that is labeled ''Hospital Price Transparency'' and links directly to the publicly available web page that hosts the link to the MRF. We believed these proposed revisions would result in an increased collection burden to hospitals, both an initial one-time burden and an on-going annual cost.

Additionally, as explained in the CY2024 OPPS/ASC proposed rule, we increased the number of hospitals we believe to be subject to these requirements from 6,002 to 7,098, which, in turn, increased the estimated national burden. The reason for this increase is because in the CY 2020 HPT final rule (84 FR 65591), we relied on data from the American Hospital Association (AHA).[837] For the collection of information estimate in the CY2024 OPPS/ASC proposed rule we used updated hospital numbers based on the publicly available dataset from the Homeland Infrastructure Foundation-Level Data (HIFLD) [838] hospital dataset. The HIFLD dataset compiles a directory of hospital facilities based on data acquired directly from state hospital licensure information and Federal sources and validates this data annually. Thus, we stated our belief that the HIFLD dataset is more comprehensive than the AHA Directory. To estimate the number of hospitals subject to these requirements in the CY 2024 OPPS/ASC proposed rule, we leveraged the HIFLD hospital dataset to identify 8,013 total hospitals. We then subtracted out 379 hospitals HIFLD identified as ''closed'' as well as hospitals that are deemed under the regulation to have met requirements (see 45 CFR 180.30) which included 339 federally owned non-military and military hospitals, and 197 State, local, and district run forensic hospitals. We therefore estimated that the CY 2024 OPPS/ASC proposed rule would apply to 7,098 hospitals operating within the U.S that meet the HPT regulation's definition of ''hospital'' at 45 CFR 180.20. Finally, we estimated the hourly cost for each labor category used in this analysis by referencing Bureau of Labor Statistics report on Occupational Employment and Wages (May 2022).[839] We included labor categories for General and Operations Managers, Business Operations Specialists, and Network and Computer Systems Administrators. We did not include a Lawyer labor category in the CY 2024 OPPS/ASC proposed rule.

We indicated in the CY 2024 OPPS/ASC proposed rule that we believed hospitals would incur an initial one-time cost to update their processes and systems to (1) identify and collect the standard charge information represented by the newly proposed data elements, and (2) to conform the standard charge information for both the existing and newly proposed data elements in the proposed CMS template layout. To implement these requirements, we estimated that it would take, on average, 1 hour (at a cost of $118.14 per hour) for a General and Operations Manager (BLS 11–1021) to review and determine proposed compliance requirements. We estimated it will take a Business Operations Specialist (BLS 13–1000), on average, 10 hours (at a cost of $80.08 per hour) to develop and update the necessary processes and procedures and develop the requirements to implement the proposed CMS template. Once the existing systems have been identified and requirements developed, we estimated that a network and computer system administrator (BLS 15–1244) would spend, on average, 20 hours (at a cost of $93.42 per hour), to make updates to existing systems to conform to the proposed CMS template layout and post it to the internet, including developing and posting the proposed .txt file in the root folder of the public web page it selects to host its MRF in the form and manner specified by CMS that includes a standardized set of fields specified by the proposed rule. Therefore, we proposed the total burden estimate for the first year to be 31 hours (1 hours + 10 hours + 20 hours) per hospital with a cost of $2,787.34 ($118.14 + $800.80 + $1,868.40) per hospital. The initial one-time national burden was calculated to be $19,784,539.32 dollars ($2,787.34 per hospital × 7,098 hospitals).

In addition to the initial one-time cost to implement the proposals, we proposed to increase the ongoing annual burden estimate to take into account the increase in data elements the hospital must collect and encode in the MRF. Specifically, we estimated an increased ongoing amount of time for a business operations specialist, from 32 hours to 40 hours per hospital, to identify and gather required additional data elements on an annual basis. This increase acknowledged that some hospitals may not update their systems in the first year to maintain and abstract newly required data elements in an automated way to facilitate future annual updates to the MRF, thus we expected a subset of hospitals would continue to spend time annually to gather and manually encode their standard charge information. Therefore, we proposed an estimated ongoing annual national burden of 383,292 hours (54 hours × 7,098 hospitals) and an ongoing annual national cost of $32,370,571 dollars ($4,560.52 per respondent × 7,098 hospitals), which represents a $10,698,069 ($32,370,571 − $21,672,502) increase over our previous estimated national annual burden for subsequent years.

We received the following comments related to our burden estimates, which we have summarized below.

Comment: Several commenters expressed concern that CMS underestimated the cost to comply with HPT requirements and noted that price transparency activities are complex, expensive, and burdensome for hospitals, although a few noted that standardization of the data would help hospitals comply with the regulation. Commenters noted that hospitals have already dedicated significant resources toward complying with the machine-readable file requirements, with hospitals reporting that they are spending thousands of dollars and significant labor resources to implement

[837] American Hospital Association. Fast Facts on U.S. Hospitals, 2019. Available at: *https://www.aha.org/statistics/fast-facts-us-hospitals.* The AHA listed 6,210 total hospitals operating in the US. To arrive at 6,002 hospitals, we subtracted the 208 federally owned or operated hospitals.

[838] Homeland Infrastructure Foundation-Level Data hospital dataset accessed on May 3, 2023, located at *https://hifld-geoplatform.opendata.arcgis.com/datasets/hospitals/data.*

[839] U.S. Bureau of Labor Statistics, May 2022 national Occupational Employment and Wage Estimates United States, Occupational Employment and Wage Statistics. Accessed at *https://www.bls.gov/oes/tables.htm.*

these requirements, asserting their belief that these costs were not benefitting patients.

A few commenters provided more detailed information on costs incurred by hospitals for implementation. One commenter believed that our estimates do not fully account for attorney time, financial specialists, and meetings between contracting, billing, finance, legal, and technical teams. Another commenter noted they invest several thousand hours of staff full time equivalents (FTEs) annually in its 40-hospital system. Several commenters noted that member hospitals reported spending $15,000–25,000 per hospital on vendors to build the initial machine-readable files, and $10,000–20,000 to maintain the files and update them annually. These commenters noted that a hospital system producing its own file, without vendor help, reported spending 1,600 hours annually, across 23 individuals, to produce their machine-readable files. Another commenter stated that converting to a new CMS template with payer-specific notes would require seven full-time employees with the appropriate level of payer contracting expertise.

Finally, commenters noted that requiring a rapid change in format may increase their expenses when the hospital uses a third-party vendor to make their data public, noting that vendors would not likely begin work until the policies are finalized. Commenters stated that detailed guidance would be required to properly ensure that the new standard format is implemented consistently across hospitals and to avoid excessive updates to the guidance in the future.

Response: We appreciate commenters' concerns and that hospitals have different operational and administrative systems that impact projected burden for implementation of the CMS standard template and encoding of new data elements. To address this variability, CMS is allowing hospitals to choose which CMS template format they will use, providing hospitals some flexibility to select the least burdensome format and layout to incorporate into their current MRF development process. CMS expects that, nearly 3 years after the implementation of the initial rule, most hospitals have well developed automated processes in place that they leverage to minimize the burden associated with making hospital standard charge information public in their current MRFs.

We agree with commenters that standardization may help streamline hospital efforts. As noted in section XVIII.B.3 of this final rule with comment period we relied on recommendations from the FFRDC that convened a TEP to discuss the potential benefits to both hospitals and the public if CMS required hospitals to display standard charge information that better described or contextualized their standard charges. The TEP also weighed the benefits with the potential burden hospitals would incur to display those new data elements and encode data in a more specified way and recommended the use of a standard template. Additionally, as discussed in more detail in the economic analysis (section XXVI of this final rule with comment period), we continue to believe that increased competition benefits consumers, and that this benefit outweighs the burden imposed by these requirements.

Moreover, in order to reduce burden, we are finalizing a phased implementation timeline applicable to the new requirements we are finalizing in this final rule. Specifically, and as discussed in more detail in section XVIII.B.3.c of this final rule with comment, we are finalizing that the effective date of the changes to the hospital price transparency regulations at 45 CFR part 180 will be January 1, 2024. However, the regulation text will specify later dates by which hospitals must be in compliance with some of these new requirements, and we will begin enforcing those requirements on those specified dates. In response to comments, we will increase the initial one-time burden to take into account an additional labor category (lawyer) and increase increasing number of total hours.

Finally, we are developing detailed technical specifications and guidance, in the form of a data dictionary and other resources, that will be available to assist hospitals in correctly formatting the standard charge information into a standardized CMS template layout. The policies CMS is finalizing closely approximate the voluntary sample formats and technical guidance found on our HPT website which CMS has made available in November 2022. Thus, we estimate that hospitals that have already voluntarily adopted this format and collected and encoded the additional data elements would incur little additional burden.

To summarize, we are swayed by commenters that the proposal to increase the number of data elements will result in an increased initial one-time expense for hospitals to collect and encode in the CMS template. We are therefore increasing the initial one-time burden estimate to more closely approximate commenter's estimates, to the extent they were expressed as a 'per hospital' amount and not a 'per health system' amount. We are also finalizing our estimate of ongoing annual costs as proposed, which approximates the per hospital amount provided by commenters.

After consideration of the comments, and based on the policies we are finalizing in this final rule, we now estimate it will take, on average, 5 hours (at a cost of $157.48 per hour) for a Lawyer (BLS 23–1011) to review the rule. We estimate it will take, on average, 5 hours (at a cost of $118.14 per hour) for a General and Operations Manager (BLS 11–1021) to review and determine proposed compliance requirements. We estimate it will take a Business Operations Specialist (BLS 13–1000), on average, 80 hours (at a cost of $80.08 per hour) to develop and update the necessary processes and procedures and develop the requirements to implement a CMS template layout. Once the existing systems have been identified and requirements developed, we estimate that a network and computer system administrator (BLS 15–1244) would spend, on average, 30 hours (at a cost of $93.42 per hour), to make updates to existing systems to conform to a CMS template layout and post it to the internet, including developing and posting the .txt file in the root folder of the public web page it selects to host its MRF in the form and manner specified by CMS that includes a standardized set of fields specified by this final rule with comment period. Occupation titles and wage rates included in the final estimate are in Table 165.

TABLE 165: OCCUPATION TITLES AND WAGE RATES

Occupational Title	Occupation code	Mean hourly wage ($/hr)	Fringe benefit ($/hr)	Adjusted hourly wage ($/hr)
Lawyer	BLS 23-1011	$78.74	$78.74	$157.48
General and Operations Managers	BLS 11-1021	$59.07	$59.07	$118.14
Business Operations Specialists	BLS 13-1000	$40.04	$40.04	$80.08
Network and Computer Systems Administrators	LS 15-1244	$46.71	$46.71	$93.42

The total initial one-time burden estimate for the first year is now estimated to be 120 hours (5 hours + 5 hours + 80 hours + 30 hours) per hospital with a cost of $10,587.10 ($787.40 + $590.70 + $6,406.40 + $2,802.60) per hospital. The initial one-time national burden is calculated to be $75,147,235.80 dollars ($10,587.10 per hospital × 7,098 hospitals) (See Table 166.)

TABLE 166: SUMMARY OF INFORMATION OF COLLECTION BURDENS FOR THE FIRST YEAR

Regulation section	OMB control no.	Number of respondents	Number of responses	Burden per response (hours)	Total annual burden (hours)	Total labor cost of reporting ($)
§ 180.50	0938-1369	7,098	7,098	120	851,760	$75,147,235.80

Additionally, we are finalizing an estimated ongoing annual national burden of 383,292 hours (54 hours × 7,098 hospitals) and an annual national cost of $32,370,571 dollars ($4,560.52 per respondent × 7,098 hospitals), which represents a $10,698,069 ($32,370,571 − $21,672,502) increase over our previous estimated ongoing national annual burden for subsequent years (See Table 167.)

TABLE 167: SUMMARY OF INFORMATION OF COLLECTION BURDENS FOR SUBSEQUENT YEARS

Regulation section	OMB control no.	Number of respondents	Number of responses	Burden per response (hours)	Total annual burden (hours)	Total labor cost of reporting ($)
§ 180	0938-1369	7,098	7,098	54	383,292	$32,370,571

The new information collection requirements, as well as the initial one-time cost estimates and updated ongoing annual burden estimates discussed in this section will be submitted for OMB review and approval for OMB control number is 0938–1369.

XXV. 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 preamble; and, when we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

XXVI. Economic Analyses

A. Statement of Need

This final rule with comment period is necessary to make updates to the Medicare hospital OPPS rates. It is also necessary to make changes to the payment policies and rates for outpatient services furnished by hospitals and CMHCs in CY 2024. 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 are revising the APC relative payment weights using claims data for services furnished on and after January 1, 2022, through and including December 31, 2022, and processed through June 30, 2023, and updated HCRIS cost report information, as discussed in section X.F of this final rule with comment period.

This final rule with comment period is also necessary to make updates to the ASC payment rates for CY 2024, enabling CMS to make changes to payment policies and payment rates for covered surgical procedures and covered ancillary services that are performed in ASCs in CY 2024. 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. In this CY 2024 OPPS/ASC final rule with comment period, we are finalizing a policy to extend the 5-year interim period by an additional 2 years, through CY 2024 and CY 2025, to enable us to more accurately analyze whether the application of the hospital market basket update to the ASC payment system resulted in a migration of services from the hospital setting to the ASC setting. Further discussion of this final policy can be found in section XIII.G.2.b of this final rule with comment period.

B. Overall Impact of Provisions of This Final Rule With Comment Period

We have examined the impacts of this rule, as required by Executive Order 12866, as amended, on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), Executive Order 14094, entitled ''Modernizing Regulatory Review'' (April 6, 2023), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), section 1102(b) of the Social Security Act, section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995, Pub. L. 104–4), and Executive Order 13132 on Federalism (August 4, 1999) and the Congressional Review Act (5 U.S.C. 804(2)).

Executive Orders 12866, as amended, 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 14094, titled ''Modernizing Regulatory Review'' (hereinafter the Modernizing E.O.), amends section 3(f) of Executive Order 12866 (Regulatory Planning and Review). The amended section 3(f) of Executive Order 12866 defines a ''significant regulatory action'' as an action that is likely to result in a rule: (1) having an annual effect on the economy of $200 million or more in any 1 year (adjusted every 3 years by the Administrator of the Office of Information and Regulatory Affairs (OIRA) for changes in gross domestic product), or adversely effect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, territorial, or tribal governments or communities; (2) creating a serious inconsistency or otherwise interfering with an action taken or planned by another agency; (3) materially altering the budgetary impacts of entitlement grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raise legal or policy issues for which centralized review would meaningfully further the President's priorities or the principles set forth in this Executive order, as specifically authorized in a timely manner by the Administrator of OIRA in each case. A regulatory impact analysis (RIA) must be prepared for major rules with significant regulatory action/s and/or with significant effects as per section 3(f)(1) ($200 million or more in any 1 year). Based on our estimates, OMB's Office of Information and Regulatory Affairs has determined this rulemaking is significant per section 3(f)(1) as measured by the $200 million or more in any 1 year, and hence also a major rule under Subtitle E of the Small Business Regulatory Enforcement Fairness Act of 1996 (also known as the Congressional Review Act). Accordingly, we have prepared a Regulatory Impact Analysis that to the best of our ability presents the costs and benefits of the rulemaking. Therefore, OMB has reviewed this final rule with comment period, and the Departments have provided the following assessment of their impact.

We estimate that the total increase in Federal Government expenditures under the OPPS for CY 2024, compared to CY 2023, due to the changes to the OPPS in this final rule with comment period, will be approximately $2.2 billion. Taking into account our estimated changes in enrollment, utilization, and case-mix for CY 2024, we estimate that the OPPS expenditures, including beneficiary cost-sharing, for CY 2024 will be approximately $88.9 billion, which is approximately $6.0 billion higher than estimated OPPS expenditures in CY 2023. Table 168 of this final rule with comment period displays the distributional impact of the CY 2024 changes in OPPS payment to various groups of hospitals and for CMHCs.

We note that under our final CY 2024 policy, drugs and biologicals are generally paid at ASP plus 6 percent, WAC plus 6 percent, or 95 percent of AWP, as applicable. The impacts on hospital rates as a result of this final policy are reflected in the discussion of the estimated effects of this final rule with comment period.

We estimate that the final update to the conversion factor and other budget neutrality adjustments will increase total OPPS payments by 3.1 percent in CY 2024. The final changes to the APC relative payment weights, the final changes to the wage indexes, the final continuation of a payment adjustment for rural SCHs, including EACHs, and the final payment adjustment for cancer hospitals would not increase total OPPS payments because these changes to the OPPS are budget neutral. However, these updates would change the distribution of payments within the budget neutral system. We estimate that the total change in payments between CY 2023 and CY 2024, considering all budget-neutral payment adjustments, changes in estimated total outlier payments, 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 will increase total estimated OPPS payments by 3.2 percent.

We estimate the total increase (from changes to the ASC provisions in this final rule with comment period, 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 2024 compared to CY 2023, to be approximately $207 million. Tables 169 and 170 of this final rule with comment period display the redistributive impact of the CY 2024 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 Final Rule

a. Limitations of Our Analysis

The distributional impacts presented here are the projected effects of the final CY 2024 policy changes on various hospital groups. We post our hospital-specific estimated payments for CY 2024 on the CMS website with the other supporting documentation for this final rule with comment period. To view the hospital-specific estimates, we refer readers to the CMS website at: *https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient.* On the website, select ''Regulations and Notices'' from the left side of the page and then select ''CMS–1786–FC'' 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 final rule with comment period. We show hospital-specific data only for hospitals whose claims were used for modeling the impacts shown in Table 168 of this final rule with comment period. 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 final rule with comment period for a discussion of the hospitals whose claims we do not use for ratesetting or 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 any adjustments for future changes in variables, such as service volume, service-mix, or number of encounters.

b. Estimated Effects of OPPS Changes on Hospitals

Table 168 shows the estimated impact of this final 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-Balanced Budget Act (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 168, and we discuss them separately below, because CMHCs have historically been paid only for partial hospitalization services under the OPPS and are a different provider type from hospitals. In CY 2024, we are finalizing paying CMHCs for partial hospitalization services under APCs 5853 (Partial Hospitalization (three services per day) for CMHCs) and 5854 (Partial Hospitalization (four or more services per day) for CMHCs) and to pay hospitals for partial hospitalization services under APCs 5863 (Partial Hospitalization (three services per day) for hospital-based PHPs) and 5864 (Partial Hospitalization (four or more services per day) for hospital-based PHPs). In addition, we are finalizing payment for four Intensive Outpatient Program (IOP) APCs, two for each provider type, including an APC for three services per day and an APC for four or more services per day. 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 final 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 final IPPS market basket percentage increase applicable to the OPD fee schedule for CY 2024 is 3.3 percent. Section 1833(t)(3)(F)(i) of the Act reduces that 3.3 percent by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act, which is 0.2 percentage point for CY 2024 (which is also the productivity adjustment for FY 2024 in the FY 2024 IPPS/LTCH PPS final rule (88 FR 59035)), resulting in the final CY 2024 OPD fee schedule increase factor of 3.1 percent. We are using the OPD fee schedule increase factor of 3.1 percent in the calculation of the final CY 2024 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 estimates in Table 168 of this final rule with comment period.

To illustrate the impact of the CY 2024 changes, our analysis begins with a baseline simulation model that uses the CY 2023 relative payment weights, the FY 2023 final IPPS wage indexes that include reclassifications, and the final CY 2023 conversion factor. Table 168 shows the estimated redistribution of the increase or decrease in payments for CY 2024 over CY 2023 payments to hospitals and CMHCs as a result of the following factors: the impact of the APC reconfiguration and recalibration changes between CY 2023 and CY 2024 (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 3.1 percent OPD fee schedule increase factor update to the conversion factor (Column 4); the estimated impact taking into account all payments for CY 2024 relative to all payments for CY 2023, including the impact of changes in estimated outlier payments and changes to the pass-through payment estimate (Column 5).

We did not model an explicit budget neutrality adjustment for the rural adjustment for SCHs because we proposed to maintain the current adjustment percentage for CY 2024. Because the final 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 2024 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 would 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 final rule would redistribute money during implementation also will depend on changes in volume, practice

patterns, and the mix of services billed between CY 2023 and CY 2024 by various groups of hospitals, which CMS cannot forecast.

Overall, we estimate that the final rates for CY 2024 will increase Medicare OPPS payments by an estimated 3.2 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 3.3 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 168 shows the total number of facilities (3,611), including designated cancer and children's hospitals and CMHCs, for which we were able to use CY 2022 hospital outpatient and CMHC claims data to model CY 2023 and CY 2024 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 2023 or CY 2024 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 final rule with comment period. 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 (3,511), 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 32 CMHCs at the bottom of the impact table (Table 168) 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 a 0.0 increase, with the impact ranging from a decrease of 0.4 percent to an increase of 0.5, depending on the number of beds. Rural hospitals will experience an estimated increase of 0.3 overall. Major teaching hospitals will experience an estimated decrease of 0.5 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 2024 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 2023 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 updated wage indexes, including the application of budget neutrality for the rural floor policy on a nationwide basis, as well as the final CY 2024 changes in wage index policy, discussed in section II.C of this final rule. We did not model a budget neutrality adjustment for the rural adjustment for SCHs because we are continuing the rural payment adjustment of 7.1 percent to rural SCHs for CY 2024, as described in section II.E of this final rule. We modeled a budget neutrality adjustment for the final cancer hospital payment adjustment because the final payment-to-cost ratio target for the cancer hospital payment adjustment in CY 2024 is 0.88, which is different from the 0.89 PCR target for the CY 2023 OPPS/ASC final rule with comment period (87 FR 71788). 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 0.89, not the 0.88 target payment-to-cost ratio we are finalizing in section II.F of this final 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 2024 scaled weights and a CY 2023 conversion factor that included a budget neutrality adjustment for the effect of the changes to the wage indexes between CY 2023 and CY 2024.

Column 4: All Budget Neutrality Changes Combined With the Market Basket Update

Column 4 demonstrates the combined impact of all the final changes previously described and the update to the conversion factor of 3.1 percent. Overall, these changes will increase payments to urban hospitals by 3.2 percent and to rural hospitals by 4.6 percent. Rural sole community hospitals will receive an estimated increase of 4.8 percent while other rural hospitals would receive an estimated increase of 4.3 percent.

Column 5: All Changes for CY 2024

Column 5 depicts the full impact of the final CY 2024 policies on each hospital group by including the effect of all changes for CY 2024 and comparing them to all estimated payments in CY 2023. Column 5 shows the combined budget neutral effects of Columns 2 and 3; the OPD fee schedule increase; the impact of estimated OPPS outlier payments, as discussed in section II.G of this final 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 final rule with comment period); and other final adjustments to the CY 2024 OPPS payments.

Of those hospitals that failed to meet the Hospital OQR Program reporting requirements for the full CY 2023 update (and assumed, for modeling purposes, to be the same number for CY 2023), we included 56 hospitals in our model because they had both CY 2022 claims data and recent cost report data. We estimate that the cumulative effect of all changes for CY 2024 would increase payments to all facilities by 3.2 percent for CY 2023. We modeled the independent effect of all changes in Column 5 using the final relative payment weights for CY 2023 and the final relative payment weights for CY 2024. We used the final conversion factor for CY 2023 of $85.585 and the final CY 2024 conversion factor of $87.382 discussed in section II.B of this final rule with comment period.

Column 5 contains simulated outlier payments for each year. We used the 1-year charge inflation factor used in the FY 2024 IPPS/LTCH PPS final rule (87 FR 49427) of 5.8 percent (1.05755) to increase charges on the CY 2022 claims, and we used the overall CCR in the April 2023 Outpatient Provider-Specific File (OPSF) to estimate outlier payments for CY 2023. Using the CY 2022 claims and a 5.8 percent charge inflation factor, we currently estimate that outlier payments for CY 2024, using a multiple threshold of 1.75 and a fixed-dollar threshold of $7,750, would be approximately 0.83 percent of total payments. The estimated current outlier payments of 0.83 percent are incorporated in the comparison in Column 5. We used the same set of claims and a charge inflation factor of 11.9 percent (1.11904) and the CCRs in the July 2023 OPSF, with an adjustment of 0.990843 (88 FR 59353), to reflect relative changes in cost and charge inflation between CY 2022 and CY 2024, to model the final CY 2024 outliers at 1.0 percent of estimated total payments using a multiple threshold of 1.75 and a fixed dollar threshold of $7,750. The charge inflation and CCR inflation factors are discussed in detail in the FY 2024 IPPS/LTCH PPS final rule (88 FR 59348 through 59354).

Overall, we estimate that facilities will experience an increase of 3.2 percent under this final rule with comment period in CY 2024 relative to total spending in CY 2023. This projected increase (shown in Column 5) of Table 168 of this final rule with comment period reflects the final 2.8 percent OPD fee schedule increase factor, added by the difference in estimated outlier payments between CY 2023 (0.78 percent) and CY 2024 (1.0 percent), minus 0.11 percent for the change in the pass-through payment estimate between CY 2023 and CY 2024. We estimate that the combined effect of all changes for CY 2024 will increase payments to urban hospitals by 3.2 percent. Overall, we estimate that rural hospitals will experience a 4.2 percent increase as a result of the combined effects of all the changes for CY 2024.

Among hospitals, by teaching status, we estimate that the impacts resulting from the combined effects of all changes will include an increase of 2.4 percent for major teaching hospitals and an increase of 3.9 percent for nonteaching hospitals. Minor teaching hospitals will experience an estimated increase of 3.5 percent.

In our analysis, we also have categorized hospitals by type of ownership. Based on this analysis, we estimate that voluntary hospitals would experience an increase of 3.2 percent, proprietary hospitals will experience an increase of 4.6 percent, and governmental hospitals will experience an increase of 2.8 percent.

c. Estimated Effects of OPPS Changes on CMHCs

The last line of Table 168 demonstrates the isolated impact on CMHCs, which historically have only furnished partial hospitalization services under the OPPS. As discussed in section VIII.D of this CY 2024 OPPS/ASC final rule, we are finalizing the proposal for CY 2024 to pay CMHCs under APC 5853 (Partial Hospitalization (3 services per day) for CMHCs) for PHP days with three or fewer services, and APC 5854 (Partial Hospitalization (four or more services per day) for CMHCs) for days with four or more services. We modeled the impact of this APC policy assuming CMHCs will continue to provide the same PHP care as seen in the CY 2022 claims used for ratesetting in this final rule. We did not exclude days with one or two services from our modeling for CY 2024, because our final policy will pay the per diem rate for APC 5853 for such days beginning in CY 2024. As a result of the final PHP APC changes for CMHCs, we estimate that CMHCs will experience a 9.2 percent increase in CY 2024 payments relative to their CY 2023 payments (shown in Column 5). For a detailed discussion of our final PHP policies, please see section VIII of this final rule with comment period.

Column 3 shows the estimated impact of adopting the final FY 2024 wage index values, which result in an estimated change of 0 percent to CMHCs. Column 4 shows that combining the OPD fee schedule increase factor, along with the final changes in APC policy for CY 2024 and the final FY 2024 wage index updates, will result in an estimated increase of 10 percent.

Lastly, we note that as discussed in section VIII of this final rule with comment period, we are finalizing the proposal to establish payment for intensive outpatient services furnished by CMHCs under APCs 5851 (Intensive Outpatient (3 services per day) for CMHCs) and 5852 (Intensive Outpatient (4 or more services per day) for CMHCs). Payment estimates for APCs 5851 and 5852 are not reflected in Table 168 but are discussed in section XXI.C.1.i of this final rule with comment period.

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TABLE 168: ESTIMATED IMPACT OF THE FINAL CY 2024 CHANGES FOR THE HOSPITAL OUTPATIENT PROSPECTIVE PAYMENT SYSTEM

	(1)	(2)	(3)	(4)	(5)
	Number of Hospitals	**APC Recalibration (all changes)**	**New Wage Index and Provider Adjustments**	**All Budget Neutral Changes (combined cols 2 & 3) with Market Basket Update**	**All Changes**
ALL PROVIDERS *	3,611	0.0	0.1	3.2	3.2
ALL HOSPITALS	3,511	0.1	0.2	3.4	3.3
(excludes hospitals held harmless and CMHCs)					
URBAN HOSPITALS	2,801	0.1	0.1	3.2	3.2
LARGE URBAN	1,452	0.0	-0.1	3.0	3.1
(GT 1 MILL.)					
OTHER URBAN	1,349	0.1	0.3	3.4	3.2
(LE 1 MILL.)					
RURAL HOSPITALS	710	0.3	1.2	4.6	4.2
SOLE COMMUNITY	373	0.1	1.5	4.8	4.3
OTHER RURAL	337	0.5	0.6	4.3	4.2
BEDS (URBAN)					
0 - 99 BEDS	979	0.1	0.1	3.3	3.1
100-199 BEDS	780	0.5	0.1	3.7	3.5
200-299 BEDS	418	0.3	0.3	3.7	3.5
300-499 BEDS	391	0.2	0.7	4.0	3.8
500 + BEDS	233	-0.4	-0.5	2.1	2.3
BEDS (RURAL)					
0 - 49 BEDS	347	0.4	0.9	4.5	4.2
50- 100 BEDS	207	0.2	2.1	5.4	5.0
101- 149 BEDS	83	0.2	0.7	4.1	3.4
150- 199 BEDS	42	0.4	1.0	4.5	4.0
200 + BEDS	31	0.3	0.5	3.9	3.9
REGION (URBAN)					
NEW ENGLAND	131	-0.2	-2.1	0.7	0.8
MIDDLE ATLANTIC	307	-0.2	0.9	3.8	3.9
SOUTH ATLANTIC	464	0.1	0.1	3.4	3.4
EAST NORTH CENT.	423	0.0	-1.3	1.7	1.8
EAST SOUTH CENT.	163	-0.2	-0.6	2.3	2.3
WEST NORTH CENT.	185	-0.1	-0.1	3.0	1.8
WEST SOUTH CENT.	470	0.6	-0.8	2.8	2.9
MOUNTAIN	216	0.1	0.3	3.5	3.3
PACIFIC	392	0.2	2.6	6.0	6.0
PUERTO RICO	50	0.9	-0.9	3.1	3.0

	(1)	(2)	(3)	(4)	(5)
	Number of Hospitals	**APC Recalibration (all changes)**	**New Wage Index and Provider Adjustments**	**All Budget Neutral Changes (combined cols 2 & 3) with Market Basket Update**	**All Changes**
REGION (RURAL)					
NEW ENGLAND	19	-0.1	-1.1	1.8	1.9
MIDDLE ATLANTIC	47	-0.2	7.9	11.1	10.9
SOUTH ATLANTIC	106	0.4	0.4	3.9	3.9
EAST NORTH CENT.	112	0.2	0.2	3.5	3.4
EAST SOUTH CENT.	139	0.9	-0.2	3.9	3.8
WEST NORTH CENT.	84	-0.1	1.3	4.4	3.3
WEST SOUTH CENT.	133	1.1	-0.1	4.2	4.1
MOUNTAIN	46	-0.2	1.6	4.5	2.4
PACIFIC	24	0.0	4.1	7.3	7.3
TEACHING STATUS					
NON-TEACHING	2,204	0.4	0.5	4.0	3.9
MINOR	874	0.3	0.4	3.8	3.5
MAJOR	433	-0.5	-0.4	2.2	2.4
DSH PATIENT PERCENT					
0	9	-2.3	-1.4	-0.6	1.4
GT 0 - 0.10	242	0.0	0.1	3.2	2.9
0.10 - 0.16	245	0.4	-0.2	3.4	3.2
0.16 - 0.23	545	0.4	0.0	3.5	3.4
0.23 - 0.35	1,144	0.1	0.1	3.3	3.1
GE 0.35	878	-0.2	0.5	3.4	3.5
DSH NOT AVAILABLE **	448	3.5	1.5	8.4	8.4
URBAN TEACHING/DSH					
TEACHING & DSH	1,163	-0.1	-0.1	2.9	2.9
NO TEACHING/DSH	1,181	0.4	0.4	3.9	3.7
NO TEACHING/NO DSH	9	-2.3	-1.4	-0.6	1.4
DSH NOT AVAILABLE2	448	3.5	1.5	8.4	8.4
TYPE OF OWNERSHIP					
VOLUNTARY	1,991	0.0	0.2	3.3	3.2
PROPRIETARY	1,077	1.1	0.5	4.7	4.6
GOVERNMENT	443	-0.3	-0.1	2.7	2.8
CMHCs	32	6.7	0.0	10.0	9.2

Column (1) shows total hospitals and/or CMHCs.

Column (2) includes all final CY 2024 OPPS policies and compares those to the CY 2023 OPPS.

		(1)	(2)	(3)	(4)	(5)
		Number of Hospitals	**APC Recalibration (all changes)**	**New Wage Index and Provider Adjustments**	**All Budget Neutral Changes (combined cols 2 & 3) with Market Basket Update**	**All Changes**
Column (3) shows the budget neutral impact of updating the wage index by applying the final FY 2024 hospital inpatient wage index. The final rural SCH adjustment would continue our current policy of 7.1 percent, so the budget neutrality factor is 1. The final budget neutrality adjustment for the cancer hospital adjustment is 1.0005 because the final CY 2024 target payment-to-cost ratio is less than the CY 2023 PCR target.						
Column (4) shows the impact of all budget neutrality adjustments and the addition of the final 3.1 percent OPD fee schedule update factor (3.3 percent reduced by 0.2 percentage points for the productivity adjustment).						
Column (5) 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 3,611 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 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 of the calculation of the national unadjusted copayments and minimum unadjusted copayments, we refer readers to section II.H of this final 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 approximately 18.0 percent for all services paid under the OPPS in CY 2024. The estimated aggregate beneficiary coinsurance reflects general system adjustments, including the final CY 2024 comprehensive APC payment policy discussed in section II.A.2.b of this final rule. We note that the individual payments, and therefore copayments, associated with services may differ based on the setting in which they are furnished. However, at the aggregate system level, we do not currently observe significant impact on beneficiary coinsurance as a result of those policies.

e. 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 this final rule. Hospitals, CMHCs, and ASCs would be affected by the changes in this final rule. Additionally, as discussed in section VIII of this final rule with comment period, we are establishing payment for IOP furnished by RHCs, FQHCs, and OTPs. These providers of IOP are not paid under the OPPS and are not included in the impact analysis shown in Table 100; however, the final payment amount for OPPS APC 5861 will affect payments to these providers. We discuss estimated effects of final IOP policies in section XXI.C.1.i of this final rule with comment period.

f. Estimated Effects of OPPS Changes on the Medicare and Medicaid Programs

The effect of the update on the Medicare program is expected to be an increase of $2.1 billion in program payments for OPPS services furnished in CY 2024. 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 changes in this final rule with comment period will increase these Medicaid beneficiary payments by approximately $135 million in CY 2024. Currently, there are approximately 10 million dual-eligible beneficiaries, which represent approximately 30 percent of Medicare Part B fee-for-service beneficiaries. The impact on Medicaid was determined by taking 30 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 $135 million Medicaid increase, approximately $75 million would be from the Federal government and $60 million will be from State governments.

g. Alternative OPPS Policies Considered

Alternatives to the OPPS changes we proposed and the reasons for our selected alternatives are discussed throughout this final rule with comment period.

• Alternatives Considered for the Claims Data used in OPPS and ASC Ratesetting due to the PHE.

We refer readers to section X.F of this final rule with comment period for a discussion of our final policy of returning to the standard update process of using updated cost report data for OPPS ratesetting. In that section, we discussed our consideration of issues regarding data updates, and in particular the selection of cost report data used, which would include some cost report data including the timeframe of the PHE. We note that were we to continue using cost report data from prior to the PHE it would potentially not be reflective of more updated cost and charging patterns. In this final rule, as discussed in section X.F. of this final rule with comment period, we are finalizing our policy of resuming our regular cost report update process for CY 2024 OPPS ratesetting.

We note that these policy considerations also have ASC implications since the relative weights for certain surgical procedures performed in the ASC setting are developed based on the OPPS relative weights and claims data.

h. Health Equity Comment Solicitation

Advancing health equity is the first pillar of the CMS 2022 Strategic Framework.[840] To gain insight into how OPPS and ASC policies could affect health equity, we are considering adding elements to our impact analysis that would detail how OPPS and ASC policies impact particular beneficiary populations. Beneficiary populations that have been disadvantaged or underserved by the healthcare system may include patients with the following characteristics, among others: members of racial and ethnic minorities; members of federally recognized Tribes; people with disabilities; members of the lesbian, gay, bisexual, transgender, and queer (LGBTQ+) community; individuals with limited English proficiency; members of rural communities; and persons otherwise adversely affected by persistent poverty or inequality.

We sought comment from interested parties about how we might structure an impact analysis that addresses how OPPS and ASC changes may impact beneficiaries of different groups. We currently present OPPS impacts by provider type, rural versus urban area, geographic region, teaching status, and ownership type. We stated that we were interested in what health equity questions we can examine within these existing categories to better understand the heath equity impact of our policies. We also welcomed suggestions about adding new categories or measures of health equity in our impact analyses, such as using the area deprivation index (ADI) as a proxy for disparities related to geographic variation. Additionally, we sought comment on ways to continue building an OPPS health equity framework that allows us to develop policies that enhance health equity under our existing statutory authority.

Comment: Commenters were supportive of CMS efforts to incorporate health equity elements into future impact analyses and provided other recommendations for policies to promote health equity using the OPPS. Suggestions included: engaging with interested parties or beneficiaries to identify instances where payment policy negatively impacts beneficiary care and to determine which health equity elements should be included in impact analyses; adding elements that address policy impacts on social drivers of health, racial and ethnically minoritized groups, the LGBTQIA+ community, those living with disabilities, and other underserved populations; using of health equity accreditation programs or the NCQA health equity framework to examine whether payment adjustments worsen health disparities or produce unintended results; conducting research to better understand how beneficiaries are made aware of outpatient services and whether this leads to disparities in accessing outpatient services; assessing whether utilization by geographic areas is skewed by socioeconomic circumstances or inequities that pose barriers to beneficiaries accessing and utilizing services; outlining specific health equity goals for providers; adopting the ONC HIT certification requirements as a model for embedding health equity in all components of data measurement; adopting payment policies that recognize the unique role of essential hospitals in promoting health equity; considering hospital performance and the proportion of vulnerable populations served by the hospitals in any health equity framework; and continuing efforts to advance interoperable data systems that collect health equity data.

Response: We appreciate the input from commenters. We will take these suggestions into consideration for future rulemaking.

i. Effects of IOP Policies on Hospitals, CMHCs, FQHCs, RHCs, and OTPs

As discussed in section VIII of this CY 2024 OPPS/ASC final rule with comment period, we are establishing payment for intensive outpatient services furnished by hospitals, CMHCs, FQHCs, and RHCs under a new IOP benefit. We are also finalizing our proposal to establish payment for intensive outpatient services provided by OTPs under the existing OTP benefit. Estimates of the payment impacts for IOP furnished by hospitals are included in Table 168 of this final rule with comment period, based on utilization in the CY 2022 claims for days that we believe would likely be billed as IOP beginning in CY 2024. Specifically, we modeled non-PHP days furnished by hospitals with 3 and 4 or more services from Table 98 of this final rule with comment period and at least one service from the list of primary services shown in Table 99 of this final rule with comment period.

Because CMHCs are currently only permitted to bill for partial hospitalization services, we are unable to model payments for IOP APCs 5851 and 5852 based on utilization from CY 2022 claims. Therefore, the payment impacts for IOP furnished by CMHCs are not included in Table 168. However, we anticipate there would be an increase in utilization for CMHCs beginning in CY 2024. We simulated potential utilization for IOP APCs 5851 and 5852 based on estimates of the volume of such services that we expect would be provided beginning in CY 2024. We calculated the number of non-PHP 3-service and 4 or more service days in the hospital setting and compared this to the number of PHP 3-service and 4 or more service days in the hospital setting. We applied the same ratio of non-PHP to PHP days to estimate anticipated IOP claims in the CMHC setting for CY 2024. We believe this is appropriate, because as discussed in section VIII.C of this final rule with comment period, IOP and PHP days will consist of the same services and use the same HCPCS codes. Therefore, for public awareness, we are including projections about potential IOP utilization for CMHCs using claims with a comparable number and type of services, which we believe is the best available estimate of IOP utilization in the future. Based on this methodology, we estimate that CMHCs would provide approximately 52,608 IOP days with

[840] Available at: *https://www.cms.gov/files/document/2022-cms-strategic-framework.pdf.*

three services and approximately 18,034 IOP days with four or more services. These projections correspond to an estimated $9.4 million in additional payments to CMHCs for the provision of intensive outpatient services. This represents an increase of roughly 165 percent relative to current CMHC payments for partial hospitalization services. We solicited comment on our assumptions and the methodology used to derive this estimate.

In section VIII.F.4 of this final rule with comment period, we discuss the special payment rules for FQHCs and RHCs to furnish intensive outpatient services as mandated by sections 4124(c)(1) and (c)(2) of the CAA, 2023. For both FQHCs and RHCs, we are finalizing that the IOP payment rate will be based on the per diem payment amount determined for APC 5861 (Intensive Outpatient (3 services per day) for hospital-based IOPs). However, for IOP services furnished in FQHCs, the payment amount will be based on the lesser of a FQHC's actual charges or the rate determined for APC 5861. Additionally, we are finalizing that grandfathered tribal FQHCs will continue to have their payment based on the outpatient per visit rate when furnishing IOP services. That is, payment is based on the lesser of a grandfathered tribal FQHC's actual charges or the outpatient per visit rate.

FQHCs and RHCs currently bill for mental health services. Beginning January 1, 2024, these settings will be able to bill for certain mental health services determined to be IOP services that they were not able to furnish previously, for example group therapy. We anticipate there would be utilization of IOP services for both RHCs and FQHCs in CY 2024; however, since this is a new program for both settings, we are unable to project what that utilization would be or the associated Medicare expenditures. FQHCs and RHCs typically furnish primary care services therefore we believe that it may take time for these settings to build the internal framework needed to initiate and foster an IOP. With regard to RHCs, we note the statutory provision which defines the term ''rural health clinic'' in section 1861(aa)(2)(K)(iv) of the Act, states that a RHC is not a facility which is primarily for the care and treatment of mental diseases. We believe this provision could cause low utilization of IOP services until RHCs can determine what they can or cannot furnish. Therefore, we believe extending payment coverage for IOP services in FQHCs and RHCs is unlikely to have a significant impact on overall Medicare spending.

As discussed in section VIII.G of this final rule with comment period, for CY 2024 and subsequent years, we are finalizing to establish a weekly add-on code for IOP services furnished by OTPs for the treatment of opioid use disorder (OUD) and to revise the definition of OUD treatment services to include IOP services. In accordance with our methodology for other add-on adjustments to the bundled payment for OUD treatment services, we are finalizing to apply an annual update based on the Medicare Economic Index (MEI) described in § 414.30, and apply a geographic adjustment based on the Geographic Adjustment Factor (GAF) described in § 414.26. We are finalizing to allow OTPs to bill a new HCPCS code (G0137) for IOP services based on a minimum of at least nine IOP services furnished to eligible patients per week, which results in a payment rate of $778.20.

We estimate that these finalized policies to allow OTPs to bill for IOP services beginning in CY 2024 will result in a negligible cost increase, that is, the overall estimated impact of this final policy is increased spending of less than $5 million. In our analysis, we evaluated mental health services furnished to beneficiaries receiving care at OTPs, including for levels of care and types of services that are not currently reflected in the OTP benefit. Approximately 557 OTPs offer IOP services nationwide according to the National Substance Use and Mental Health Services Survey in 2021.[841] However, our analysis of claims data from Medicare beneficiaries receiving care under the OTP benefit from CY 2020–2022 indicated a small number of beneficiaries actually receive intensive care services equivalent to 9 hours or more a week to meet the minimum threshold for IOP services. Specifically, 85 percent of Medicare beneficiaries received only medications for OUD with basic counseling and no other mental health care, and thus did not likely utilize a higher level of care required for IOP services. For the remaining 15 percent of Medicare beneficiaries, approximately 0.5–0.7 percent received a higher acuity of care likely to meet the minimum 9 hours or more of services under IOPs. The estimated total annual cost per Medicare beneficiary with an OUD receiving IOP services at an OTP would be approximately $40,466, however, this estimate assumes that a beneficiary would require this level of care every week of the calendar year, which we do not believe would be likely. Therefore, extending coverage for IOP services in OTP settings is unlikely to have a significant impact on overall Medicare spending.

[841] Substance Abuse and Mental Health Services Administration, National Substance Use and Mental Health Services Survey (N–SUMHSS), 2021: Annual Detailed Tables. Rockville, MD: Substance Abuse and Mental Health Services Administration, 2023. Weblink: *https://www.samhsa.gov/data/sites/default/files/reports/rpt39450/2021%20N-SUMHSS%20Annual%20Detailed%20Tables_508_Compliant_2_8_2023.pdf.*

2. Estimated Effects of CY 2024 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 final rule with comment period, we are setting the CY 2024 ASC relative payment weights by scaling the final CY 2024 OPPS relative payment weights by the final CY 2024 ASC scalar of 0.8881. The estimated effects of the updated relative payment weights on payment rates are varied and are reflected in the estimated payments displayed in Tables 169 and 170.

Beginning in CY 2011, section 3401 of the Affordable Care Act requires that the annual update to the ASC payment system after application of any quality reporting reduction be reduced by a productivity adjustment. In CY 2019, we adopted a policy for the annual update to the ASC payment system to be the hospital market basket update for CY 2019 through CY 2023. Section 1886(b)(3)(B)(xi)(II) of the 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 (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, the CY 2024 payment determinations will be based on the application of a 2.0 percentage point reduction to the annual update factor, which is the hospital market basket update for CY 2024. We calculated the final CY 2024 ASC conversion factor by adjusting the CY 2023 ASC conversion factor by 1.0010 to account for changes in the pre-floor and pre-reclassified hospital wage indexes between CY 2023 and CY 2024 and by applying the CY 2024 productivity-adjusted hospital market basket update factor of 3.1 percent (which is equal to the final inpatient hospital market basket percentage increase of 3.3 percent reduced by a productivity adjustment of 0.2 percentage point). The final CY 2024 ASC conversion factor is $53.514 for

ASCs that successfully meet the quality reporting requirements.

a. Limitations of Our Analysis

Presented here are the projected effects of the final changes for CY 2024 on Medicare payment to ASCs. A key limitation of our analysis is our inability to predict changes in ASC service-mix between CY 2022 and CY 2024 with precision. We believe the net effect on Medicare expenditures resulting from the final CY 2024 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 would 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 of the final update to the CY 2024 payments on an individual ASC 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 includes tables that display estimates of the impact of the final CY 2024 updates to the ASC payment system on Medicare payments to ASCs, assuming the same mix of services, as reflected in our CY 2022 claims data. Table 169 depicts the estimated aggregate percent change in payment by surgical specialty or ancillary items and services group by comparing estimated CY 2023 payments to estimated CY 2024 payments, and Table 170 shows a comparison of estimated CY 2023 payments to estimated CY 2024 payments for procedures that we estimate would receive the most Medicare payment in CY 2023.

In Table 169, 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 169.

- 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 2023 ASC Payments were calculated using CY 2022 ASC utilization data (the most recent full year of ASC utilization) and CY 2023 ASC payment rates. The surgical specialty groups are displayed in descending order based on estimated CY 2023 ASC payments.
- Column 3—Estimated CY 2024 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 final updates to ASC payment rates for CY 2024 compared to CY 2023.

As shown in Table 169, for the six specialty groups that account for the most ASC utilization and spending, we estimate that the final update to ASC payment rates for CY 2024 will result in a 8 percent increase in aggregate payment amounts for eye and ocular adnexa procedures, an 11 percent decrease in aggregate payment amounts for nervous system procedures, 1 percent increase in aggregate payment amounts for musculoskeletal system procedures, a 9 percent increase in aggregate payment amounts for digestive system procedures, a 4 percent increase in aggregate payment amounts for cardiovascular system procedures, and a 8 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 changes in policy. In general, spending in each of these categories of services is increasing due to the 3.1 percent 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 3.1 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 8 percent increase in aggregate eye and ocular adnexa procedure payments. The increase in payment rates for eye and ocular andexa procedures is a result of increased OPPS relative weights as a result of the APC restructuring to the Intraocular APC family and an offsetting increase in the ASC weight scalar to account for an expected decrease in ASC expenditures from other surgical specialties. These changes are further increased by the 3.1 percent ASC rate update for these procedures. Conversely, we estimate an 11 percent decrease in nervous system procedures related to the American Medical Association's RVU Update Committee (RUC) estimated shift in utilization from an existing high-cost neurostimulator procedure (CPT code 63685) to a new, lower-cost neurostimulator procedure (CPT code 64596) for CY 2024. For estimated changes for selected procedures, we refer readers to Table 169 provided later in this section.

TABLE 169: ESTIMATED IMPACT OF THE FINAL CY 2024 UPDATE TO THE ASC PAYMENT SYSTEM ON AGGREGATE CY 2023 MEDICARE PROGRAM PAYMENTS BY SURGICAL SPECIALTY OR ANCILLARY ITEMS AND SERVICES GROUP

Surgical Specialty Group (1)	Estimated CY 2023 ASC Payments (in Millions) (2)	Estimated CY 2024 Percent Change (3)
Total	$6,309	**3**
Eye	$1,880	**8**
Nervous System	$1,274	**-11**
Musculoskeletal	$1,188	**1**
Gastrointestinal	$937	**9**
Cardiovascular	$310	**4**
Genitourinary	$225	**8**

Table 170 shows the estimated impact of the updates to the revised ASC payment system on aggregate ASC payments for selected surgical procedures during CY 2024. The table displays 30 of the procedures receiving the greatest estimated CY 2023 aggregate Medicare payments to ASCs. The HCPCS codes are sorted in descending order by estimated CY 2023 program payment.

- Column 1—CPT/HCPCS code.
- Column 2—Short Descriptor of the HCPCS code.
- Column 3—Estimated CY 2023 ASC Payments were calculated using CY 2022 ASC utilization (the most recent full year of ASC utilization) and the CY 2023 ASC payment rates.

The estimated CY 2023 payments are expressed in millions of dollars.

- Column 4—Estimated CY 2024 Percent Change reflects the percent differences between the estimated ASC payment for CY 2023 and the estimated payment for CY 2024 based on the final update.

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TABLE 170: ESTIMATED IMPACT OF THE FINAL CY 2024 UPDATE TO THE ASC PAYMENT SYSTEM ON AGGREGATE PAYMENTS FOR SELECTED PROCEDURES

CPT/HCPCS Code (1)	Short Descriptor (2)	Estimated CY 2023 ASC Payment (in millions) (3)	Estimated CY 2024 Percent Change (4)
66984	Xcapsl ctrc rmvl w/o ecp	$1,251	8
63685	Insrt/redo spine n generator	$314	-39
27447	Total knee arthroplasty	$263	-3
45380	Colonoscopy and biopsy	$244	9
45385	Colonoscopy w/lesion removal	$213	9
63650	Implant neuroelectrodes	$194	-12
43239	Egd biopsy single/multiple	$158	9
27130	Total hip arthroplasty	$130	-3
66991	Xcapsl ctrc rmvl insj 1+	$113	13
64590	Insrt/redo pn/gastr stimul	$106	-17
64483	Njx aa&/strd tfrm epi l/s 1	$100	7
66982	Xcapsl ctrc rmvl cplx wo ecp	$94	8
J1097	Phenylep ketorolac opth soln	$82	1
64635	Destroy lumb/sac facet jnt	$76	5
29827	Sho arthrs srg rt8tr cuf rpr	$75	8
36902	Intro cath dialysis circuit	$67	9
64493	Inj paravert f jnt l/s 1 lev	$66	7
G0105	Colorectal scrn; hi risk ind	$65	10
27279	Arthrodesis sacroiliac joint	$63	-14
66821	After cataract laser surgery	$61	9
64561	Implant neuroelectrodes	$53	1
65820	Relieve inner eye pressure	$45	4
C9740	Cysto impl 4 or more	$45	2
62323	Njx interlaminar lmbr/sac	$41	7
G0121	Colon ca scrn not hi rsk ind	$40	10
15823	Revision of upper eyelid	$38	5
45378	Diagnostic colonoscopy	$37	10
0275T	Perq lamot/lam lumbar	$36	5
64721	Carpal tunnel surgery	$36	5
J1096	Dexametha opth insert 0.1 mg	$34	-5

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c. Estimated Effects of ASC Payment System Policies on Beneficiaries

We estimate that the CY 2024 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 to be designated as office-based for CY 2024. 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 finalized to designate as office-based in CY 2024, 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).

Accounting Statements and Tables for OPPS and ASC Payment System

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 final rule with comment period. The first accounting statement, Table 171, illustrates the classification of expenditures for the CY 2024 estimated hospital OPPS incurred benefit impacts associated with the final CY 2024 OPD fee schedule increase. The second accounting statement, Table 172, illustrates the classification of expenditures associated with the 3.1 percent CY 2024 update to the ASC payment system, based on the provisions of this final rule with comment period and the baseline spending estimates for ASCs. Both tables classify most estimated impacts as transfers. Table 173 displays the annual estimated impact of hospital price transparency.

TABLE 171: ACCOUNTING STATEMENT: CY 2024 ESTIMATED HOSPITAL OPPS TRANSFERS FROM CY 2023 TO CY 2024 ASSOCIATED WITH THE CY 2024 HOSPITAL OUTPATIENT OPD FEE SCHEDULE INCREASE

Category	Transfers
Annualized Monetized Transfers	$2,110 million
From Whom to Whom	Federal Government to outpatient hospitals and other providers who receive payment under the hospital OPPS

TABLE 172: ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED TRANSFERS FROM CY 2023 TO CY 2024 AS A RESULT OF THE FINAL CY 2024 UPDATED TO THE ASC PAYMENT SYSTEM

Category	Transfers
Annualized Monetized Transfers	$170 million
From Whom to Whom	Federal Government to Medicare Providers and Suppliers
Total	$170 million

TABLE 173: ESTIMATED COSTS IN CY 2024 FOR HOSPITAL PRICE TRANSPARENCY

CATEGORY	Costs
Burden	$75.147million
Regulatory Familiarization	$3.715 million*

* Regulatory familiarization costs occur upfront only.

3. Effects of Changes in Requirements for the Hospital Outpatient Quality Reporting (OQR) Program

a. Background

We refer readers to the CY 2023 OPPS/ASC final rule with comment period (87 FR 72278 through 72279) for the previously estimated effects of changes to the Hospital OQR Program for the CY 2025 payment determination. Of the 3,097 hospitals that met eligibility requirements for the CY 2023 payment determination for the Hospital OQR Program, we determined that 77 hospitals did not meet the requirements to receive the full annual Outpatient Department (OPD) fee schedule increase factor.

b. Impact of CY 2024 OPPS/ASC Final Rule Policies

We do not anticipate that the Hospital OQR Program policies will significantly impact the number of hospitals that will receive payment reductions. In this final rule with comment period, we are finalizing to: (1) modify the COVID–19 Vaccination Coverage Among Healthcare Personnel (HCP) measure, beginning with the CY 2024 reporting period/CY 2026 payment determination; (2) modify the Cataracts: Improvement in Patient's Visual Function Within 90 Days Following Cataract Surgery measure beginning with the voluntary CY 2024 reporting period; (3) modify the Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients measure, beginning with the CY 2024 reporting period/CY 2026 payment determination.

We are finalizing with modification our proposal to adopt the Risk-Standardized Patient-Reported Outcome-Based Performance Measure (PRO–PM) Following Elective Primary Total Hip Arthroplasty (THA) and/or

Total Knee Arthroplasty (TKA) in the HOPD Setting (THA/TKA PRO–PM) with voluntary reporting beginning with the CY 2025 reporting period and mandatory reporting beginning one year later than proposed with the CY 2028 reporting period/CY 2031 payment determination.

We are finalizing with modification our proposal to adopt the Excessive Radiation Dose or Inadequate Image Quality for Diagnostic Computed Tomography (CT) in Adults (Hospital Level—Outpatient) electronic clinical quality measure (eCQM) with voluntary reporting beginning with the CY 2025 voluntary reporting period and mandatory reporting beginning 1 year later than proposed with the CY 2027 reporting period/CY 2029 payment determination.

We are not finalizing our proposals to: (1) re-adopt with modification the Hospital Outpatient Volume Data on Selected Outpatient Surgical Procedures measure; and (2) remove the Left Without Being Seen measure.

We refer readers to section XXIV.B of this final rule with comment period entitled ''Collection of Information'' for a detailed discussion of the calculations estimating the changes to the information collection burden for submitting data to the Hospital OQR Program where we state that for purposes of burden estimation, 3,350 hospitals will be considered and Table 157 where we estimate a total information collection burden increase for 3,350 OPPS hospitals of 67,842 hours at a cost of $1,536,526 annually associated with our finalized policies for the CYs 2030 reporting period/CY 2032 payment determination and subsequent years, compared to our currently approved information collection burden estimates.

In section XIV.B.2.a of this final rule with comment period, we finalized our proposal to modify the COVID–19 Vaccination Coverage Among HCP measure to utilize the term ''up to date'' in the HCP vaccination definition and update the numerator to specify the time frames within which an HCP is considered up to date with recommended COVID–19 vaccines, including booster doses. Although we anticipate this modification may require some hospitals to update information technology (IT) systems or workflow related to maintaining accurate vaccination records for HCP, we assume most hospitals are currently recording all necessary information for HCP such that this modification would not require additional information to be collected. Therefore, the financial impact of any required updates would be minimal. Finally, we do not estimate any changes to the effects previously discussed in the CY 2022 OPPS/ASC final rule with comment period for the Hospital OQR Program (86 FR 63984).

In section XIV.B.2.b of this final rule with comment period, we finalized our proposal to modify the Cataracts: Improvement in Patient's Visual Function Within 90 Days Following Cataract Surgery measure by limiting the survey instrument that can be used to administer this measure to three assessment tools: National Eye Institute Visual Function Questionnaire (NEI VFQ–25), Visual Function Index (VF–14), and VF–8R. These surveys were found to have fewer noted limitations, present the lowest administrative burden, and achieve adequate validity and reliability compared to other surveys. We understand some hospitals may be currently using one of the other surveys which would no longer be allowable for collecting data for this measure, however, we believe any costs associated with modifying clinical practices would be negligible as these surveys are all publicly available at no additional cost and are comparable survey instruments in form and manner for data collection and measure calculation to other surveys used for this measure.

In section XIV.B.3.b of this final rule with comment period, we finalized with modification our proposal to adopt the THA/TKA PRO–PM. We assume the effects on outpatient hospitals would be similar to the effects previously discussed in the FY 2023 IPPS/LTCH PPS final rule for the inpatient hospital setting under the Hospital Inpatient Quality Reporting (IQR) Program (87 FR 49492). For hospitals that would not already be collecting these data for the Hospital IQR Program, there would be some non-recurring costs associated with changes in workflow and IT systems to collect the data for the Hospital OQR Program. The extent of these costs is difficult to quantify as different hospitals may utilize different modes of data collection (such as paper-based, electronically patient-directed, or clinician-facilitated). While we assume the majority of hospitals would report data for this measure directly to CMS via the CMS-designated information system (currently, the Hospital Quality Reporting (HQR) system), we assume some hospitals may elect to submit measure data using a third-party vendor, for which there are associated costs. To determine an estimate of third-party vendor costs, we looked at the Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) measure (OMB control number 0938–098; expiration date September 30, 2024), which used an estimate of approximately $4,000 per hospital to account for these costs. This per hospital cost estimate originates from this Paperwork Reduction Act analysis performed for 2012, therefore, to account for inflation (assuming end of CY 2012 to January CY 2023), we adjust the price using the Bureau of Labor Statistics Consumer Price Index and estimate an updated cost of approximately $5,212 ($4,000 × 130.3 percent).[842]

In section XIV.B.3.c of this final rule with comment period, we finalized with modification our proposal to adopt the Excessive Radiation Dose or Inadequate Image Quality for Diagnostic CT in Adults (Hospital Level—Outpatient) eCQM. Similar to the CY 2022 OPPS/ASC final rule with comment period (86 FR 63837 through 63840), we believe that costs associated with adoption of eCQMs are multifaceted and include not only the burden associated with reporting but also the costs associated with implementing and maintaining program requirements, such as maintaining measure specifications in hospitals' electronic health record (EHR) systems for the eCQMs used in the Hospital OQR Program (83 FR 41771). For the Excessive Radiation eCQM, hospitals will be required to create a secure account through the measure developer's website and link their EHR and PACS data to the Alara Imaging Software for CMS Measure Compliance. Similar to our assumptions for the Hospital IQR Program in the FY 2024 IPPS/lTCH PPS final rule (88 FR 59431), we estimate this one-time activity will require no more than 1 hour to complete and therefore estimate a total of 3,350 hours (1 hour × 3,350 hospitals) at a cost of $174,602 (3,350 hours × $52.12) for all OPPS hospitals.

Regarding the remaining finalized proposals, we do not believe any of these policies would result in any additional economic impact beyond those discussed in section XXIV ''Collection of Information'' of this final rule with comment period.

4. Effects of Requirements for the Ambulatory Surgical Center Quality Reporting (ASCQR) Program

a. Background

In section XV of this final rule with comment period, we discuss our finalized policies affecting the ASCQR Program. Based on the most recent

[842] U.S. Bureau of Labor Statistics. Historical CPI–U data. Accessed on March 9, 2023. Available at: *https://www.bls.gov/cpi/tables/supplemental-files/historical-cpi-u-202301.pdf.*

analysis of the CY 2023 payment determination data, we found that, of the 5,375 ambulatory surgical centers (ASCs) that were actively billing Medicare, 3,733 were required to participate in the ASCQR Program and met all reporting requirements, whereas 194 did not. Of the 1,448 ASCs not required to participate in the program, 687 ASCs did so. In addition, 195 Hospitals Without Walls have returned to active ASC billing and will be eligible to participate toward CY 2024 payment determinations. On this basis, we estimate that 4,809 ASCs (3,733 + 194 + 687 + 195) will submit data for the ASCQR Program for the CY 2026 payment determination unless otherwise noted. We note that this estimate is a decrease of 248 ASCs from our estimate of 5,057 provided in the CY 2024 OPPS/ASC proposed rule (88 FR 49881) due to results from more recent data analysis regarding numbers of eligible ASCs.

b. Impact of CY 2024 OPPS/ASC Finalized Policies

In this final rule with comment period, we are finalizing our proposals to: (1) modify the COVID–19 Vaccination Coverage Among Healthcare Personnel (HCP) measure, beginning with the CY 2024 reporting period/CY 2026 payment determination; (2) modify the Cataracts: Improvement in Patient's Visual Function Within 90 Days Following Cataract Surgery measure beginning with the voluntary CY 2024 reporting period; and (3) modify the Endoscopy/Polyp Surveillance: Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients measure, beginning with the CY 2024 reporting period/CY 2026 payment determination.

We are finalizing with modification our proposal to adopt the Risk-Standardized Patient-Reported Outcome-Based Performance Measure (PRO–PM) Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA) in the ASC Setting (THA/TKAPRO–PM) with voluntary reporting beginning with the CY 2025 reporting period through the CY 2027 reporting period followed by mandatory reporting beginning one year later than proposed with the CY 2028 reporting period/CY 2031 payment determination.

We are not finalizing our proposal to re-adopt with modification the ASC Facility Volume Data on Selected ASC Surgical Procedures measure.

We refer readers to section XXIV.C of this final rule with comment period (addressing information collection requirements) for a detailed discussion of the calculations estimating the changes to the information collection burden for submitting data to the ASCQR Program and Table 163 where we estimate a total information collection burden increase for 4,089 ACSs of 302 hours at a cost of $6,670 annually associated with our finalized policies and updated burden estimates for the CY 2030 reporting period/CY 2032 payment determination and subsequent years, compared to our currently approved information collection burden estimates. We note that our burden estimate has been updated from the CY 2024 OPPS/ASC proposed rule (88 FR 49906) due to the previously discussed decrease in our estimate of ASCs submitting data for the CY 2026 payment determination as well as the decision not to finalize our proposal to re-adopt with modification the ASC Facility Volume on Selected ASC Surgical Procedures measure.

In section XV.B.4.a of this final rule with comment period, we finalized our proposal to modify the COVID–19 Vaccination Coverage Among HCP measure to utilize the term ''up to date'' in the HCP vaccination definition and update the numerator to specify the time frames within which an HCP is considered up to date with recommended COVID–19 vaccines, including booster doses. Although we anticipate this modification may require some facilities to update information technology (IT) systems or workflow related to maintaining accurate vaccination records for HCP, we assume most facilities are currently recording all necessary information for HCP such that this modification will not require additional information to be collected and, therefore, the financial impact of any required updates will be minimal. Finally, we do not estimate any changes to the effects previously discussed in the CY 2022 OPPS/ASC final rule with comment period for the ASCQR Program (86 FR 63985).

In section XV.B.4.b of this final rule with comment period, we finalized our proposal to modify the Cataracts: Improvement in Patient's Visual Function Within 90 Days Following Cataract Surgery measure by limiting the survey instrument that can be used to administer this measure to three assessment tools: NEI VFQ–25, VF–14, and VF–8R. These surveys were found to have fewer noted limitations, present the lowest administrative burden, and achieve adequate validity and reliability compared to other surveys. We understand some ASCs may be currently using one of the other surveys which will no longer be allowable for collecting data for this measure, however, we believe any costs associated with modifying clinical practices will be negligible as these surveys are all publicly available at no additional cost and are comparable survey instruments in form and manner for data collection and measure calculation to other surveys used for this measure.

In section XV.B.5.b of this final rule with comment period, we finalized with modification the adoption of the THA/TKA PRO–PM. We assume the effects on ASCs will be similar to those previously finalized for the inpatient hospital setting under the Hospital IQR Program as discussed in the FY 2023 IPPS/LTCH PPS final rule (87 FR 49492). For ASCs that are not currently collecting these data, there will be some non-recurring costs associated with changes in workflow and information systems to collect the data. The extent of these costs is difficult to quantify as different ASCs may utilize different modes of data collection (such as paper-based, electronically patient-directed, or clinician-facilitated). While we assume the majority of ASCs will report data for this measure directly to CMS via the CMS-designated information system (currently, the HQR System), we also assume some ASCs may elect to submit measure data via a third-party vendor, for which there are associated costs. To determine an estimate of third-party vendor costs, we looked at the HCAHPS measure (OMB control number 0938–0981; expiration date September 30, 2024), which used an estimate of approximately $4,000 per hospital to account for these costs. This estimate originates from 2012, therefore, to account for inflation (assuming end of CY 2012 to January CY 2023), we adjust the price using the Bureau of Labor Statistics Consumer Price Index and estimate an updated cost of approximately $5,212 ($4,000 × 130.3 percent).[843]

Regarding the remaining proposals finalized, we do not believe any of these finalized proposals would result in any additional economic impact beyond those discussed in section XXIV of this final rule with comment period, if adopted.

5. Effects of Requirements for the Rural Emergency Hospital Quality Reporting (REHQR) Program

a. Background

In section XVI of this final rule with comment period, we discuss our

[843] U.S. Bureau of Labor Statistics. Historical CPI–U data. Accessed on March 9, 2023. Available at: *https://www.bls.gov/cpi/tables/supplemental-files/historical-cpi-u-202301.pdf.*

finalized policies affecting the Rural Emergency Hospital Quality Reporting (REHQR) Program. We are finalizing the adoption of four new measures, beginning with the CY 2024 reporting period: (1) the Abdomen Computed Tomography (CT)—Use of Contrast Material measure; (2) the Median Time from ED Arrival to ED Departure for Discharged ED Patients measure; (3) the Facility 7-Day Risk-Standardized Hospital Visit Rate After Outpatient Colonoscopy measure; and (4) the Risk-Standardized Hospital Visits Within 7 Days After Hospital Outpatient Surgery measure.

We refer readers to section XXIV.D of this final rule with comment period for a detailed discussion of the calculations estimating the changes to the information collection burden for submitting data to the REHQR Program and Table 164 where we estimate a total information collection burden for 746 REHs of 9,101 hours at a cost of $474,344 annually associated with our finalized policies for the CY 2024 reporting period and subsequent years. Regarding the remaining policies we are finalizing, we do not believe any of these policies will result in any additional economic impact beyond those discussed in section XXIV of this final rule with comment period.

b. Impact of CY 2024 OPPS/ASC Finalized REHQR Program Policies

For CY 2024, we have determined there are 1,716 CAHs and rural subsection (d) hospitals with 50 or fewer beds that are eligible to convert to become an REH in the nation based on current available data. Based on our analysis of CAHs and subsection (d) hospitals participating in the Hospital OQR Program with 50 beds or less, we have estimated 746 hospitals could transition to REH status assuming that all eligible hospitals in states which have passed or amended necessary legislation enabling transition to occur as of March 2023 choose to do so. We use this number of REHs for our impact analyses knowing that more jurisdictions will pass or amend necessary legislation enabling transitions, acknowledging that the number of conversions could be less than or significantly greater than this estimate with time noting that as of October 13, 2023, 16 hospitals had converted to REH status.

As hospitals eligible to convert to REH status have been eligible to report quality measures under the Hospital OQR Program and most of these hospitals have been reporting, we do not believe any of our administrative policies will result in additional impact on these hospitals.

6. Estimated Effects of Changes to the CMHC CoPs

a. Impacts Related to Conditions of Participation: Admission, Initial Evaluation, Comprehensive Assessment, and Discharge or Transfer of the Client (§ 485.914)

Under the Medicare Program, in accordance with section 4124 of division FF of the CAA. 2023, we proposed conforming regulations text changes to establish coverage for Intensive Outpatient Services (IOP) in CMHC at § 485.914 ''Admission, initial evaluation, comprehensive assessment, and discharge or transfer of the client''. At § 485.914(a), we require that for clients who are assessed and admitted to receive partial hospitalization services, the CMHC must also meet separate requirements specified in § 485.918(f). In § 418.918(d)(2), we proposed to add IOP services to the update of the assessment no less frequently than every 30 days. We do not expect any increase in burden for this modification, nor do we expect the changes for this provision will cause any appreciable expense or anticipated savings. Therefore, we do not believe this standard would impose any additional regulatory burden.

b. Impacts Related to Conditions of Participation: Treatment Team, Person-Centered Active Treatment Plan, and Coordination of Services (§ 485.916)

We received several comments requesting that we revise the CoPs at § 485.916(a)(1) and (3) to specifically identify MFTs and MHCs as potential members of the CMHC interdisciplinary team. We have modified the language at § 485.916(a)(1) to include the MFT or MHC as providers who can lead the CMHC interdisciplinary team. The standard at § 485.916(d) requires the active treatment plan to be updated with current information from the client's comprehensive assessment and information concerning the client's progress toward achieving outcomes and goals specified in the active treatment plan. With the addition of IOP services to CMHCs, we proposed to add IOP into this requirement and to reference the specific IOP program requirements being proposed (at § 424.24(d)) in section VIII.B.2 of this final rule with comment period. We do not expect any increase in burden for these modifications, nor do we expect the changes for this provision will cause any appreciable expense or anticipated savings. Therefore, we do not believe this standard would impose any additional regulatory burden.

7. Impacts Related to Conditions of Participation: Organization, Governance, Administration of Services, Partial Hospitalization Services (§ 485.918)

The requirement at § 485.918(b) Standard: Provision of services, specifies a comprehensive list of services that a CMHC is required to furnish. This list of services that CMHCs provide corresponds directly to the Statutory requirements in (section 1861(ff)(3) of the Act). We proposed to modify the title at § 485.918, by adding intensive outpatient services after partial hospitalization services. In addition, we proposed to add IOP to the requirement at § 485.918(b)(1)(iii) for the provision of services. This change will recognize IOP, along with day treatment and PHP, as services that can be provided by a CMHC, other than in an individual's home or in an inpatient or residential setting, or psychosocial rehabilitation services.

Lastly, we proposed to add a new standard for IOP services at § 485.918(g). This requirement specifies the additional requirements a CMHC providing IOP services must meet under proposed requirements at §§ 410.2, 410.44, 410.111, and 424.24(d). We believe that modifying the title of this CoP to include IOP services, as well as adding IOP services to § 485.918(b)(1)(iii) and the new standard at § 485.918(g) will not increase the burden for this modification. In addition, we do not expect the changes to this provision will cause any appreciable amount of expense or anticipated savings, and we do not believe this standard would impose any additional regulatory burden.

8. Effects of Requirements Relating to Hospital Price Transparency

a. Background

Since the hospital price transparency regulation's (at 45 CFR part 180) effective date on January 1, 2021, hospitals have been required to make their standard charges available to the public.

As discussed in section XVIII of the CY 2024 OPPS/ASC proposed rule (88 FR 49847 through 49864), we proposed a number of changes to the hospital price transparency regulations at 45 CFR part 180 to accelerate automated aggregation of hospital standard charge information, improve the public's ability to meaningfully understand and use the data, and support and streamline CMS compliance efforts.

Specifically, we are finalizing: (1) definitions of several terms; (2) a requirement that hospitals make a good faith effort to ensure standard charge information is true, accurate, and complete, and to include a statement affirming this in the MRF; (3) new data elements that hospitals must include in their MRFs, as well a requirement that hospitals encode standard charge information in a CMS template layout; (4) a phased implementation timeline applicable to the new requirements we are finalizing in this final rule with comment period; (5) a requirement that hospitals to include a .txt file in the root folder that includes a direct link to the MRF and a link in the footer on its website that links directly to the publicly available web page that hosts the link to the MRF; and (6) improvements to our enforcement process by updating our methods to assess hospital compliance, requiring hospitals to acknowledge receipt of warning notices, working with health system officials to address noncompliance issues in one or more hospitals that are part of a health system, and publicizing more information about CMS enforcement activities related to individual hospital compliance.

b. Overall Estimated Burden on Hospitals Due to Hospital Price Transparency Requirements

The hospital price transparency policies are estimated to increase burden on hospitals (as defined at 45 CFR 180.20), as detailed in section XXIV, including a one-time cost and a modest increase in recurring costs. We believe that the benefits to the public, some of which are noted above, justify this regulatory action.

To analyze the costs of this requirement, we used a baseline that assumes the existing requirements (adopted in the CY 2020 HPT final rule and the CY 2022 OPPS/ASC final rule with comment period and codified at 45 CFR part 180) remain in place over the time horizon of this RIA. That is, the retrospective analysis and revised cost estimates for recurring administrative burden contained in section XXIV inform our baseline scenario of no further regulatory action.

As detailed in section XXIV of this final rule with comment period, commenters generally expressed concern that the cost to comply with new HPT requirements was underestimated in the proposed rule. Accordingly, we have revised our burden estimates in the section XXIV of this final rule with comment period, as well as the assumptions used in this RIA to establish a range of quantifiable effects that accounts for uncertainty. We now estimate a one-time cost for this requirement of approximately $10,587.10 per hospital, or $75,147,236 ($10,587.10 × 7,098) for all hospitals combined. This is an increase of $7,800.10 per hospital, or $55,362,696.80 for all hospitals combined compared to the cost estimates in the CY 2024 OPPS/ASC proposed rule. To estimate upper and lower bounds of potential burden, we assume hospitals may be sorted into three subsets. First, we note that the proposed MRF templates have been available since November 2022 and a number of hospitals may be already voluntarily meeting nearly all of the proposed requirements. Moreover, some hospitals may have robust information systems in which the information we are finalizing is readily available. As a result, a subset of these hospitals may only need to review this regulation to ensure that all finalized requirements are being met, which represents our low estimate. A second group of hospitals may have adopted automated processes to allow for automated processing of the data that is currently required for display, but would have to collect and encode the newly finalized data elements for the first time; for these hospitals we assume the full collection and implementation cost estimated above. A third subset of hospitals are assumed not to have adopted an automated process to collect and display the currently required data elements and would not do so for the data elements finalized in this final rule. As such, these hospitals would be making more time-consuming manual updates each year to comply with the new HPT requirements. The marginal annual burden on these hospitals would be limited to the difference in burden under this regulation compared to the existing requirements; we assume the marginal annual burden to be 20 percent of the initial implementation cost. For the low estimate we assume hospitals are distributed 10, 70, and 20 percent across the three subsets described above, respectively, and for the high estimate we assume hospitals are distributed 0, 50, and 50 percent across the three subsets. Finally, to account for uncertainty inherent in these types of estimates of administrative costs, we further adjusted our high estimate upward by 50 percent, and our low estimate downward by 50 percent. These cost range estimates are displayed in Table 174.

TABLE 174: COST RANGE ESTIMATES FOR FIRST YEAR

	Hospitals	Mean Cost / Hospital	Total Cost Burden
Primary Estimate	7,098	$10,587	$75,147,236
High Estimate	7,098	$15,881	$112,720,854
Low Estimate	7,098	$4,833	$34,305,344

In the CY 2020 HPT final rule, we estimated an on-going annual burden of 46 hours per hospital with a cost of $3,610.88 per hospital, resulting in a total national burden of 276,092 hours and total cost of $21,672,502 (in 2019 dollars). We estimated in the CY 2024 OPPS/ASC proposed rule that the requirements would increase hospital annual burden by 8 hours per year (88 FR 49892). This would result in increasing the total national annual burden to 383,292 hours (54 hours × 7,098 hospitals) and an annual national cost of $32,370,571 dollars ($4,560.52

per respondent × 7,098 hospitals). This represents a $10,698,069 ($32,370,571 − $21,672,502) increase over our previously estimated national annual burden for subsequent years.

c. Benefits of Final Policies

Although we cannot quantify the benefits of including additional data elements and encoding such data in a CMS template layout, we believe standardization requirements will help streamline the hospital's development and public's consumption of the MRF data, making it more actionable for consumers, employers, third party tool developers, and researchers.

(1) Benefits to Hospitals

We believe that requiring a standardized CMS template will assist hospitals with implementing the hospital price transparency regulation, create administrative efficiencies, and improve compliance rates, thereby supporting the overarching goal of increasing healthcare pricing competition and lowering costs. As discussed in section XXIV of this final rule with comment period, hospitals have sought clarification on how to display their standard charges, particularly payer-specific negotiated charges established by the hospital, and they have indicated that having access to a CMS-developed template could be useful for improving hospital compliance with the HPT regulation.[844] As we noted in section XXIV ''Collection of Information'' of this final rule with comment period, in response to the CY 2022 OPPS/ASC proposed rule request for information, hospitals urged CMS to be more prescriptive, requesting that CMS standardize the MRF format and contents. Additionally, researchers and experts suggest that a clear standard format would better support hospital compliance with the regulation.[845] [846] [847] [848] This sentiment was echoed in a Congressional hearing, when witnesses favored a standard template for MRF data, as a means, to support more hospitals complying with the regulation.[849]

(2) Benefits to Other Interested Parties

As discussed in the CY 2020 HPT final rule (84 FR 65538), we believe public access to hospital standard charge information is useful to the public, including patients who need to obtain items and services from a hospital, consumers of healthcare who wish to view hospital prices prior to selecting a hospital, clinicians who use the data at the point of care when making referrals, employers searching for lower cost options for healthcare coverage, and other users of the data who may develop consumer-friendly price transparency tools or perform analyses to drive value-based policy-development. Since the establishment of the HPT regulation, interested parties have reported success in using the data to realize savings. These interested parties come from various parts of the healthcare industry and range from individuals to large organizations. Individual consumers of healthcare have accessed the pricing data to shop for care and save money, and they have created tutorials to teach others how to use this information to achieve similar results.[850] Employers have used the data to reconsider their employee healthcare plans and renegotiate hospital contracts.[851] [852] [853] Innovators have identified and aggregated the data allowing consumers of healthcare to more easily make meaningful comparisons.[854] Insurers have evaluated data, identified hospitals that are cost outliers, and successfully renegotiated their contracts.[855] Researchers [856] and industry experts [857] continue to expose potential savings by publishing on the variation in negotiated charges and discounted cash prices for the same items and services both within and across hospitals. Taken together, such actions can motivate hospitals to compete on prices. Furthermore, as interested parties continue to identify new sources of value in this pricing data, the full potential is likely beyond what we previously imagined.

Numerous peer-reviewed academic studies have used the MRF data to conduct price analyses.[858] [859] [860] [861] Additionally, journalists and news outlets are now commonly conducting their own price analyses and research with HPT data obtained either directly from the hospital MRF or vendor price estimator tools. For example, some have compared prices of common medical procedures like childbirth, or hip and

[844] American Hospital Association. AHA Statement on Lowering Unaffordable Costs: Examining Transparency and Competition in Health Care. March 28, 2023 *https://www.aha.org/testimony/2023-03-28-aha-statement-lowering-unaffordable-costs-examining-transparency-and-competition-health-care.*

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[846] Fourth Semi-Annual Hospital Price Transparency Report. Patient Rights Advocate. February 14, 2023. Available at: *https://www.patientrightsadvocate.org/february-semi-annual-compliance-report-2023.*

[847] Severn, Chris. Price Transparency Hospital Data: Why Am I Seeing Different Assessments of Hospital Compliance? Turquoise Health. October 18, 2022. Available at: *https://blog.turquoise.health/hospital-compliance-assessments/.*

[848] Andrews, M. A Progress Check on Hospital Price Transparency. KFF News. March 29, 2023. Available at: *https://kffhealthnews.org/news/article/hospital-price-transparency-federal-rule-checkup-2023/?utm_campaign=KHN%3A%20Daily%20Health%20Policy%20Report&utm_medium=email&_hsmi=252217703&_hsenc=p2ANqtz-9H9illkRczNZhnmE0zhKuwC1oytcDvawv29aM7Fq7gAXWHc_9mjsY3PZkLrJX2vjIDADMQaZ0Yh01jC-NkJqQqflpFlg&utm_content=252217703&utm_source=hs_email.*

[849] ''Lowering Unaffordable Costs: Examining Transparency and Competition in Health Care.'' Congressional House Committee on Energy and Commerce, Subcommittee on Health. March 28, 2023. Available at: *https://energycommerce.house.gov/events/health-subcommittee-hearing-lowering-unaffordable-costs-examining-transparency-and-competition-in-health-care.*

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[852] Hansard, S. One County Combed Hospital Data to Slash Health Plan Costs 43 percent. Bloomberg. February 6, 2023. Available at: *https://news.bloomberglaw.com/health-law-and-business/employer-health-plan-eyes-43-savings-from-payment-data-audits.*

[853] Hansard, S. Employer, Hospital Tensions Rise Over Price Transparency. Bloomberg. August 2, 2022. Available at: *https://news.bloomberglaw.com/health-law-and-business/tensions-between-employers-hospitals-up-with-transparency-push.*

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[855] Pierce, S. Why BlueCross Blue Shield Tennessee is Renegotiating Provider Network Contracts. The Tennessean. August 18, 2022. Available at: *https://www.tennessean.com/story/opinion/2022/08/18/bluecross-blue-shield-tennessee-health-insurance-contracts/10333329002/.*

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[857] Smith, C., et al. Hospital Price Transparency Data: Case Studies for How to Use It. Milliman. May 3, 2022. Available at: *https://us.milliman.com/en/insight/hospital-price-transparency-data-case-studies-for-how-to-use-it.*

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[860] Jiang, X., et al. Price Variability for Common Radiology Services Within U.S. Hospitals. Radiology. October 18, 2022. Available at: *https://pubs.rsna.org/doi/10.1148/radiol.221815.*

[861] Mullens, C., et al. Evaluation of Prices for Surgical Procedures Within and Outside Hospital Networks in the US. JAMA. February 13, 2023. Available at: *https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2801354?utm_source=For_The_Media&utm_medium=referral&utm_campaign=ftm_links&utm_term=021323.*

knee replacements among hospitals within specific regions.[862] [863] However, lack of standardization has hampered these efforts; across these publications, authors routinely state that some price comparisons may not be fully accurate due to lack of specificity and standardization of the available hospital MRF data.

Feedback from interested parties, particularly from IT specialists, researchers, employers, and others who seek to use the standard charge information that hospitals are now required to make public, has indicated that increased standardization, including an increase in data elements that provide context for the standard charges established by hospitals, may be necessary to improve the public's understanding of the standard charges established by hospitals and the public's ability to make comparisons of standard charges from one hospital to the next.[864] [865] As discussed by industry experts, standardization will require all hospitals to provide this ''much-needed'' context in their machine-readable files, thereby enhancing innovators' ability to develop tools to help consumers of healthcare effectively compare prices.[866] Patient advocates echo the need for standardization.[867] Beyond providing additional context, a required template and data elements improves the quality and usefulness of MRF data available to consumers of the data, including researchers, innovators, employers, and payers. Studies suggest that standardization would improve the accuracy of price comparisons, the quality and usefulness of MRF data, and perhaps reduce wide variations in hospital prices.[868] [869] In the CY 2020 OPPS/ASC final rule, we cited literature regarding consumer engagement with existing price transparency interventions demonstrating that disclosing price information positively impacts consumers of healthcare by allowing them to compare prices for common procedures and shift their demand towards lower-priced options (84 FR 65600). Similarly, studies have indicated that, as these MRF analyses are becoming more widespread, consumers are able to make better use of the pricing information. Standardization would likely remove many of the existing barriers to allow innovators to create more useful data products for consumers of healthcare and reduce some of the uncertainty that currently exists about how hospitals establish standard charges for the items and services they provide.[870]

d. Consideration of Increased Burden to Hospitals Due to Hospital Price Transparency Requirements

(1) MRF Standardization and Accessibility of Hospital MRFs

Many hospitals have expressed concern over two major hurdles in implementing the HPT rule requirements: administrative burden [871] and cost,[872] [873] and we acknowledge that requiring additional data elements and use of a CMS template would impose an additional one-time burden on hospitals. However, for the reasons discussed in this rule and the CY 2024 OPPS proposed rule (88 FR 49847 through 49864), we believe that transparency is necessary to improve healthcare value, and that the proposals related to MRF standardization would assist hospitals in implementing the HPT regulations and assist numerous interested parties by creating clearer, more accurate data for purposes of price comparison and data analysis that can then be used to drive down healthcare costs. We believe these benefits justify the additional burden to hospitals. We continue to believe that improved hospital compliance with the required disclosure of this pricing information would allow providers, hospitals, insurers, employers, and patients to begin to engage each other and better utilize market forces to address the high cost of healthcare in a more widespread fashion. In addition, we continue to believe, as we noted in the CY 2020 HPT final rule (84 FR 65528), that there is a direct connection between transparency in hospital standard charge information and having more affordable healthcare and lower healthcare costs.

In the CY 2020 HPT final rule, we finalized requirements for MRF location and accessibility (45 CFR 180.50(d)). We prioritized accessibility because we want to be sure hospital standard charge information can be available for automated use by the public for creating price transparency tools, to be integrated into EHRs for purposes of clinical decision-making and referrals, or to be used by researchers and policy officials to help bring more value to healthcare (45 FR 65555). Despite the requirement for the MRF and the standard charge information contained in that file to be digitally searchable and the required naming convention, users of the MRF information, such as IT developers and innovators, continue to express concerns related to challenges in efficiently aggregating the files in an automated way.[874] [875] Some innovators and researchers noted the difficulty in locating hospital MRFs because they are posted on obscure website locations or with links redirecting to vendor

[862] Maddox, W. How Much Do Insurance Plans Pay for Childbirth in North Texas? D Magazine. April 11, 2023. Available at: *https://www.dmagazine.com/healthcare-business/2023/04/how-much-do-insurance-plans-pay-for-childbirth-in-north-texas/.*

[863] Analysis: Inconsistencies Within Hospital Price Transparency Data Make Costs Comparisons Difficult. KFF. February 10, 2023. Available at: *https://www.kff.org/health-costs/press-release/analysis-inconsistencies-within-hospital-price-transparency-data-make-cost-comparisons-difficult/.*

[864] *https://www.healthsystemtracker.org/brief/ongoing-challenges-with-hospital-price-transparency/.*

[865] *https://familiesusa.org/wp-content/uploads/2023/04/Power-of-Price-Transparency-final-4.19.23.pdf.*

[866] Turquoise Health. CMS Releases Required Schemas for Hospital MRFs. July 13, 2023. Available at: *https://blog.turquoise.health/cms-releases-required-schemas-for-hospital-mrfs/.*

[867] *https://static1.squarespace.com/static/60065b8fc8cd610112ab89a7/t/60de0380cc0972060d0354eb/1625162631437/PRA+OPPS+Recommendations+June+2021%5B3%5D.pdf.*

[868] Lo, J, et al. Ongoing Challenges with Hospital Price Transparency. Peterson-KFF Health System Tracker. February 10, 2023. Available here: *https://www.healthsystemtracker.org/brief/ongoing-challenges-with-hospital-price-transparency/#Select%20data%20for%20University%20of%20Chicago%20Hospitals.*

[869] Hospital Price Transparency: Understanding and Using the Data. National Consumer Law Center. January 25, 2023. Available at: *https://www.nclc.org/event/hospital-pricing-transparency-understanding-and-using-the-data/.*

[870] Severn, Chris. Price Transparency Impact Report Q3 2022. Turquoise Health. October 19, 2022. Available at: *https://s3.us-west-1.amazonaws.com/assets.turquoise.health/impact_reports/TQ_Price-Transparency-Impact-Report_2022_Q3.pdf.*

[871] Kacik, A. Hospital Price Transparency: Fines or Full Compliance? Modern Healthcare. January 24, 2023. Available at: *https://www.modernhealthcare.com/finance/hospital-price-transparency-compliance-cms-deaconess-sanford.*

[872] Jiang, J., et al. Price Transparency in Hospitals-Current Research and Future Directions. JAMA. January 5, 2023. Available at: *https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2800088.*

[873] Meghjani, T. Lawmakers Question Why Hospital Pricing Isn't Living Up to Transparency Goals. Bloomberg. March 28, 2023. Available at: *https://www.bloomberg.com/news/articles/2023-03-28/what-s-the-best-way-to-compare-hospital-costs-us-hearing-seeks-transparency?leadSource=uverify%20wall#xj4y7vzkg.*

[874] Kona, M. CMS Proposes Updates To The Hospital Price Transparency Rule. Health Affairs. August 3, 2023. Available at: *https://www.healthaffairs.org/content/forefront/cms-proposes-updates-hospital-price-transparency-rule.*

[875] Rhee, B. and Kalliainen, L. Ongoing Challenges With Prices Transparency in Hospital Charges for Hand Procedures. In Press. Available at: *https://www.sciencedirect.com/science/article/abs/pii/S0363502323004112.*

websites.[876] [877] We believe that ensuring the MRFs and the data contents are easily accessible to automation aligns with the intended use of the MRFs and their content. Therefore, to increase access to the MRFs, we are finalizing the requirement for hospitals to post a .txt file to the root folder of the public website. To reduce burden on hospitals, CMS intends to provide both plain language instruction and develop a .txt generator to support the proposed requirement.

As we noted in the preamble, there would be several benefits to requiring a hospital to post a .txt file to the root folder of the public website. This requirement would allow for automated tools to directly link to the MRF, as opposed to the manual location of the correct web page within the website and may make the location of the MRFs more visible to individual consumers who are manually searching for such files. We believe that the benefit of automating the identification of the MRF location would outweigh the minimal burden to maintainers of the public web page that hosts the MRF. Feedback received during public comment confirmed the burden on hospitals to post a .txt file to the root folder of a public website is minimal.

Comment: Several commenters expressed concern about the financial and administrative burden for hospitals to comply with adopting the new required hospital price transparency template and encoding additional data elements. These commenters indicated that the addition of new data elements would not be feasible within the proposed timeframe. Moreover, these commenters indicated that encoding new data, at least initially, would be a manual process for hospitals that don't already have such data formatted as separate data elements in their systems. Others noted that the desired data is not simply available from a single data source or always maintained by the chargemaster or billing vendor, often requiring a manual review and calculations for services and procedures, requiring extensive reprogramming and file manipulation to populate this information. Several commenters noted that while some hospitals may already be using the current optional CMS provided template for their MRFs, many are not, and all facilities will have to make at least some operational changes to encode the new data elements. While several commenters noted appreciation for CMS's willingness to address issues with the current format raised by hospitals and other stakeholders, they also noted the tremendous increase in cost and workforce burden. Several commenters indicated that the burden from the CY 2024 OPPS/ASC proposed rule will far outweigh the utility of this information for patients.

Response: We believe the benefits of standardization to innovators, researchers and other entities utilizing the MRFs to promote competition (through, for example, creating consumer-friendly price comparison tools) and reduce healthcare costs outweigh the operational challenges faced by hospitals. We believe standardization helps streamline the development and consumption of the MRF data, making it more actionable for employers, third party tool developers, and researchers. Researchers and experts suggest that a clear standard format would better support hospital compliance with the regulation.[878] [879] [880] [881] Additional studies have also suggested that standardization would improve the accuracy of price comparisons, the quality and usefulness of MRF data, and perhaps reduce wide variations in hospital prices.[882] [883] In response to commenters' concerns about additional burden we are finalizing an approach to phase in the implementation of the new requirements we are finalizing in this final rule with comment period. Specifically, we are finalizing that the effective date of all of the changes to the hospital price transparency regulations at 45 CFR part 180 will be January 1, 2024. However, the regulation text will specify later dates by which hospitals must be in compliance with some of these new requirements, and we will begin enforcing hospital compliance with those new requirements on the applicable later compliance date. The date by which hospitals must comply with each of the new requirements is described in Table 151A and 151B in section XVIII.B.3.c of this final rule with comment period. Finally, in response to comments, we are also increasing the estimate as discussed above.

Comment: A few commenters noted that the HPT regulations have prompted an entirely new industry of vendors and consultants eager to help hospitals comply at great expense creating financial hardship. A few commenters also noted that rural and CAH facilities will suffer further burden since they already struggle with dedicating staff and resources to complying with existing HPT regulations.

Response: As indicated in section XXIV.H of this final rule with comment period, we note that hospitals have different operational and administrative systems that impact projected burden for implementation of the CMS standard template and encoding of new data elements. To address this variability, CMS is allowing hospitals a choice of CMS template format and layout they will use, providing hospitals some flexibility to select the least burdensome format and layout to incorporate into their current MRF development process. CMS expects that most hospitals have automated processes in place to minimize the burden associated with developing their current MRFs. Furthermore, as indicated in sections XVIII.B.3.c. and XXIV.H. of this final rule with comment period (above), we have taken the burden associated with adopting the CMS standard template and encoding the new data elements into account, and we are finalizing additional time for hospitals to implement the changes to their MRFs and have revised our burden estimates.

(2) Improvements in CMS Enforcement of Hospital Price Transparency

We received several comments regarding the potential burden associated with the proposals to improve and enhance enforcement. We

[876] Zuradzki, P. How to Parse Hospital Price Transparency Files. Turquoise Health. October 3, 2022. Available at: *https://blog.turquoise.health/how-to-parse-hospital-price-transparency-files/.*

[877] Fourth Semi-Annual Hospital Price Transparency Report. Patient Rights Advocate. February 14, 2023. Available at: *https://www.patientrightsadvocate.org/february-semi-annual-compliance-report-2023.*

[878] The State of Hospital Pricing Transparency in Texas. Texas 2036. Available at: *http://pricetransparency.texas2036.org/.*

[879] Fourth Semi-Annual Hospital Price Transparency Report. Patient Rights Advocate. February 14, 2023. Available at: *https://www.patientrightsadvocate.org/february-semi-annual-compliance-report-2023.*

[880] Severn, Chris. Price Transparency Hospital Data: Why Am I Seeing Different Assessments of Hospital Compliance? Turquoise Health. October 18, 2022. Available at: *https://blog.turquoise.health/hospital-compliance-assessments/.*

[881] Andrews, M. A Progress Check on Hospital Price Transparency. KFF News. March 29, 2023. Available at: *https://kffhealthnews.org/news/article/hospital-price-transparency-federal-rule-checkup-2023/?utm_campaign=KHN%3A%20Daily%20Health%20Policy%20Report&utm_medium=email&_hsmi=252217703&_hsenc=p2ANqtz-9H9illkRczNZhnmE0zhKuwC1oytcDvawv29aM7Fq7gAXWHc_9mjsY3PZkLrJX2vjIDADMQaZ0Yh01jC-NkJqQqflpFlg&utm_content=252217703&utm_source=hs_email.*

[882] Lo, J, et al. Ongoing Challenges with Hospital Price Transparency. Peterson-KFF Health System Tracker. February 10, 2023. Available at: *https://www.healthsystemtracker.org/brief/ongoing-challenges-with-hospital-price-transparency/#Select%20data%20for%20University%20of%20Chicago%20Hospitals.*

[883] Hospital Price Transparency: Understanding and Using the Data. National Consumer Law Center. January 25, 2023. Available at: *https://www.nclc.org/event/hospital-pricing-transparency-understanding-and-using-the-data/.*

have summarized those comments and responded to them in section XVIII.C of this final rule with comment period. We do not believe that our compliance activities represent a burden to hospitals because we expect hospitals to comply with the requirements of 45 CFR part 180. We therefore have not included any costs estimates related to CMS enforcement activities.

e. Limitations of our Analysis

It would be difficult for us to conduct a detailed quantitative analysis, given the lack of studies at the national level, on the regulatory impact of making price transparency information publicly available. Additionally, implementation of the requirements is relatively new, so the impacts may not yet be realized. We also note that several other price transparency initiatives have been implemented, or are in the process of being implemented, that may make a definitive and specific analysis challenging. Since we cannot produce a detailed quantitative analysis, we have developed a qualitative discussion for this regulatory impact analysis, drawing from examples of experiences of the use of public price transparency data that has been released publicly. We have taken an approach that assesses the potential directional impact of these new requirements (that is, increasing versus decreasing health care costs, increasing, or decreasing likelihood of certain market behaviors) rather than attempting more specific estimates due to the lack of empirical data. We believe there are many benefits with this regulation, particularly to speed the ability of users of the machine-readable files to identify, ingest, analyze and draw more meaningful comparisons of the hospital standard charge data and ultimately for consumers who will be able to benefit from cost savings through employer-payer negotiations, or through direct access to hospital cost comparison data developed by innovators and researchers, allowing the ability to shop for the best value.

f. Alternatives Considered

We considered a number of alternative approaches including reducing or increasing the number of data elements or limiting the CMS template to a single format (for example, JSON).

The requirement of additional data elements is necessary to provide context to hospital standard charges and represents nearly the entire cost in our burden estimate. Thus, reducing the number of data elements would reduce hospital burden and the cost associated with gathering the data necessary to display while increasing the number of proposed data elements would increase hospital burden and the cost associated with gathering data for display. The additional required data elements are based on the FFRDC recommendations which took into consideration technical expert input (including input from hospital experts). These technical experts indicated that the data elements currently included in the sample formats found on the CMS website were necessary for providing context to hospital standard charges. They also indicated that the data elements we included in the sample formats strike a balance between burden on the hospital and benefit to the public. The alternative proposal we considered was to limit hospital choice of format for the MRF to JSON, which we concluded would be expected to increase hospital burden for hospitals that lack technical expertise, as discussed in XVIII of this final rule with comment period.

We therefore have not finalized any alternatives because we determined that the alternatives would either limit the usefulness of hospital standard charge information or increase burden for hospitals without any additional benefit to for users of MRF standard charge information.

D. Regulatory Review Cost Estimation

If regulations impose administrative costs on private entities, such as the time needed to read and interpret this final 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 the rule, we assume that the total number of unique commenters on this year's proposed rule will be the number of reviewers of this final rule with comment period. We acknowledge that this assumption may understate or overstate the costs of reviewing this final rule with comment period. It is possible that not all commenters reviewed this year's rule in detail, and it is also possible that some reviewers chose not to comment on the proposed rule. For these reasons we thought that the number of past commenters would be a fair estimate of the number of reviewers of this rule.

We welcomed any public comments on the approach in estimating the number of entities that would review the proposed rule. We did not receive any public comments specific to our solicitation. We also recognize that different types of entities are in many cases affected by mutually exclusive sections of the proposed rule, and therefore for the purposes of our estimate we assume that each reviewer reads approximately 50 percent of the rule. We sought public comments on this assumption. We did not receive any public comments specific to our solicitation.

Using the wage information from the BLS for medical and health service managers (Code 11–9111), we estimate that the cost of reviewing this rule is $123.06 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 would take approximately 8 hours for the staff to review half of this final rule with comment period. For each entity that reviews the rule, the estimated cost is $984.48 (8 hours × $123.06). Therefore, we estimate that the total cost of reviewing this regulation is $3,715,428 ($984.48 × 3,774).

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, we estimate that, many hospitals are considered small businesses either by the Small Business Administration's size standards with total revenues of $47.0 million or less in any single year or by the hospital's not-for-profit status. Most ASCs (NAICS code 621493 with a $19 million threshold) and most CMHCs (NAICS code 621498 with a $25.5 million threshold) are considered small businesses 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 *https://www.sba.gov/document/support-table-size-standards.*

Individuals and States are not included in the definition of a small entity. 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 believe that this threshold will be reached by the requirements in this final rule with comment period. Therefore, the Secretary has certified that this final rule with comment period will have a significant economic 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 final rule with comment period will increase payments to small rural hospitals by approximately 5 percent; therefore, it should have a negligible impact on approximately 554 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. In 2023, that threshold is approximately $177 million. This final rule with comment period will not impose a mandate that will result in the expenditure by State, local, and Tribal governments, in the aggregate, or by the private sector, of more than $177 million in any 1 year.

G. Federalism

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on State and local governments, preempts state law, or otherwise has federalism implications. We have examined the OPPS and ASC provisions included in this final rule with comment period 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 168 of this final rule with comment period, we estimate that OPPS payments to governmental hospitals (including State and local governmental hospitals) would increase by 2.8 percent under this final rule with comment period. 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 final rule with comment period, in conjunction with the remainder of this document, demonstrate that this final rule with comment period is consistent with the regulatory philosophy and principles identified in Executive Order 12866, the RFA, and section 1102(b) of the Act.

This final rule with comment period 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. However, as noted in section XXIII of this final rule with comment period, this rule should not have a significant effect on small rural hospitals.

H. Conclusion

The changes we are finalizing in this final rule with comment period will affect all classes of hospitals paid under the OPPS as well as 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 2024. Table 168 demonstrates the estimated distributional impact of the OPPS budget neutrality requirements that will result in a 3.2 percent increase in payments for all services paid under the OPPS in CY 2024, 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, and estimated payment for outliers, changes to the pass-through payment estimate, and changes to outlier payments. However, some classes of providers that are paid under the OPPS would experience more significant gains or losses in OPPS payments in CY 2024.

The updates we are making to the ASC payment system for CY 2024 will affect each of the approximately 6,000 ASCs currently approved for participation in the Medicare program. The effect on an individual ASC will 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 than in previous years. Table 169 demonstrates the estimated distributional impact among ASC surgical specialties of the productivity-adjusted hospital market basket update factor of 3.1 percent for CY 2024.

I. Congressional Review

This final rule with comment period 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.

Chiquita Brooks-LaSure, Administrator of the Centers for Medicare & Medicaid Services, approved this document on October 27, 2023.

List of Subjects

42 CFR Part 405

Administrative practice and procedure, Diseases, Health facilities, Health professions, Medical devices, Medicare, Reporting and recordkeeping requirements, Rural areas, X-rays.

42 CFR Part 410

Diseases, Health facilities, Health professions, Laboratories, Medicare, Reporting and recordkeeping requirements, Rural areas, X-rays.

42 CFR Part 416

Health facilities, Health professions, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 419

Hospitals, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 424

Emergency medical services, Health facilities, Health professions, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 485

Grant programs-health, Health facilities, Medicaid, Privacy, Reporting and recordkeeping requirements.

42 CFR Part 488

Administrative practice and procedure, Health facilities, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 489

Health facilities, Medicare, Reporting and recordkeeping requirements.

45 CFR Part 180

Hospitals, Reporting and recordkeeping requirements.

42 CFR Chapter IV

For the reasons set forth in the preamble, the Centers for Medicare and Medicaid Services amends 42 CFR chapter IV as set forth below:

PART 405—FEDERAL HEALTH INSURANCE FOR THE AGED AND DISABLED

■ 1. The authority citation for part 405 continues to read as follows:

Authority: 42 U.S.C. 263a, 405(a), 1302, 1320b–12, 1395x, 1395y(a), 1395ff, 1395hh, 1395kk, 1395rr, and 1395ww(k).

■ 2. Section 405.2400 is amended by adding paragraph (d) to read as follows:

§ 405.2400 Basis.

* * * * *

(d) Section 1834(y)—Payment for certain services furnished by rural health clinics.

■ 3. Section 405.2401 is amended in paragraph (b) by adding the definition of ''Intensive outpatient services'' in alphabetical order to read as follows:

§ 405.2401 Scope and definitions.

* * * * *

(b) * * *

Intensive outpatient services means a distinct and organized intensive ambulatory treatment program that offers less than 24-hour daily care other than in an individual's home or in an inpatient or residential setting and that furnishes the services as described in § 410.44 of this chapter.

* * * * *

■ 4. Section 405.2410 is amended by adding paragraph (c) to read as follows:

§ 405.2410 Application of Part B deductible and coinsurance.

* * * * *

(c) *Application of deductible and coinsurance for RHCs and FQHCs paid on the basis of the special payment rule described under § 405.2462(j).* (1) For RHCs, a coinsurance amount that does not exceed 20 percent of the payment determined under § 405.2462(j)(1); or

(2) For FQHCs, a coinsurance amount that does not exceed 20 percent of the payment determined under § 405.2462(j)(2).

■ 5. Section 405.2411 is amended by adding paragraph (a)(7) to read as follows:

§ 405.2411 Scope of benefits.

(a) * * *

(7) Intensive outpatient services when provided in accordance with section 1861(ff)(4) of the Act and § 410.44 of this chapter.

* * * * *

■ 6. Section 405.2446 is amended by adding paragraph (b)(10) to read as follows:

§ 405.2446 Scope of services.

* * * * *

(b) * * *

(10) Intensive outpatient services when provided in accordance with section 1861(ff)(4) of the Act and § 410.44 of this chapter.

* * * * *

■ 7. Section 405.2462 is amended by adding paragraph (j) to read as follows:

§ 405.2462 Payment for RHC and FQHC services.

* * * * *

(j) *Payment amount for intensive outpatient services.* An RHC is paid the payment rate determined under § 419.21(a) of this chapter for services described under § 410.44 of this chapter. There are no adjustments to this rate.

(1) If the deductible has been fully met by the beneficiary prior to the RHC service, Medicare pays eighty (80) percent of the payment amount determined under paragraph (j)(1) of this section.

(2) If the deductible has not been fully met by the beneficiary prior to the RHC service, Medicare pays eighty (80) percent of the difference between the remaining deductible and the payment amount determined under paragraph (j)(1) of this section; or

(3) If the deductible has not been fully met by the beneficiary prior to the RHC service, no payment is made to the RHC if the deductible is equal to or exceeds the payment amount determined under paragraph (j)(1) of this section.

(4) FQHCs are paid the payment rate determined under § 419.21(a) of this chapter for services described under § 410.44 of this chapter. There are no adjustments to this rate, except that grandfathered tribal FQHCs are paid pursuant to paragraph (j)(4)(ii) of this section.

(i) Medicare pays eighty (80) percent of the lesser of the FQHC's actual charge or the payment rate determined under paragraph (j)(2) of this section; or

(ii) Medicare pays eighty (80) percent of the lesser of a grandfathered tribal FQHC's actual charge or the amount described under paragraphs (f)(2) and (3) of this section.

(iii) No deductible is applicable to FQHC services.

■ 8. Section 405.2463 is amended by revising paragraphs (c)(1)(ii) and (iii) and (c)(4)(ii) to read as follows:

§ 405.2463 What constitutes a visit.

* * * * *

(c) * * *

(1) * * *

(ii) Has a medical visit and a mental health visit or intensive outpatient services on the same day; or

(iii) Has an initial preventive physical exam visit and a separate medical, mental health, or intensive outpatient services visit on the same day.

* * * * *

(4) * * *

(ii) Has a medical visit and a mental health visit or intensive outpatient services on the same day.

■ 9. Section 405.2464 is amended by adding paragraph (f) to read as follows:

§ 405.2464 Payment rate.

* * * * *

(f) *Payment for intensive outpatient services.* Payment to RHCs and FQHCs is at the rate determined under § 405.2462(j).

■ 10. Section 405.2468 is amended by adding paragraph (g) to read as follows:

§ 405.2468 Allowable costs.

* * * * *

(g) *Intensive outpatient services.* (1) For RHCs, costs associated with intensive outpatient services are not used to determine the amount of payment for RHC services under the methodology for all-inclusive rates under section 1833(a)(3) of the Act as described in § 405.2464(a).

(2) For FQHCs, costs associated with intensive outpatient services are not used to determine the amount of payment for FQHC services under the prospective payment system under section 1834(o)(2)(B) of the Act as described in § 405.2464(b).

■ 11. Section 405.2469 is amended by:

■ a. Revising paragraphs (a)(1) and (2);

■ b. Adding paragraph (a)(3);

■ c. Removing the period at the end of paragraph (b)(3) and adding ''; or'' in its place; and

■ d. Adding paragraph (b)(4).

The revisions and additions read as follows:

§ 405.2469 FQHC supplemental payments.

(a) * * *

(1) The PPS rate if the FQHC is authorized to bill under the PPS;

(2) The Medicare outpatient per visit rate as set annually by the Indian Health Service for grandfathered tribal FQHCs; or

(3) The payment rate as determined in § 405.2462(j).

(b) * * *

(4) Payments received by the FQHC from the MA plan as determined on a per visit basis and the payment rate as determined in § 405.2462(j), less any amount the FQHC may charge as described in section 1857(e)(3)(B) of the Act.

* * * * *

PART 410—SUPPLEMENTARY MEDICAL INSURANCE (SMI) BENEFITS

■ 12. The authority citation for part 410 continues to read as follows:

Authority: 42 U.S.C. 1302, 1395m, 1395hh, 1395rr, and 1395ddd.

■ 13. Section 410.2 is amended by—
■ a. In the definition of ''Community mental health center (CMHC)'', revising paragraph (3);
■ b. Adding the definition ''Intensive outpatient services'' in alphabetical order; and
■ c. Revising the definition for ''Participating''.

The revisions and addition read as follows:

§ 410.2 Definitions.

* * * * *

Community mental health center (CMHC) * * *

(3) Provides day treatment or other partial hospitalization services or intensive outpatient services, or psychosocial rehabilitation services;

* * * * *

Intensive outpatient services mean a distinct and organized intensive ambulatory treatment program that offers less than 24-hour daily care other than in an individual's home or in an inpatient or residential setting and furnishes the services as described in § 410.44. Intensive outpatient services are not required to be provided in lieu of inpatient hospitalization.

* * * * *

Participating refers to a hospital, critical access hospital (CAH), skilled nursing facility (SNF), home health agencies (HHA), comprehensive outpatient rehabilitation facility (CORF), or hospice that has in effect an agreement to participate in Medicare; or a clinic, rehabilitation agency, or public health agency that has a provider agreement to participate in Medicare but only for purposes of providing outpatient physical therapy, occupational therapy, or speech pathology services; or a CMHC that has in effect a similar agreement but only for purposes of providing partial hospitalization services and intensive outpatient services, and nonparticipating refers to a hospital, CAH, SNF, HHA, CORF, hospice, clinic, rehabilitation agency, public health agency, or CMHC that does not have in effect a provider agreement to participate in Medicare.

* * * * *

■ 14. Section 410.3 is amended by revising paragraph (a)(2) to reads as follows:

§ 410.3 Scope of benefits.

(a) * * *

(2) Services furnished by ambulatory surgical centers (ASCs), HHAs, CORFs, and partial hospitalization services and intensive outpatient services provided by CMHCs.

* * * * *

■ 15. Section 410.10 is amended by revising paragraph (c) to read as follows:

§ 410.10 Medical and other health services: Included services.

* * * * *

(c) Services and supplies, including partial hospitalization services and intensive outpatient services, that are incident to physician services and are furnished to outpatients by or under arrangements made by a hospital or a CAH.

* * * * *

■ 16. Section 410.27 is amended by revising paragraphs (a)(1)(iv)(B)(*1*), (a)(2), (e) introductory text, and (g) to read 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) * * *

(B) * * *

(*1*) 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 as specified in §§ 410.47 and 410.49, respectively. Through December 31, 2024, the presence of the physician or nonphysician practitioner for the purpose of the supervision of pulmonary rehabilitation, cardiac rehabilitation, and intensive cardiac rehabilitation services includes virtual presence through audio/video real-time communications technology (excluding audio-only); and

* * * * *

(2) In the case of partial hospitalization services or intensive outpatient services, also meet the conditions of paragraph (e) of this section.

* * * * *

(e) Medicare Part B pays for partial hospitalization services and intensive outpatient services if they are—

* * * * *

(g) For purposes of this section, *nonphysician practitioner* means a clinical psychologist, licensed clinical social worker, marriage and family therapist, mental health counselor, physician assistant, nurse practitioner, clinical nurse specialist, or certified nurse-midwife.

■ 17. Section 410.28 is amended by revising paragraph (e)(2)(iii) to read as follows:

§ 410.28 Hospital or CAH diagnostic services furnished to outpatients: Conditions.

* * * * *

(e) * * *

(2) * * *

(iii) Through December 31, 2024, the presence of the physician or nonphysician practitioner under paragraphs (e)(2)(i) and (ii) of this section includes virtual presence through audio/video real-time communications technology (excluding audio-only).

* * * * *

■ 18. Section 410.43 is amended by revising paragraphs (a)(4)(i) and (iii) and (c)(5) to read as follows:

§ 410.43 Partial hospitalization services: Conditions and exclusions.

(a) * * *

(4) * * *

(i) Individual and group therapy with physicians or psychologists or other mental health professionals (including substance use disorder professionals) to the extent authorized under State law.

* * * * *

(iii) Services of social workers, trained psychiatric nurses, and other staff trained to work with psychiatric patients (including patients with substance use disorder).

* * * * *

(c) * * *

(5) Have a mental health or substance use disorder diagnosis;

* * * * *

■ 19. Section 410.44 is added to read as follows:

§ 410.44 Intensive outpatient services: Conditions and exclusions.

(a) Intensive outpatient services are services that—

(1) Are reasonable and necessary for the diagnosis or active treatment of the individual's condition;

(2) Are reasonably expected to improve or maintain the individual's condition and functional level and to prevent relapse or hospitalization;

(3) Are furnished in accordance with a physician certification and plan of care as specified under § 424.24(d) of this chapter; and

(4) Include any of the following:

(i) Individual and group therapy with physicians or psychologists or other mental health professionals (including substance use disorder professionals) to the extent authorized under State law.

(ii) Occupational therapy requiring the skills of a qualified occupational therapist, provided by an occupational therapist, or under appropriate supervision of a qualified occupational therapist by an occupational therapy assistant as specified in part 484 of this chapter.

(iii) Services of social workers, trained psychiatric nurses, and other staff trained to work with psychiatric patients (including patients with substance use disorder).

(iv) Drugs and biologicals furnished for therapeutic purposes, subject to the limitations specified in § 410.29.

(v) Individualized activity therapies that are not primarily recreational or diversionary.

(vi) Family counseling, the primary purpose of which is treatment of the individual's condition.

(vii) Patient training and education, to the extent the training and educational activities are closely and clearly related to the individual's care and treatment.

(viii) Diagnostic services.

(b) The following services are separately covered and not paid as intensive outpatient services:

(1) Physician services that meet the requirements of § 415.102(a) of this chapter for payment on a fee schedule basis.

(2) Physician assistant services, as defined in section 1861(s)(2)(K)(i) of the Act.

(3) Nurse practitioner and clinical nurse specialist services, as defined in section 1861(s)(2)(K)(ii) of the Act.

(4) Qualified psychologist services, as defined in section 1861(ii) of the Act.

(5) Services furnished to SNF residents as defined in § 411.15(p) of this chapter.

(c) Intensive outpatient programs are intended for patients who—

(1) Require a minimum of 9 hours per week of therapeutic services as evidenced in their plan of care;

(2) Are likely to benefit from a coordinated program of services and require more than isolated sessions of outpatient treatment;

(3) Do not require 24-hour care;

(4) Have an adequate support system while not actively engaged in the program;

(5) Have a mental health or substance use disorder diagnosis;

(6) Are not judged to be dangerous to self or others; and

(7) Have the cognitive and emotional ability to participate in the active treatment process and can tolerate the intensity of the intensive outpatient program.

■ 20. Section 410.67 is amended by—

■ a. In paragraph (b), in the definition of ''Opioid use disorder treatment service,'' adding paragraph (ix);

■ b. Adding paragraph (c)(5);

■ d. Revising paragraph (d)(3);

■ e. Adding (d)(4)(i)(F); and

■ f. Revising paragraphs (d)(4)(ii) and (iii).

The revisions and additions read as follows:

§ 410.67 Medicare coverage and payment of Opioid use disorder treatment services furnished by Opioid treatment programs.

* * * * *

(b) * * *

Opioid use disorder treatment service * * *

(ix) Opioid treatment program (OTP) intensive outpatient services, which means one or more services specified in § 410.44(a)(4) when furnished by an OTP as part of a distinct and organized intensive ambulatory treatment program for the treatment of opioid use disorder (OUD) and that offers less than 24-hour daily care other than in an individual's home or in an inpatient or residential setting. OTP intensive outpatient services are reasonable and necessary for the diagnosis or active treatment of the individual's condition; are reasonably expected to improve or maintain the individual's condition and functional level and to prevent relapse or hospitalization; and are furnished in accordance with a physician or non-physician practitioner (as defined in section 1842(b)(18)(C) of the Act) certification and plan of care, as permitted by State law and scope of practice requirements, in which a physician or non-physician practitioner must certify that the individual has a need for a minimum of nine hours of services per week and requires a higher level of care intensity compared to other non-intensive outpatient OTP services. OTP intensive outpatient services do not include FDA-approved opioid agonist or antagonist medications for the treatment of OUD or opioid antagonist medications for the emergency treatment of known or suspected opioid overdose, or toxicology testing.

* * * * *

(c) * * *

(5) OTPs that provide OTP intensive outpatient services must meet the requirements set forth in § 424.24(d)(1) through (3) of this chapter related to content of certification, plan of treatment, and recertification for the purposes of furnishing OTP intensive outpatient services, except that the recertification required under § 424.24(d)(3)(ii) of this chapter may occur any time during an episode of care and any reference to a physician requirement in § 424.24(d)(1) through (3) may also be performed by a non-physician practitioner (as defined in section 1842(b)(18)(C) of the Act, as permitted by state law and scope of practice requirements.

(d) * * *

(3) At least one OUD treatment service described in paragraphs (i) through (v) of the definition of *opioid use disorder treatment service* in paragraph (b) of this section must be furnished to bill for the bundled payment for an episode of care.

(4) * * *

(i) * * *

(F) For OTP intensive outpatient services, an adjustment will be made when at least nine OTP intensive outpatient services described in paragraph (ix) of the definition of *opioid use disorder treatment service* in paragraph (b) of this section are furnished in a week. This adjustment will be based on the per diem payment rate for intensive outpatient services at hospital-based programs defined at § 410.44(c) and multiplied by a factor of three for a weekly payment adjustment.

(ii) The payment amounts for the non-drug component of the bundled payment for an episode of care, the adjustments for counseling or therapy, intake activities, periodic assessments, and OTP intensive outpatient services, and the non-drug component of the adjustment for take-home supplies of opioid antagonist medications will be geographically adjusted using the geographic adjustment factor described in § 414.26 of this chapter. For purposes of this adjustment, OUD treatment services that are furnished via an OTP mobile unit will be treated as if they were furnished at the physical location of the OTP registered with the Drug Enforcement Administration (DEA) and certified by SAMHSA.

(iii) The payment amounts for the non-drug component of the bundled payment for an episode of care, the adjustments for counseling or therapy, intake activities, periodic assessments and OTP intensive outpatient services, and the non-drug component of the adjustment for take-home supplies of opioid antagonist medications will be updated annually using the Medicare Economic Index described in § 405.504(d) of this chapter.

* * * * *

■ 21. Revise the heading to subpart E to read as follows:

Subpart E—Community Mental Health Centers (CMHCs) Providing Partial Hospitalization Services and Intensive Outpatient Services

■ 22. Section 410.111 is added to read as follows:

§ 410.111 Requirements for coverage of intensive outpatient services in CMHCs.

Medicare part B covers intensive outpatient services furnished by or under arrangements made by a CMHC if they are provided by a CMHC as defined in § 410.2 that has in effect a provider agreement under part 489 of this chapter and if the services are—

(a) Prescribed by a physician and furnished under the general supervision of a physician;

(b) Subject to certification by a physician in accordance with § 424.24(d)(1) of this chapter; and

(c) Furnished under a plan of treatment that meets the requirements of § 424.24(d)(2) of this chapter.

■ 23. Section 410.150 is amended by revising paragraph (b)(13) to read as follows:

§ 410.150 To whom payment is made.

* * * * *

(b) * * *

(13) To a community mental health center (CMHC) on the individual's behalf, for partial hospitalization services or intensive outpatient services furnished by the CMHC (or by others under arrangements made with them by the CMHC).

* * * * *

■ 24. Section 410.155 is amended by revising paragraph (b)(2)(iii) to read as follows:

§ 410.155 Outpatient mental health treatment limitation.

* * * * *

(b) * * *

(2) * * *

(iii) Partial hospitalization services or intensive outpatient services not directly provided by a physician.

* * * * *

■ 25. Section 410.173 is added to read as follows:

§ 410.173 Payment for intensive outpatient services in CMHCs: Conditions.

Medicare Part B pays for intensive outpatient services furnished in a CMHC on behalf of an individual only if the following conditions are met:

(a) The CMHC files a written request for payment on the CMS form 1450 and in the manner prescribed by CMS; and

(b) The services are furnished in accordance with the requirements described in § 410.111.

PART 416—AMBULATORY SURGICAL SERVICES

■ 26. The authority citation for part 416 continues to read as follows:

Authority: 42 U.S.C. 1302 and 1395hh.

■ 27. Section 416.171 is amended by revising paragraphs (a)(2)(iii), (iv), (vi), and (vii) and (a)(2)(viii)(B) and (C) to read as follows:

§ 416.171 Determination of payment rates for ASC services.

(a) * * *

(2) * * *

(iii) For CY 2019 through CY 2025, the update is the hospital inpatient market basket percentage increase applicable under section 1886(b)(3)(B)(iii) of the Act.

(iv) For CY 2026 and subsequent years, the update is the Consumer Price Index for All Urban Consumers (U.S. city average) as estimated by the Secretary for the 12-month period ending with the midpoint of the year involved.

* * * * *

(vi) For CY 2019 through CY 2025, the hospital inpatient market basket update determined under paragraph (a)(2)(iii) of this section is reduced by 2.0 percentage points for an ASC that fails to meet the standards for reporting of ASC quality measures as established by the Secretary for the corresponding calendar year.

(vii) For CY 2026 and subsequent years, the Consumer Price Index for All Urban Consumers update determined under paragraph (a)(2)(iv) of this section is reduced by 2.0 percentage points for an ASC that fails to meet the standards for reporting of ASC quality measures as established by the Secretary for the corresponding calendar year.

(viii) * * *

(B) For CY 2019 through CY 2025, the hospital inpatient market basket update determined under paragraph (a)(2)(iii) of this section, after application of any reduction under paragraph (a)(2)(vi) of this section, is reduced by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act.

(C) For CY 2026 and subsequent years, the Consumer Price Index for All Urban Consumers determined under paragraph (a)(2)(iv) of this section, after application of any reduction under paragraph (a)(2)(vii) of this section, is reduced by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act.

* * * * *

■ 28. Section 416.172 is amended by revising paragraph (d) to read as follows:

§ 416.172 Adjustments to national payment rates.

* * * * *

(d) *Deductibles and coinsurance.* Part B deductible and coinsurance amounts apply as specified in §§ 410.152(a) and (i)(2) and 489.30(b)(6) of this chapter.

* * * * *

■ 29. Section 416.305 is amended by revising paragraph (b)(1) to read as follows:

§ 416.305 Participation and withdrawal requirements under the ASCQR Program.

* * * * *

(b) * * *

(1) An ASC may withdraw from the ASCQR Program by submitting to CMS a withdrawal of participation form that can be found in the secure portion of the CMS-designated information system.

* * * * *

■ 30. Section 416.310 is amended by revising paragraphs (c)(1)(i) and (d)(1) to read as follows:

§ 416.310 Data collection and submission requirements under the ASCQR Program.

* * * * *

(c) * * *

(1) * * *

(i) *CMS-designated information system account for web-based measures.* ASCs, and any agents submitting data on an ASC's behalf, must maintain an account for the CMS-designated information system in order to submit quality measure data to the CMS-designated information system for all web-based measures submitted via a CMS online data submission tool. A security official is necessary to set up such an account for the CMS-designated information system for the purpose of submitting this information.

* * * * *

(d) * * *

(1) *Upon request of the ASC.* Specific requirements for submission of a request for an exception are available on the CMS website.

* * * * *

■ 31. Section 416.320 is amended by revising paragraph (b) to read as follows:

§ 416.320 Retention and removal of quality measures under the ASCQR Program.

* * * * *

(b) *Immediate measure removal.* In cases where CMS believes that the continued use of a measure as specified raises patient safety concerns, CMS will immediately remove a quality measure from the ASCQR Program and will

promptly notify ASCs and the public of the removal of the measure and the reasons for its removal through the ASCQR Program ListServ and the ASCQR Program CMS website. CMS will confirm the removal of the measure for patient safety concerns in the next ASCQR Program rulemaking.

* * * * *

■ 32. Section 416.325 is amended by revising paragraph (c) to read as follows:

§ 416.325 Measure maintenance under the ASCQR Program.

* * * * *

(c) *Non-substantive changes.* If CMS determines that a change to a measure previously adopted in the ASCQR Program is non-substantive, CMS will use a sub-regulatory process to revise the ASCQR Program Specifications Manual so that it clearly identifies the changes to that measure and provide links to where additional information on the changes can be found. When a measure undergoes sub-regulatory maintenance, CMS will provide notification of the measure specification update on the CMS website and in the ASCQR Program Specifications Manual, and will provide sufficient lead time for ASCs to implement the revisions where changes to the data collection systems would be necessary.

PART 419—PROSPECTIVE PAYMENT SYSTEMS FOR HOSPITAL OUTPATIENT DEPARTMENT SERVICES

■ 33. The authority citation for part 419 continues to read as follows:

Authority: 42 U.S.C. 1302, 1395l(t), and 1395hh.

■ 34. Section 419.20 is amended by adding paragraph (b)(5) to read as follows:

§ 419.20 Hospitals subject to the hospital outpatient prospective payment system.

* * * * *

(b) * * *

(5) A rural emergency hospital (REH).

■ 35. Section 419.21 is amended by revising paragraph (c) for read as follows:

§ 419.21 Hospital services subject to the outpatient prospective payment system.

* * * * *

(c) Partial hospitalization services and intensive outpatient services furnished by community mental health centers (CMHCs).

* * * * *

■ 36. Section 419.22 is amended by adding paragraphs (w) and (x) to read as follows:

§ 419.22 Hospital services excluded from payment under the hospital outpatient prospective payment system.

* * * * *

(w) Services of marriage and family therapists, as defined in section 1861(lll)(1) of the Act.

(x) Services of mental health counselors, as defined in section 1861(lll)(3) of the Act.

■ 37. Section 419.41 is amended by adding paragraphs (d) through (g) to read as follows:

§ 419.41 Calculation of national beneficiary copayment amounts and national Medicare program payment amounts.

* * * * *

(d) Notwithstanding paragraphs (a) through (c) of this section, for a drug or biological for which payment is not packaged into a payment for a covered outpatient department (OPD) service (or group of services) and is not a rebatable drug (as defined in section 1847A(i)(2)(A) of the Act), to calculate the program payment and copayment amounts CMS does the following:

(1) Determines the payment rate for the drug or biological for the quarter established under the methodology described by section 1842(o), section 1847A, or section 1847B of the Act, as the case may be, as calculated and adjusted by the Secretary as necessary for purposes of paragraph (14) of section 1833(t) of the Act.

(2) Subtracts from the amount determined under paragraph (d)(1) of this section the amount of the applicable Part B deductible provided under § 410.160 of this chapter.

(3) Multiples the amount determined under paragraph (d)(1) of this section (less any applicable deductible under paragraph (d)(2) of this section) by 20 percent. This is the beneficiary's copayment amount for the drug or biological.

(4) Subtracts the amount determined under paragraph (d)(3) of this section from the amount determined under paragraph (d)(1) of this section (less any applicable deductible determined under paragraph (d)(2) of this section). This amount is the preliminary program amount.

(5) Adds to the preliminary program amount determined under paragraph (d)(4) of this section the amount by which the copayment amount would have exceeded the inpatient hospital deductible for that year. This amount is the final Medicare program payment amount.

(e) In the case of a rebatable drug (as defined in section 1847A(i)(2)(A) of the Act), except if such drug does not have a copayment amount as a result of application of section 1833(t)(8)(E) of the Act, for which payment is not packaged into payment for a covered OPD service (or group of services) furnished on or after April 1, 2023, and the payment for such drug under the outpatient prospective payment system (OPPS) is the same as the amount for a calendar quarter under section 1847A(i)(3)(A)(ii)(I) of the Act, in lieu of the calculation of the copayment amount and the Medicare program payment amount otherwise applicable under paragraph (d) of this section (other than application of the limitation described in paragraph (c)(4)(i) of this section), the copayment and Medicare program payment amounts determined under §§ 410.152(m) and 489.30(b)(6) of this chapter shall apply.

(f) In the case of a qualifying biosimilar biological product (as defined in § 414.902 of this chapter) that is furnished during the applicable five-year period (as defined in § 414.902 of this chapter) for such product, the payment amount for such product with respect to such period is the amount determined in § 414.904(j)(2) of this chapter.

(g) For dates of service on or after July 1, 2024, the payment amount for a biosimilar biological product (as defined in § 414.902 of this chapter) during the initial period is the amount determined in § 414.904(e)(4)(ii) of this chapter.

■ 38. Section 419.46 is amended by revising the section heading and paragraphs (b), (c), (d)(2), (e)(1), (g)(1), and (i)(2) to read as follows:

§ 419.46 Requirements under the Hospital Outpatient Quality Reporting (OQR) Program.

* * * * *

(b) *Participation in the Hospital OQR Program.* To participate in the Hospital OQR Program, a hospital as defined in section 1886(d)(1)(B) of the Act and is paid under the OPPS must—

(1) Register on the CMS-designated information system before beginning to report data;

(2) Identify and register a CMS-designated information system security official as part of the registration process under paragraph (b)(1) of this section; and

(3) Submit at least one data element.

(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 CMS-designated information system. 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 paragraph (i) of this section 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) * * *

(2) *Submission deadlines.* Submission deadlines by measure and by data type are posted on the CMS 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 non-work 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 non-work day for Federal employees by statute or Executive order.

* * * * *

(e) * * *

(1) *Upon request by the hospital.* Specific requirements for submission of a request for an exception are available on the CMS website.

* * * * *

(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 in paragraph (b) of this section 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 CMS-designated information system, 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 paragraph (d)(2) of this section, of the affected payment year as determined using the date the request was mailed or submitted to CMS.

* * * * *

(i) * * *

(2) *Immediate measure removal.* For cases in which CMS believes that the continued use of a measure as specified raises patient safety concerns, CMS will immediately remove a quality measure from the Hospital OQR Program and will promptly notify hospitals and the public of the removal of the measure and the reasons for its removal through the Hospital OQR Program ListServ and the CMS website.

* * * * *

■ 39. Section 419.92 is amended by adding paragraphs (e) and (f) to read as follows:

§ 419.92 Payment to rural emergency hospitals.

* * * * *

(e) *Payment for Indian Health Service (IHS) or tribal REHs.* An IHS or tribal REH, as defined in paragraph (f) of this section will be paid under the outpatient hospital All-Inclusive Rate that is established and published annually by the IHS rather than the rates for REH services described in paragraph (a)(1) of this section.

(f) *IHS or tribal REHs.* An IHS or tribal REH is an REH, as defined in § 485.502 of this chapter, that is operated by the IHS or by a tribe or tribal organization with funding authorized by Title I or V of the Indian Self-Determination and Education Assistance Act (Pub. L. 93–638).

■ 40. Section 419.93 is amended by revising paragraph (a)(2) to read as follows:

§ 419.93 Payment for an off-campus provider-based department of a rural emergency hospital.

(a) * * *

(2) Services that do not meet the definition of REH services under § 419.91 that are furnished by an off-campus provider-based department of an REH are paid as described under § 419.92(c) or, if applicable, § 419.92(e).

* * * * *

■ 41. Section 419.95 is added to read as follows:

§ 419.95 Requirements under the Rural Emergency Hospital Quality Reporting (REHQR) Program.

(a) *Statutory authority.* Section 1861(kkk)(7) of the Social Security Act authorizes the Secretary to implement a quality reporting program requiring Rural Emergency Hospitals (REHs) to submit data on measures in accordance with the Secretary's requirements in this part.

(b) *Participation in the REHQR Program.* To participate in the REHQR Program, an REH as defined in section 1861(kkk)(2) of the Act must—

(1) Register on a CMS website before beginning to report data;

(2) Identify and register a security official as part of the registration process under paragraph (b)(1) of this section; and

(3) Submit data on all quality measures to CMS as specified under paragraph (c) of this section.

(c) *Submission of REHQR Program data*—(1) *General rule.* REHs that participate in the REHQR Program must submit to CMS data on measures selected under section 1861(kkk)(7)(C) of the Act in a form and manner and at a time specified by CMS. REHs sharing the same CMS Certification Number (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 a CMS 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 non-work 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 non-work day for Federal employees by statute or Executive order.

(3) *Review and corrections period.* For all quality data submitted, REHs will have a review and corrections period, which runs concurrently with the data submission period. During this timeframe, REHs can enter, review, and correct data submitted. However, after the submission deadline, these data cannot be changed.

(d) *Technical specifications and measure maintenance under the REHQR Program.* (1) CMS will update the specifications manual for measures in the REHQR Program at least every 12 months.

(2) CMS follows different procedures to update the measure specifications of a measure previously adopted under the REHQR Program based on whether the change is substantive or non-substantive. CMS will determine what constitutes a substantive versus a non-substantive change to a measure's specifications.

(i) *Substantive changes.* CMS will use rulemaking to adopt substantive updates to measures in the REHQR Program.

(ii) *Non-substantive changes.* If CMS determines that a change to a measure previously adopted in the REHQR Program is non-substantive, CMS will use a sub-regulatory process to revise the specifications manual for the REHQR Program so that it clearly identifies the change to that measure and provide links to where additional information on the change can be found. When a measure undergoes sub-regulatory maintenance, CMS will provide notification of the measure specification update on a designated website and in the specifications manual and will provide sufficient lead time for REHs to implement the revisions where changes to the data collection systems would be necessary.

(e) *Retention and removal of quality measures under the REHQR Program*—(1) *General rule for the retention of quality measures.* Quality measures

adopted for the REHQR Program measure set are retained for use, except when they are removed, suspended, or replaced as set forth in paragraphs (e)(2) and (3) of this section.

(2) *Immediate measure suspension from reporting.* In cases where CMS believes that the collection and reporting activities related to a quality measure as specified raises patient safety concerns, CMS will immediately suspend the measure from the REHQR Program and will promptly notify REHs and the public of the suspension of the measure. CMS will address the suspension and propose any permanent action regarding the measure in the next appropriate rulemaking cycle.

(3) *Measure removal, suspension, or replacement through the rulemaking process.* Unless a measure raises specific safety concerns as set forth in paragraph (e)(2) of this section, CMS will use rulemaking to remove, suspend, or replace quality measures in the REHQR Program.

(i) *Factors for consideration for removal of quality measures.* CMS will weigh whether to remove measures based on the following factors:

(A) *Factor 1.* Measure performance among REHs is so high and unvarying that meaningful distinctions and improvements in performance can no longer be made (''topped-out'' measures);

(B) *Factor 2.* Performance or improvement on a measure does not result in better patient outcomes;

(C) *Factor 3.* A measure does not align with current clinical guidelines or practice;

(D) *Factor 4.* The availability of a more broadly applicable (across settings, populations, or conditions) measure for the topic;

(E) *Factor 5.* The availability of a measure that is more proximal in time to desired patient outcomes for the particular topic;

(F) *Factor 6.* The availability of a measure that is more strongly associated with desired patient outcomes for the particular topic;

(G) *Factor 7.* Collection or public reporting of a measure leads to negative unintended consequences other than patient harm; and

(H) *Factor 8.* The costs associated with a measure outweigh the benefit of its continued use in the program.

(ii) *Criteria to determine topped-out measures.* For the purposes of the REHQR Program, a measure is considered to be topped-out under paragraph (e)(3)(i)(A) of this section when it meets both of the following criteria:

(A) Statistically indistinguishable performance at the 75th and 90th percentiles (defined as when the difference between the 75th and 90th percentiles for an REH's measure is within two times the standard error of the full data set); and

(B) A truncated coefficient of variation less than or equal to 0.10.

(iii) *Application of measure removal factors.* The benefits of removing a measure from the REHQR Program will be assessed on a case-by-case basis. Under this case-by-case approach, a measure will not be removed solely on the basis of meeting any specific factor.

(f) *Public reporting of data under the REHQR Program.* Data that an REH submits for the REHQR Program will be made publicly available on a CMS website in an easily understandable format after providing the REH an opportunity to review the data to be made public. CMS will publicly display REH data by the CCN when data are submitted under the CCNs.

(g) *Exception.* CMS may grant an exception to one or more data submission deadlines and requirements in the event of extraordinary circumstances beyond the control of the hospital, such as when an act of nature affects an entire region or locale or a systemic problem with one of CMS' data collection systems directly or indirectly affects data submission. CMS may grant an exception as follows:

(1) *Upon request by the REH.* Specific requirements for submission of a request for an exception are available on a CMS website.

(2) *At the discretion of CMS.* CMS may grant exceptions to REHs that have not requested them when CMS determines that an extraordinary circumstance has occurred.

PART 424—CONDITIONS FOR MEDICARE PAYMENT

■ 42. The authority citation for part 424 continues to read as follows:

Authority: 42 U.S.C. 1302 and 1395hh.

■ 43. Section 424.24 is amended by—
■ a. Revising paragraphs (b);
■ b. Adding paragraph (d); and
■ c. Revising paragraph (e)(1)(i).

The revisions and addition read as follows:

§ 424.24 Requirements for medical and other health services furnished by providers under Medicare Part B.

* * * * *

(b) *General rule.* Medicare Part B pays for medical and other health services furnished by providers (and not exempted under paragraph (a) of this section) only if a physician certifies the content specified in paragraph (c)(1) or (4), (d)(1), or (e)(1) of this section, as appropriate.

* * * * *

(d) *Intensive outpatient services: Content of certification and plan of treatment requirements—*

(1) *Content of certification.* (i) The individual requires such services for a minimum of 9 hours per week.

(ii) The services are or were furnished while the individual was under the care of a physician.

(iii) The services were furnished under a written plan of treatment that meets the requirements of paragraph (d)(2) of this section.

(2) *Plan of treatment requirements.* (i) The plan is an individualized plan that is established and is periodically reviewed by a physician in consultation with appropriate staff participating in the program, and that sets forth—

(A) The physician's diagnosis;

(B) The type, amount, duration, and frequency of the services; and

(C) The treatment goals under the plan.

(ii) The physician determines the frequency and duration of the services taking into account accepted norms of medical practice and a reasonable expectation of improvement in the patient's condition.

(3) *Recertification requirements*—(i) *Signature.* The physician recertification must be signed by a physician who is treating the patient and has knowledge of the patient's response to treatment.

(ii) *Timing.* Recertifications are required at intervals established by the provider, but no less frequently than every 60 days.

(iii) *Content.* The recertification must specify that the patient continues to require at least 9 hours of intensive outpatient services and describe the following:

(A) The patient's response to the therapeutic interventions provided by the intensive outpatient program.

(B) The patient's psychiatric symptoms that continue to place the patient at risk of relapse or hospitalization.

(C) Treatment goals for coordination of services to facilitate discharge from the intensive outpatient program.

(e) * * *

(1) * * *

(i) The individual requires such services for a minimum of 20 hours per week and would require inpatient psychiatric care if the partial hospitalization services were not provided.

* * * * *

PART 485—CONDITIONS OF PARTICIPATION: SPECIALIZED PROVIDERS

■ 44. The authority citation for part 485 continues to read as follows:

Authority: 42 U.S.C. 1302 and 1395(hh).

■ 45. Section 485.506 is amended by revising paragraphs (b) and (c) to read as follows:

§ 485.506 Designation and certification of REHs.

* * * * *

(b) A hospital as defined in section 1886(d)(1)(B) of the Act with not more than 50 beds located in a county (or equivalent unit of local government) that is considered rural (as defined in section 1886(d)(2)(D) of the Act); or

(c) A hospital as defined in section 1886(d)(1)(B) of the Act with not more than 50 beds that was treated as being located in a rural area that has had an active reclassification from urban to rural status as specified in § 412.103 of this chapter as of December 27, 2020.

■ 46. Section 485.900 is amended by revising paragraphs (a)(1) through (3) to read as follows:

§ 485.900 Basis and scope.

(a) * * *

(1) Section 1832(a)(2)(J) of the Act specifies that payments may be made under Medicare Part B for partial hospitalization services and intensive outpatient services furnished by a community mental health center (CMHC) as described in section 1861(ff)(3)(B) of the Act.

(2) Section 1861(ff) of the Act describes the items and services that are covered under Medicare Part B as ''partial hospitalization services'' and ''intensive outpatient services'' and the conditions under which the items and services must be provided. In addition, section 1861(ff) of the Act specifies that the entities authorized to provide partial hospitalization services and intensive outpatient services under Medicare Part B include CMHCs and defines that term.

(3) Section 1866(e)(2) of the Act specifies that a provider of services for purposes of provider agreement requirements includes a CMHC as defined in section 1861(ff)(3)(B) of the Act, but only with respect to providing partial hospitalization services and intensive outpatient services.

* * * * *

■ 47. Section 485.904 is amended by revising paragraph (b)(5) and adding paragraph (b)(12) to read as follows:

§ 485.904 Condition of participation: Personnel qualifications.

* * * * *

(b) * * *

(5) *Mental health counselor.* An individual who meets the applicable education, training, and other requirements of § 410.54 of this chapter.

* * * * *

(12) *Marriage and family therapist.* An individual who meets the applicable education, training, and other requirements of § 410.53 of this chapter

■ 48. Section 485.914 is amended by revising paragraphs (a)(2) and (d)(2) to read as follows:

§ 485.914 Condition of participation: Admission, initial evaluation, comprehensive assessment, and discharge or transfer of the client.

* * * * *

(a) * * *

(2) For clients assessed and admitted to receive partial hospitalization services and intensive outpatient services, the CMHC must also meet separate requirements as specified in § 485.918(f) and (g), as applicable.

* * * * *

(d) * * *

(2) For clients that receive partial hospitalization program (PHP) or intensive outpatient (IOP) services, the assessment must be updated no less frequently than every 30 days.

* * * * *

■ 49. Section 485.916 is amended by revising paragraphs (a)(1) and (d) to read as follows:

§ 485.916 Condition of participation: Treatment team, person-centered active treatment plan, and coordination of services.

* * * * *

(a) * * *

(1) An interdisciplinary treatment team, led by a physician, nurse practitioner (NP), physician assistant (PA), clinical nurse specialist (CNS), clinical psychologist, clinical social worker, marriage and family therapist (MFT), or mental health counselor (MHC), must provide the care and services offered by the CMHC.

* * * * *

(d) *Standard: Review of the person-centered active treatment plan.* The CMHC interdisciplinary treatment team must review, revise, and document the individualized active treatment plan as frequently as the client's condition requires, but no less frequently than every 30-calendar day. A revised active treatment plan must include information from the client's initial evaluation and comprehensive assessments, the client's progress toward outcomes and goals specified in the active treatment plan, and changes in the client's goals. The CMHC must also meet partial hospitalization program requirements specified under § 424.24(e) of this chapter or intensive outpatient service requirements as specified under § 424.24(d) of this chapter, as applicable, if such services are included in the active treatment plan.

* * * * *

■ 50. Section 485.918 is amended by:

■ a. Revising the section heading and paragraph (b)(1)(iii);

■ b. Redesignating paragraph (g) as paragraph (h); and

■ c. Adding new paragraph (g).

The revisions and addition read as follows:

§ 485.918 Condition of participation: Organization, governance, administration of services, partial hospitalization services, and intensive outpatient services.

* * * * *

(b) * * *

(1) * * *

(iii) Provides day treatment, partial hospitalization services, or intensive outpatient services, other than in an individual's home or in an inpatient or residential setting, or psychosocial rehabilitation services.

* * * * *

(g) *Standard: Intensive outpatient services.* A CMHC providing intensive outpatient services must—

(1) Provide services as defined in § 410.2 of this chapter.

(2) Provide the services and meet the requirements specified in § 410.44 of this chapter.

(3) Meet the requirements for coverage as described in § 410.111 of this chapter.

(4) Meet the content of certification and plan of treatment requirements as described in § 424.24(d) of this chapter.

* * * * *

PART 488—SURVEY, CERTIFICATION, AND ENFORCEMENT PROCEDURES

■ 51. The authority citation for part 488 continues to read as follows:

Authority: 42 U.S.C. 1302 and 1395hh.

■ 52. Section 488.2 is amended by revising the entry in table 1 for ''1832(a)(2)(J)'' to read as follows:

§ 488.2 Statutory basis.

* * * * *

TABLE 1 TO § 488.2

Section	Subject
* * * * * * *	
1832(a)(2)(J)	Requirements for partial hospitalization services and intensive outpatient services provided by CMHCs.
* * * * * * *	

PART 489—PROVIDER AGREEMENTS AND SUPPLIER APPROVAL

■ 53. The authority citation for part 489 continues to read as follows:

Authority: 42 U.S.C. 1302, 1395i–3, 1395x, 1395aa(m), 1395cc, 1395ff, and 1395hh.

■ 54. Section 489.2 is amended by revising paragraph (c)(2) to read as follows:

§ 489.2 Scope of part.

* * * * *

(c) * * *

(2) CMHCs may enter into provider agreements only to furnish partial hospitalization services and intensive outpatient services.

* * * * *

45 CFR Subtitle A

For the reasons set forth in the preamble, the Department of Health and Human Services amends 45 CFR part 180 as set forth below:

PART 180—HOSPITAL PRICE TRANSPARENCY

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

Authority: 42 U.S.C. 300gg–18, 42 U.S.C. 1302.

■ 56. Section 180.20 is amended by—

■ a. Adding definitions for ''CMS template'', ''Encode'', ''Estimated allowed amount'', and ''Machine-readable file'' in alphabetical order.

■ b. In the definition of ''Machine-readable format'', removing the second sentence.

The additions read as follows:

§ 180.20 Definitions.

* * * * *

CMS template means a CSV format or JSON schema that CMS makes available for purposes of compliance with § 180.40(a).

* * * * *

Encode means to convert hospital standard charge information into a machine-readable format that complies with § 180.50(c)(2).

Estimated allowed amount means the average dollar amount that the hospital has historically received from a third party payer for an item or service.

* * * * *

Machine-readable file means a single digital file that is in a machine-readable format.

* * * * *

■ 57. Section 180.50 is amended by—

■ a. Adding paragraph (a)(3);

■ b. Revising paragraphs (b) and (c);

■ c. In paragraph (d)(4), removing the phrase ''The digital file and standard charge information contained in that file must be'' and adding in its place the phrase ''The machine-readable file and standard charge information contained in that machine-readable file must be'';

■ d. In paragraph (d)(5):

■ i. Removing the phrase ''The file must'' and adding in its place the phrase ''The machine-readable file must''; and

■ ii. Removing the phrase ''[json|xml|csv]'' and adding in its place the phrase ''[json|csv]'';

■ e. Adding paragraph (d)(6); and

■ f. In paragraph (e), removing the second sentence.

The revisions and additions read as follows:

§ 180.50 Requirements for making public hospital standard charges for all items and services.

(a) * * *

(3) Each hospital must:

(i) Beginning January 1, 2024, make a good faith effort to ensure that the standard charge information encoded in the machine-readable file is true, accurate, and complete as of the date indicated in the machine-readable file; and

(ii) Beginning July 1, 2024, affirm in its machine-readable file that, to the best of its knowledge and belief, the hospital has included all applicable standard charge information in accordance with the requirements of this section, and that the information encoded is true, accurate, and complete as of the date indicated in the machine-readable file.

(b) *Required data elements.* (1) Prior to July 1, 2024, a hospital must include all of the following corresponding data elements in its list of standard charges, as applicable:

(i) Description of each item or service provided by the hospital.

(ii) Gross charge that applies to each individual item or service when provided in, as applicable, the hospital inpatient setting and outpatient department setting.

(iii) Payer-specific negotiated charge that applies to each item or service when provided in, as applicable, the hospital inpatient setting and outpatient department setting. Each payer-specific negotiated charge must be clearly associated with the name of the third party payer and plan.

(iv) De-identified minimum negotiated charge that applies to each item or service when provided in, as applicable, the hospital inpatient setting and outpatient department setting.

(v) De-identified maximum negotiated charge that applies to each item or service when provided in, as applicable, the hospital inpatient setting and outpatient department setting.

(vi) Discounted cash price that applies to each item or service when provided in, as applicable, the hospital inpatient setting and outpatient department setting.

(vii) Any code used by the hospital for purposes of accounting or billing for the item or service, including, but not limited to, the Current Procedural Terminology (CPT) code, the Healthcare Common Procedure Coding System (HCPCS) code, the Diagnosis Related Group (DRG), the National Drug Code (NDC), or other common payer identifier.

(2) Unless otherwise specified in this paragraph (b)(2), beginning July 1, 2024, each hospital must encode in its machine-readable file all standard charge information, as applicable, for each of the following required data elements:

(i) General data elements, including:

(A) Hospital name, license number, and location name(s) and address(es) under the single hospital license to which the list of standard charges applies. Location name(s) and address(es) must include, at minimum, all inpatient facilities and stand-alone emergency departments; and

(B) The version number of the CMS template and the date of most recent update to the standard charge

information in the machine-readable file.

(ii) Each type of standard charge as defined at § 180.20 (gross charge, discounted cash price, payer-specific negotiated charge, de-identified minimum negotiated charge, and de-identified maximum negotiated charge) and, for payer-specific negotiated charges, the following additional data elements:

(A) Payer and plan names; plan(s) may be indicated as categories (such as ''all PPO plans'') when the established payer-specific negotiated charges are applicable to each plan in the indicated category;

(B) Method used to establish the standard charge; and

(C) Whether the standard charge indicated should be interpreted by the user as a dollar amount, or if the standard charge is based on a percentage or algorithm. If the standard charge is based on a percentage or algorithm, the machine-readable file (MRF) must also describe the percentage or algorithm that determines the dollar amount for the item or service, and, beginning January 1, 2025, calculate and encode an estimated allowed amount in dollars for that item or service.

(iii) A description of the item or service that corresponds to the standard charge established by the hospital, including:

(A) A general description of the item or service;

(B) Whether the item or service is provided in connection with an inpatient admission or an outpatient department visit; and

(C) Beginning January 1, 2025, for drugs, the drug unit and type of measurement.

(iv) Coding information, including:

(A) Any code(s) used by the hospital for purposes of accounting or billing for the item or service;

(B) Corresponding code type(s). Such code types may include, but are not limited to, the CPT code, the HCPCS code, the DRG, the NDC, Revenue Center Codes (RCC), or other common payer identifier; and

(C) Beginning January 1, 2025, any modifier(s) that may change the standard charge that corresponds to a hospital item or service, including a description of the modifier and how it changes the standard charge.

(c) *Format.* (1) Prior to July 1, 2024, the information described in paragraph (b)(1) of this section must be published in a single digital file that is in a machine-readable format.

(2) Beginning July 1, 2024, the hospital's machine-readable file must conform to a CMS template layout, data specifications, and data dictionary for purposes of making public the standard charge information required under paragraph (b)(2) of this section.

(d) * * *

(6) Beginning January 1, 2024, the hospital must ensure that the public website it selects to host its machine-readable file establishes and maintains, in the form and manner specified by CMS:

(i) A .txt file in the root folder that includes:

(A) The hospital location name that corresponds to the machine-readable file;

(B) The source page URL that hosts the machine-readable file;

(C) A direct link to the machine-readable file (the machine-readable file URL); and

(D) Hospital point of contact information.

(ii) A link in the footer on its website, including but not limited to the homepage, that is labeled ''Price Transparency'' and links directly to the publicly available web page that hosts the link to the machine-readable file.

* * * * *

■ 58. Section 180.70 is amended by:

■ a. Revising paragraphs (a) heading and (a)(2)(iii).

■ b. Adding paragraphs (a)(2)(iv) and (v).

■ c. Revising paragraph (b)(1).

■ d. Adding paragraphs (c) and (d).

The additions and revisions read as follows:

§ 180.70 Monitoring and enforcement.

(a) *Monitoring and assessment.* * * *

(2) * * *

(iii) CMS audit and comprehensive review.

(iv) Requiring submission of certification by an authorized hospital official as to the accuracy and completeness of the standard charge information in the machine-readable file.

(v) Requiring submission of additional documentation as may be necessary to make a determination of hospital compliance.

(b) * * *

(1) Provide a written warning notice to the hospital of the specific violation(s). CMS will require that a hospital submit an acknowledgement of receipt of the warning notice in the form and manner, and by the deadline, specified in the notice of violation issued by CMS to the hospital.

* * * * *

(c) *Actions to address noncompliance of hospitals in health systems.* In the event CMS takes an action to address hospital noncompliance (as specified in paragraph (b) of this section) and the hospital is determined by CMS to be part of a health system, CMS may notify health system leadership of the action and may work with health system leadership to address similar deficiencies for hospitals across the health system.

(d) *Publicizing assessments, compliance actions, and outcomes.* CMS may publicize on its website information related to the following:

(1) CMS' assessment of a hospital's compliance.

(2) Any compliance action taken against a hospital, the status of such compliance action, or the outcome of such compliance action.

(3) Notifications sent to health system leadership.

§ 180.90 [Amended]

■ 59. Section 180.90 is amend in paragraph (b)(2)(ii)(C) by removing the phrase ''resulting from monitoring activities'' and adding in its place the phrase ''resulting from monitoring and assessment activities''.

Xavier Becerra,

Secretary, Department of Health and Human Services.

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Part III

Department of the Treasury

Internal Revenue Service

26 CFR Part 1
Definition of Energy Property and Rules Applicable to the Energy Credit; Proposed Rule

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[REG–132569–17]

RIN 1545–BO40

Definition of Energy Property and Rules Applicable to the Energy Credit

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice of proposed rulemaking, public hearing, and partial withdrawal of notice of proposed rulemaking.

SUMMARY: This document contains proposed regulations that would amend the regulations relating to the energy credit for the taxable year in which eligible energy property is placed in service. This document also withdraws and reproposes, for additional clarity, portions of previously proposed regulations regarding the increased energy credit amount available if prevailing wage and registered apprenticeship requirements are met. In connection with the Inflation Reduction Act of 2022, the proposed regulations would: update the types of energy property eligible for the energy credit, including additional types of energy property added by that law; clarify the application of new credit transfer rules to the energy credit recapture rules applicable to failures to satisfy the prevailing wage requirements, including notification requirements for eligible taxpayers; and include qualified interconnection costs in the basis of some lower-output energy properties. The proposed regulations would also provide additional requirements and rules generally applicable to energy property, such as rules regarding: functionally interdependent components; property that is an integral part of an energy property; application of an ''80/20 Rule'' to retrofitted energy property; dual use property; separate ownership of components of an energy property; property that could be eligible for multiple Federal income tax credits; and the election to treat qualified facilities eligible for the renewable electricity production credit instead as property eligible for the energy credit. The proposed regulations would impact taxpayers who invest in energy property eligible for the energy credit.

DATES: Written or electronic comments must be received by January 22, 2024. A public hearing on these proposed regulations is scheduled to be held on February 20, 2024, at 10 a.m. ET. Requests to speak and outlines of topics to be discussed at the public hearing must be received by January 22, 2024. If no outlines are received by January 22, 2024, the public hearing will be cancelled. Requests to attend the public hearing must be received by 5 p.m. on February 15, 2024. The public hearing will be made accessible to people with disabilities. Requests for special assistance during the hearing must be received by 5 p.m. on February 14, 2024.

ADDRESSES: Commenters are strongly encouraged to submit public comments electronically. Submit electronic submissions via the Federal eRulemaking Portal at *www.regulations.gov* (indicate IRS and REG–132569–17) by following the online instructions for submitting comments. Once submitted to the Federal eRulemaking Portal, comments cannot be edited or withdrawn. The Department of Treasury (Treasury Department) and the IRS will publish for public availability any comments submitted, whether electronically or on paper, to the IRS's public docket.

Send paper submissions to: CC:PA:LPD:PR (REG–132569–17), Room 5203, Internal Revenue Service, P.O. Box 7604, Ben Franklin Station, Washington, DC 20044.

FOR FURTHER INFORMATION CONTACT: Concerning the proposed regulations, Office of Associate Chief Counsel (Passthroughs & Special Industries) at (202) 317–6853 (not a toll-free number); concerning submissions of comments or the public hearing, Vivian Hayes, (202) 317–6901 (not toll-free number) or by email to *publichearings@irs.gov* (preferred).

SUPPLEMENTARY INFORMATION:

Background

This notice of proposed rulemaking consists of several proposed amendments to the existing Income Tax Regulations (26 CFR part 1) under section 48 of the Internal Revenue Code (Code) addressing the energy credit determined under section 48 (section 48 credit) for purposes of sections 38 and 46 of the Code (proposed regulations). This notice of proposed rulemaking also withdraws and reproposes portions of another notice of proposed rulemaking (REG–100908–23) proposing regulations under section 48 that were published in the **Federal Register** (88 FR 60018) on August 30, 2023. This notice of proposed rulemaking would also propose additional regulations under section 6418 of the Code to supplement a notice of proposed rulemaking (REG–101610–23) published in the **Federal Register** (88 FR 40496) on June 21, 2023.

Section 38 allows certain business credits against the Federal income tax imposed by chapter 1 of the Code (chapter 1). Among the credits allowed by section 38 are the investment credit determined under section 46, which includes the energy credit determined under section 48. See sections 38(b)(1) and 46(2). Section 48(a)(1) generally provides that the energy credit for any taxable year is the energy percentage of the basis of each energy property placed in service during such taxable year. For most types of energy property, eligibility for the section 48 credit and, in some cases, the amount of the section 48 credit for which energy property is eligible, are dependent upon meeting certain deadlines for beginning construction of the energy property and for placing the energy property in service.

Section 48 was originally enacted by section 2 of the Revenue Act of 1962, Public Law 87–834, (76 Stat. 960, 963) to spur economic growth by encouraging investments in various capital projects across many industries including energy, transportation, and communications. Section 48 has been amended many times since its enactment, most recently by section 13102 of Public Law 117–169, 136 Stat. 1818 (August 16, 2022), commonly known as the Inflation Reduction Act of 2022 (IRA). The IRA amended section 48 in several ways, including by making additional types of energy property eligible for the section 48 credit, providing a special rule to allow certain lower-output energy properties to include qualified interconnection costs in the basis of associated energy property, and providing an increased credit amount for energy projects that satisfy prevailing wage and apprenticeship requirements, a domestic content bonus credit amount, and an increase in credit rate for energy communities.

The current Income Tax Regulations at § 1.48–9, which provide definitions and eligibility rules for determining whether property is energy property eligible for the section 48 credit, were published on January 23, 1981 (T.D. 7765, 46 FR 7287). Those regulations were amended on July 21, 1987 (T.D. 8147, 52 FR 27336), to provide rules for dual use property, but have not been updated since 1987, before many of the current types of energy property became eligible for the section 48 credit.

Prior to proposing amendments to the existing regulations under section 48, the Treasury Department and the IRS have twice requested comments on issues to be addressed. On October 26, 2015, the Treasury Department and the

IRS published Notice 2015–70, 2015–43 I.R.B. 604, to request comments regarding statutory updates to section 48 preceding those made by the IRA. On October 24, 2022, in response to the passage of the IRA, the Treasury Department and the IRS published Notice 2022–49, 2022–43 I.R.B. 321, to request general as well as specific comments on issues arising under section 48, among other sections, that were amended or added by the IRA. After consideration of comments submitted in response to Notice 2015–70 and Notice 2022–49, and after consultation with the Department of Energy, the Treasury Department and the IRS propose the revisions to the existing regulations under section 48 contained in this notice of proposed rulemaking.

On August 30, 2023, the Treasury Department and the IRS published in the **Federal Register** (88 FR 60018) a notice of proposed rulemaking (REG–100908–23) proposing rules regarding the increased credit amount available for taxpayers satisfying prevailing wage and registered apprenticeship requirements established by the IRA (August Proposed Regulations). The August Proposed Regulations provided rules addressing the recapture under section 48(a)(10)(C) of increased credit amounts from only initially satisfying the prevailing wage requirements under section 48(a)(10)(A) and (B). Comments were requested and a public hearing has been scheduled for November 21, 2023. This notice of proposed rulemaking withdraws certain portions of the August Proposed Regulations and reproposes regulations that would provide additional guidance on the prevailing wage and apprenticeship requirements under section 48, including the statutory exception for energy projects with a maximum output of less than one megawatt (MW) and the recapture rules under section 48(a)(10)(C) related to the prevailing wage requirements.

Although this notice of proposed rulemaking withdraws certain portions of the August Proposed Regulations, the Explanation of Provisions section in the preamble to the August Proposed Regulations generally remains relevant. Therefore, to the extent not inconsistent with the Summary of Comments and Explanation of Provisions section of this preamble, the Explanation of Provisions section of the August Proposed Regulations is incorporated by reference in this notice of proposed rulemaking. This notice of proposed rulemaking does not address written comments that were submitted in response to the regulations proposed in the August Proposed Regulations. Any comments received in response to this notice of proposed rulemaking, including comments on the reproposed regulations, will be addressed in the Treasury Decision adopting these regulations as final regulations. This notice of proposed rulemaking does not extend the comment period or affect the scheduled hearing for the August Proposed Regulations.

On June 21, 2023, the Treasury Department and the IRS published in the **Federal Register** (88 FR 40496) a notice of proposed rulemaking (REG–101610–23) proposing rules concerning the election under section 6418 of the Code established by the IRA to transfer certain Federal income tax credits, including the section 48 credit (June Proposed Regulations). The June Proposed Regulations provided proposed rules addressing notification requirements and the impact of credit recapture rules under sections 50(a), 49(b), and 45Q(f)(4) of the Code in proposed § 1.6418–5. Comments were requested and a public hearing on the June Proposed Regulations was held on August 23, 2023. This document amends those June Proposed Regulations to add guidance to proposed § 1.6418–5 that describes the recapture rules relating to failing to satisfy the prevailing wage and apprenticeship requirements under section 48(a)(10) and (11), including the statutory exception for energy projects with a maximum output of less than 1 MW in section 48(a)(9)(B)(i), and the recapture rules under section 48(a)(10)(C) related to the prevailing wage requirements. This notice of proposed rulemaking does not address written comments that were submitted in response to the regulations proposed in the June Proposed Regulations. Any comments received in response to this notice of proposed rulemaking, including the amendments to the June Proposed Regulations, will be addressed in the Treasury Decision adopting these regulations as final regulations. This notice of proposed rulemaking does not otherwise extend the comment period for the June Proposed Regulations.

Summary of Comments and Explanation of Provisions

I. Requirements for Energy Property

For purposes of the section 48 credit, energy property consists of all the components of property that meet the statutory requirements for an energy property as defined by section 48. Components of an energy property are those that would be included in a unit of energy property because they are functionally interdependent (as described in proposed § 1.48–9(f)(2)(ii)) as well as property owned by the same taxpayer that is an integral part of such energy property (as described in proposed § 1.48–9(f)(3)). Additionally, components of property must not be a type of property specifically excluded from energy property (as described in proposed § 1.48–9(d)).

Section 48(a)(3)(B)–(D) provides general requirements for all types of energy property. Section 48(a)(3)(B)(i) defines energy property as property that is constructed, reconstructed, or erected by the taxpayer. Alternatively, section 48(a)(3)(B)(ii) provides that energy property can also include property which the taxpayer acquires if the original use of such property commences with the taxpayer. Section 48(a)(3)(C) provides that to be eligible as energy property, depreciation (or amortization in lieu of depreciation) must be allowable for the property. Section 48(a)(3)(D) provides that to be eligible as energy property, the property must also meet any performance and quality standards that have been prescribed by the Secretary of the Treasury or her delegate (Secretary), after consultation with the Secretary of Energy, and are in effect at the time of the taxpayer's acquisition of the property. Under section 48(a)(3), energy property does not include property that is part of a qualified facility the production from which is allowed a renewable electricity production credit determined under section 45 (section 45 credit) for the taxable year or any prior taxable year. Lastly, where section 48 provides dates by which construction of energy property must begin or when energy property must be placed in service, such energy property must meet those deadlines to be eligible for the section 48 credit at specified energy percentages. Proposed § 1.48–9(a) would provide this general overview of the definition of energy property.

A. Definitions Related to Requirements for Energy Property

Before 1990, section 48 defined the term ''section 38 property'' to include, among other types of property, energy property eligible for the section 48 credit. The Revenue Reconciliation Act of 1990, Public Law 101–508, 104 Stat. 1388 (November 5, 1990) removed the term ''section 38 property'' in amending section 48. However, section 48 is one of the credits that comprise the investment credit for any taxable year determined under section 46, which is included in section 38(b)(1) and remains subject to the general business credit rules under section 38. As a result, rules

related to ''section 38 property'' remain generally applicable to the section 48 credit. The Treasury Department and the IRS published regulations under §§ 1.48–1 and 1.48–2 to provide guidance with respect to section 38 property. Section 1.48–1 was last substantially revised on October 11, 1988 (T.D. 8233, 53 FR 39592) and § 1.48–2 was last revised on June 28, 1985 (T.D. 8031, 50 FR 26698). Although subsequent amendments to section 48 have made some of the rules provided by these regulations inapplicable, those rules continue to provide useful definitions, some of which § 1.48–9 of these proposed regulations (proposed § 1.48–9) would adopt.

1. Construction, Reconstruction, or Erection of Energy Property

Section 48(a)(3)(B)(i) defines energy property as property that is constructed, reconstructed, or erected by the taxpayer. Existing § 1.48–2(b)(1) provides that property is considered as constructed, reconstructed, or erected by the taxpayer if the work is performed for the taxpayer in accordance with the taxpayer's specifications. Proposed § 1.48–9(b)(1) would largely adopt the definition of the term ''constructed, reconstructed, or erected'' from existing § 1.48–2(b)(1) while modifying it to address energy property.

2. Acquisition and Original Use of Energy Property

Section 48(a)(3)(B)(ii) provides that energy property includes property that is acquired by the taxpayer if the original use of such property commences with the taxpayer. Existing § 1.48–2(b)(6) provides that property is deemed to be acquired when reduced to physical possession or control by the taxpayer. Proposed § 1.48–9(b)(2) would adopt the concepts from existing § 1.48–2(b)(6), and provide additional clarification that the term ''acquisition of energy property'' means a transaction by which a taxpayer obtains rights and obligations with respect to energy property, including title to the energy property under the law of the jurisdiction in which the energy property is placed in service, unless the property is possessed or controlled by the taxpayer as a lessee, and physical possession or control of the energy property. In addition, existing § 1.48–2(b)(7) defines the term ''original use'' as the first use to which the property is put, whether or not such use corresponds to the use of such property by the taxpayer. Proposed § 1.48–9(b)(3) largely would adopt the § 1.48–2(b)(7) definition of original use while modifying it to address energy property.

3. Depreciation Allowable

Section 48(a)(3)(C) requires that energy property be property with respect to which depreciation (or amortization in lieu of depreciation) is allowable, and existing § 1.48–1(b) explains when depreciation is allowable with respect to section 38 property. Specifically, § 1.48–1(b) provides that a deduction for depreciation is allowable if the property is of a character subject to the allowance for depreciation under section 167 of the Code and the basis (or cost) of the property is recovered through a method of depreciation, including, for example, the unit of production method and the retirement method as well as methods of depreciation that measure the life of the property in terms of years. Proposed § 1.48–9(b)(4)(i) generally would adopt the § 1.48–1(b) rule for determining whether depreciation is ''allowable'' under section 48, with certain modifications to update the described methods of depreciation and to make the definition specific to energy property as defined in section 48. Proposed § 1.48–9(b)(4)(i) would also clarify that the 100-percent additional first year depreciation provided by section 168(k) of the Code is considered a method of depreciation.

In addition, existing § 1.48–1(b)(3) provides language describing when depreciation is not allowable to the taxpayer for purposes of defining section 38 property. Section 1.48–1(b)(3) provides that if the cost of property is not recovered through a method of depreciation but through a deduction of the full cost in one taxable year, for purposes of § 1.48–1(b)(1) a deduction for depreciation with respect to such property is not allowable to the taxpayer. However, if an adjustment with respect to the income tax return for such taxable year requires the cost of such property to be recovered through a method of depreciation, a deduction for depreciation will be considered as allowable to the taxpayer.

Proposed § 1.48–9(b)(4)(ii) generally would adopt this rule from § 1.48–1(b)(3) to determine when depreciation is not allowable, with certain modifications to update the described methods of depreciation and to make the definition specific to energy property as defined in section 48. Proposed § 1.48–9(b)(4) would provide that if the basis or cost of energy property is not recovered through a method of depreciation but through a deduction of the full cost in one taxable year, a deduction for depreciation with respect to such property is not allowable to the taxpayer.

However, proposed § 1.48–9(b)(4)(i) would provide that if an IRS adjustment with respect to an income tax return or information return for such taxable year requires the basis or cost of such property to be recovered using a method of depreciation, including any additional first year depreciation deduction provision in the Code, a deduction for depreciation will be considered as allowable to the taxpayer.

4. Performance and Quality Standards for Energy Property

Section 48(a)(3)(D) provides that energy property is property that meets the performance and quality standards (if any) that have been prescribed by the Secretary by regulations (after consultation with the Secretary of Energy), and are in effect at the time of the acquisition of the property. Existing § 1.48–9(m)(1) provides that ''energy property must meet quality and performance standards, if any, that have been prescribed by the Secretary (after consultation with the Secretary of Energy) and are in effect at the time of acquisition.'' Proposed § 1.48–9(c)(2) would adopt this rule for performance and quality standards for energy property from § 1.48–9(m)(1).

After consultation with the Department of Energy, proposed § 1.48–9(c)(2)(ii) would provide special rules for performance and quality standards with respect to both small wind and electrochromic glass property. These clarifications are needed to ensure that the intended energy production or savings occurs.

a. Performance and Quality Standards for Small Wind Energy Property

Proposed § 1.48–9(c)(2)(ii)(A) would provide that small wind energy property must meet the performance and quality standards in effect at the time of acquisition of the small wind turbine set forth in one of the following: the American Wind Energy Association Small Wind Turbine Performance and Safety Standard 9.1–2009, or subsequent revisions (AWEA); International Electrotechnical Commission 61400–1, 61400–2, 61400–11, 61400–12, or subsequent revisions (IEC); or the ANSI/ACP 101–1–2021, the Small Wind Turbine Standard, or subsequent revisions (ACP). Proposed § 1.48–9(c)(2)(ii)(A) would also provide that certification requirements applicable to such performance and quality standards for small wind energy property are provided in guidance published in the Internal Revenue Bulletin, such as Notice 2015–4, 2015–5 I.R.B. 407, and

its successor, Notice 2015–51, 2015–31 I.R.B. 133.

b. Performance and Quality Standards for Electrochromic Glass Property

As described in part I.C.2.b of this Summary of Comments and Explanation of Provisions, electrochromic glass is incorporated into either an electrochromic window or secondary glazing product. Accordingly windows, including secondary glazings, that incorporate electrochromic glass are electrochromic glass property for purposes of the section 48 credit. Proposed § 1.48–9(c)(2)(ii)(B) would also adopt the requirement that windows that incorporate electrochromic glass must be rated in accordance with the National Fenestration Rating Council (NFRC) and would provide that secondary glazing systems must be rated in accordance with the Attachments Energy Rating Council (AERC) Rating and Certification Process, or subsequent revisions.

c. Time of Acquisition

Existing § 1.48–9(m)(2) provides that the time of acquisition for purposes of applying quality and performance standards for energy property is either (i) the date the taxpayer enters into a binding contract to acquire the property; or (ii) for property constructed, reconstructed, or erected by the taxpayer, the earlier of the date that the taxpayer begins construction, reconstruction, or erection of the property, or the date the taxpayer and another person enter into a binding contract requiring the other person to construct, reconstruct, or erect property and place the property in service for an agreed upon use. Proposed § 1.48–9(c)(2)(iii) would adopt the rule for the ''time of acquisition'' from § 1.48–9(m)(2) only for purposes of applying the performance and quality standards for energy property.

d. Binding Contract

Section 1.168(k)–2(b)(5)(iii)(A) provides the following definition of a binding contract in the context of the acquisition of qualified property for the allowance of additional first year depreciation under section 168(k) of the Code:

> A contract is binding only if it is enforceable under State law against the taxpayer or a predecessor, and does not limit damages to a specified amount (for example, by use of a liquidated damages provision). For this purpose, a contractual provision that limits damages to an amount equal to at least five percent of the total contract price will not be treated as limiting damages to a specified amount.

Proposed § 1.48–9(c)(2)(iv) would adopt this definition of the term ''binding contract'' from § 1.168(k)–2(b)(5)(iii)(A) for purposes of applying the performance and quality standards for energy property.

5. Placed in Service

Section 48(a) provides that the energy credit for any taxable year is the energy percentage of the basis of each energy property placed in service during such taxable year. As part of the regulations under section 46 for the investment credit, § 1.46–3(d)(1) provides general rules for determining when a taxpayer has placed a property in service for the section 48 credit. Property is considered placed in service in the earlier of the taxable year in which, under the taxpayer's depreciation practice, the period for depreciation with respect to such property begins; or the taxable year in which the property is placed in a condition or state of readiness and availability for a specifically assigned function, whether in a trade or business, in the production of income, in a tax-exempt activity, or in a personal activity.

Proposed § 1.48–9(b)(5) largely would adopt the general rules from § 1.46–3(d)(1) for determining whether a taxpayer has placed an energy property in service with certain modifications. As discussed previously, to be eligible for the section 48 credit, energy property must be property with respect to which depreciation (or amortization in lieu of depreciation) is allowable. Further, one requirement for determining if depreciation is allowable with respect to energy property is that the basis or cost of such energy property is recovered using a method of depreciation. Accordingly, proposed § 1.48–9(b)(5)(i) clarifies that the taxable year in which energy property is placed in service would be the earlier of the taxable year in which the period for depreciation of such property begins, or the taxable year in which the energy property is placed in a condition or state of readiness and availability for a specifically assigned function in either a trade or business or in the production of income.

In addition, section 50(b)(3) of the Code provides that tax-exempt organizations cannot determine an investment tax credit, including the section 48 credit, unless the property is used predominantly in an unrelated trade or business, so the proposed regulations do not include a rule applicable to tax-exempt use. However, section 6417(d)(2) of the Code provides that an applicable entity (as defined in section 6417(d)(1), and including a tax-exempt organization) making an elective payment election under section 6417 can determine an applicable credit (defined in section 6417(b), and including the section 48 credit) without regard to section 50(b)(3), by treating any property with respect to which the section 48 credit is determined as used in a trade or business of the applicable entity. (See the rules of proposed § 1.6417–2(c)(2) contained in the notice of proposed rulemaking (REG–101607–23) published in the **Federal Register** (88 FR 40528) on June 21, 2023.) Thus, if the rules under section 6417(d)(2) apply, the general rule adopted in proposed § 1.48–9(b)(5)(i) would apply to determine when the energy property is placed in service by an applicable entity.

Section 1.46–3(d)(3) provides that notwithstanding the provisions of § 1.46–3(d)(1), property with respect to which an election is made under § 1.48–4 to treat the lessee as having purchased such property is considered placed in service by the lessor in the taxable year in which possession is transferred to such lessee. Proposed § 1.48–9(b)(5)(ii) would adopt the special rule from § 1.46–3(d)(3) for determining when a leased property has been placed in service.

B. Property Excluded From Energy Property

Section 48(a)(5) generally provides an election to treat certain types of qualified facilities as defined in section 45(d), referred to as a ''qualified investment credit facility,'' as energy property for purposes of section 48. However, section 48(a)(5)(B) provides that no section 45 credit is allowed for any taxable year with respect to any qualified investment credit facility. Section 48(a)(5)(C) provides, in part, that the term ''qualified investment credit facility'' means any qualified facility with respect to which no section 45 credit has been allowed for which the taxpayer makes an irrevocable election. Accordingly, proposed § 1.48–9(d) would exclude from energy property any property that is part of a qualified facility with respect to which a section 45 credit is allowed for any taxable year, including any prior taxable year.

The Treasury Department and the IRS understand that energy storage technologies eligible for the section 48 credit are often co-located with qualified facilities eligible for the section 45 credit and may share power conditioning and transfer equipment. In consideration of this practice, the proposed rules would provide that power conditioning and transfer equipment that is shared by a qualified

facility (as defined in section 45(d)) and an energy property may be treated as an integral part of the section 48 energy property. Such shared property is not considered part of a qualified facility and, therefore, the sharing of such property will not impact the ability of a taxpayer to claim the section 48 credit for the energy property or the section 45 credit for the qualified facility. The Treasury Department and the IRS request comments regarding whether additional guidance is needed on this rule.

C. Types of Energy Property

Proposed § 1.48–9(e) would expand upon the definitions of energy property provided in existing § 1.48–9 to account for new technologies that were added by amendments to section 48, including by section 13102 of the IRA. Generally, the definitions of the types of energy property provided in the proposed regulations do not provide specific beginning of construction or placed in service deadlines. Taxpayers should refer to the current statutory language of section 48 for specific requirements applicable to each type of energy property with respect to any particular taxable year. The following definitions in proposed § 1.48–9(e) for the different types of energy properties were developed by the Treasury Department and the IRS in consultation with the Department of Energy.

1. Solar Energy Property

Section 48(a)(3)(A)(i) provides that energy property includes solar energy property and defines solar energy property as any property that is equipment that uses solar energy to generate electricity, to heat or cool (or provide hot water for use in) a structure, or to provide solar process heat, excepting property used to generate energy for the purposes of heating a swimming pool.

Existing § 1.48–9(d)(1) defines solar energy property as including equipment and materials (and parts related to the functioning of such equipment) that use solar energy directly to (i) generate electricity, (ii) heat or cool a building or structure, or (iii) provide hot water for use within a building or structure. Further, existing § 1.48–9(d)(3), in part, defines solar electric generation equipment as equipment that uses solar energy to generate electricity through a process that involves the transformation of sunlight into electricity through the use of such devices as solar cells or other collectors.

In response to Notice 2015–70, commenters requested that the Treasury Department and the IRS provide guidance regarding specific components that may be considered solar energy property, including in photovoltaic (PV) systems (including concentrated PV systems), non-PV concentrated solar power systems (passive solar), solar process, and thermal systems. Several commenters requested that the regulations explicitly list certain types of technologies as solar energy property, such as integrated thermoplastic roofing and racking systems. Other commenters requested that the regulations simply define solar energy property to include common components such as controllers to manage use of solar energy, mounting structures, energy storage technology, power conditioning equipment, and step-up transformers.

Proposed § 1.48–9(e)(1)(i) would depart from the existing definition of solar energy property at § 1.48–9(d)(1) by adopting a modified version of the current statutory definition, which provides that solar energy property is equipment that uses solar energy to generate electricity, to heat or cool a structure, or to provide solar process heat, and parts related to the functioning of such equipment. Proposed § 1.48–9(e)(1)(ii) would define the term ''solar electric generation equipment'' as equipment that converts sunlight into electricity through the use of devices such as solar cells or other collectors, while adopting the current statutory exclusion for any property used to generate energy for the purposes of heating a swimming pool. The proposed regulations would eliminate the exclusion for passive solar in existing § 1.48–9(d)(2) because section 48 does not distinguish between passive and active solar energy systems. Finally, the proposed regulations would apply the functional interdependence test as described in part I.D.2 of this Summary of Comments and Explanation of Provisions to determine whether components are included as part of solar energy property.

Existing § 1.48–9(d)(7) provides that solar energy property does not include equipment that uses solar energy to generate steam at high temperatures for use in industrial or commercial processes (solar process heat). This definition conflicts with section 48(a)(3)(A)(i). Accordingly, the proposed regulations would adopt the statutory language by explicitly including solar process heat within the definition of the term ''solar energy property.'' After consultation with the Department of Energy, proposed § 1.48–9(e)(1)(iii) would define ''solar process heat equipment'' as equipment that uses solar energy to generate heat for use in industrial or commercial processes.

2. Fiber-Optic Solar Energy Property and Electrochromic Glass Property

a. Fiber-Optic Solar Energy Property

Section 48(a)(3)(A)(ii) provides that energy property includes equipment that uses solar energy to illuminate the inside of a structure using fiber-optic distributed sunlight. The Treasury Department and the IRS received no comments in response to Notice 2022–49 regarding fiber-optic solar energy property. Accordingly, proposed § 1.48–9(e)(2)(i) would adopt the statutory definition of fiber-optic solar energy property. Additionally, the proposed regulations would apply the functional interdependence test as described in part I.D.2 of this Summary of Comments and Explanation of Provisions to determine whether components are included as part of fiber-optic solar energy property.

b. Electrochromic Glass Property

Section 48(a)(3)(A)(ii) was modified by the IRA to add electrochromic glass property as a type of energy property. That provision defines electrochromic glass property as equipment that uses electricity to change its light transmittance properties in order to heat or cool a structure. The Treasury Department and IRS consulted with the Department of Energy to determine the types of property eligible as electrochromic glass property. Accordingly, § 1.48–9(e)(2)(ii) would provide that there are only two types of electrochromic glass property: (i) electrochromic glass incorporated into a full window that is installed directly into a building or (ii) electrochromic glass incorporated into a secondary window (known as secondary glazing) that is installed on top of an existing window. For each type of electrochromic glass property, there is a separate control package consisting of electronics, power supply, sensors, and software necessary to control the operations of the electrochromic glass property. Thus, electrochromic glass property is not only comprised of electrochromic glass but also the relevant window or secondary glazing property that incorporates the electrochromic glass property. Therefore, in addition to the electronic controls package that includes the power electronics, sensors, wires, and software systems, the electrochromic window or secondary glazing also includes the electrochromic glass coating and the balance of window and installation components including glass, flashing, framing, and sealants, as applicable, to the type of electrochromic glass property.

In response to Notice 2022–49, several commenters provided input on the definition of electrochromic glass property. Several commenters requested a narrow definition. Other commenters suggested adopting a broader definition of electrochromic glass property. One commenter stated that interpretations of the terms ''electrochromic glass'' or ''dynamic glass'' should be expanded to include any material or technology that meets or exceeds the performance criteria for such components established by the most recent Energy Star or International Energy Conservation Code (IECC) standards in effect at the time such component is placed in service.

In response to the comments and after consultation with the Department of Energy, the proposed regulations would clarify the definition of electrochromic glass property. Proposed § 1.48–9(e)(2)(ii) would adopt the statutory definition of electrochromic glass property while providing that light transmittance properties include both visible light and near infrared light. Additionally, as mentioned previously, proposed § 1.48–9(c)(2)(ii)(B) would adopt the performance and quality standards that new electrochromic windows must be rated in accordance with the NFRC and secondary glazing systems must be rated in accordance with the AERC Rating and Certification Process, or subsequent revisions. The application of these performance and quality standards are needed to ensure that the intended energy savings occurs from the installation of electrochromic glass property.

The Treasury Department and the IRS received comments requesting guidance concerning the eligible components of electrochromic glass property. Similar to the other energy properties, the proposed regulations would apply the functional interdependence test as described in part I.D.2 of this Summary of Comments and Explanation of Provisions to determine whether components are included as part of electrochromic glass property. This approach provides a technology-neutral way to determine what is considered included in the energy property that is broad enough to encompass technological changes. In the case of electrochromic glass property, for example, an electrochromic glass system includes the full controls package, the electrochromic glass coating, and the balance of window and installation components including glass, flashing, framing, and sealants.

3. Geothermal Energy Property

Section 48(a)(3)(A)(iii) provides that energy property includes geothermal property, and defines geothermal property as equipment used to produce, distribute, or use energy derived from a geothermal deposit (within the meaning of section 613(e)(2) of the Code), but only, in the case of electricity generated by geothermal power, up to (but not including) the electrical transmission stage.

Existing § 1.48–9(c)(10)(i) defines ''geothermal equipment'' as equipment that produces, distributes, or uses energy derived from a geothermal deposit. Existing § 1.48–9(c)(10) generally provides that geothermal property includes production and distribution equipment. Proposed § 1.48–9(e)(3)(i) would adopt this definitional framework by providing that geothermal energy property is equipment used to produce, distribute, or use energy derived from a geothermal deposit (within the meaning of section 613(e)(2)), and includes production equipment (as defined in proposed § 1.48–9(e)(3)(ii)) and distribution equipment (as defined in proposed § 1.48–9(e)(3)(iii)).

Proposed § 1.48–9(e)(3)(ii) would adopt a modified definition of production equipment from existing § 1.48–9(c)(10)(ii) in three respects. First, proposed § 1.48–9(e)(3)(ii) would provide, in part, that production equipment includes equipment necessary to bring geothermal energy from the subterranean deposit to the surface. Second, while existing § 1.48–9(c)(10)(ii) provides that reinjection wells required for production may qualify as production equipment, proposed § 1.48–9(e)(3)(ii) would expand the types of wells that may qualify as production equipment to production, injection, and monitoring wells. Third, proposed § 1.48–9(e)(3)(ii) would also include the electricity generating equipment as production equipment for those projects that convert geothermal energy to electricity.

Proposed § 1.48–9(e)(3)(iii) would adopt a modified definition of distribution equipment from existing § 1.48–9(c)(10)(iii). The existing regulations provide that distribution equipment includes components of a heating system, such as pipes and ductwork that distribute the energy derived from the geothermal deposit within a building. Proposed § 1.48–9(e)(3)(iii) would also add components of a building's heating or cooling system as distribution equipment. The proposed regulations would apply the functional interdependence test as described in part I.D.2 of this Summary of Comments and Explanation of Provisions to determine whether components are included as part of geothermal energy property.

In response to Notice 2015–70, one commenter requested that the regulations be modified to include as credit eligible costs incurred to drill failed or non-producing wells, and in some scenarios, for the margin or contingency that a subsidiary contractor requires to be paid to perform under an engineering, procurement, and construction (EPC) contract. While the proposed regulation would expand the types of wells that may be considered production equipment, it would not specifically include costs incurred to drill failed or non-producing wells. In many cases costs incurred to drill failed or non-producing geothermal wells are already recoverable through intangible drilling costs under § 1.612–5. It is also unclear whether the margin or contingency that a subsidiary contractor requires to be paid to perform under an EPC contract can be recovered by a taxpayer. However, if such costs are recoverable, such recovery would likely occur through capitalizing the costs to the underlying mineral interest and claiming depletion deductions under section 613(e). Therefore, the Treasury Department and the IRS have determined that these costs cannot be included in the basis of the geothermal energy property for purposes of calculating the section 48 credit.

4. Qualified Fuel Cell Property

Section 48(a)(3)(A)(iv) provides that energy property includes qualified fuel cell property. As modified by the IRA, section 48(c)(1) defines ''qualified fuel cell property'' as a fuel cell power plant that has a nameplate capacity of at least 0.5 kilowatt (kW) (1 kW in the case of a fuel cell power plant with a linear generator assembly) of electricity using an electrochemical process or electromechanical process and an electricity-only generation efficiency greater than 30 percent. Electricity-only generation efficiency may be calculated by dividing the heat rate of the fuel cell (for example, kilowatt-hours (kWh) electricity produced per kilogram (kg) of fuel consumed) by the higher heating value of the fuel (for example, kWh per kg). Section 48(c)(1)(C) defines the term ''fuel cell power plant'' as an integrated system comprised of a fuel cell stack assembly, or linear generator assembly, and associated balance of plant components that converts a fuel into electricity using electrochemical or electromechanical means.

The Treasury Department and the IRS received few comments regarding qualified fuel cell property in response to Notice 2022–49. As discussed, the

proposed regulations are intended to provide a technology-neutral way to determine what is included in energy property that is broad enough to encompass technological changes and do not include rules for a particular type of product. As a result, proposed § 1.48–9(e)(4) would adopt the statutory definition of qualified fuel cell property. The proposed regulations would also apply the functional interdependence test as described in part I.D.2 of this Summary of Comments and Explanation of Provisions to determine whether components are included as part of qualified fuel property.

5. Qualified Microturbine Property

Section 48(a)(3)(A)(iv) provides that energy property includes qualified microturbine property. Section 48(c)(2) defines ''qualified microturbine property'' as a stationary microturbine power plant that has a nameplate capacity of less than 2,000 kW and an electricity-only generation efficiency of not less than 26 percent at International Standard Organization conditions. Section 48(c)(2)(C) provides that a ''stationary microturbine power plant'' is an integrated system comprised of a gas turbine engine, a combustor, a recuperator or regenerator, a generator or alternator, and associated balance of plant components that convert a fuel into electricity and thermal energy. A stationary microturbine power plant also includes all secondary components located between the existing infrastructure for fuel delivery and the existing infrastructure for power distribution, including equipment and controls for meeting relevant power standards, such as voltage, frequency, and power factors.

The Treasury Department and the IRS received no comments regarding qualified microturbine property in response to the request for comment published in Notice 2022–49. Therefore, proposed § 1.48–9(e)(5) would adopt the statutory definition of qualified microturbine property. The proposed regulations would also apply the functional interdependence test as described in part I.D.2 of this Summary of Comments and Explanation of Provisions to determine whether components are included as part of qualified microturbine property.

6. Combined Heat and Power System Property

Section 48(a)(3)(A)(v) includes combined heat and power system (CHP) property as a type of energy property. Section 48(c)(3)(A) defines CHP property as property comprising a system that uses the same energy source for the simultaneous or sequential generation of electrical power, mechanical shaft power, or both, in combination with the generation of steam or other forms of useful thermal energy (including heating and cooling applications). Section 48(c)(3)(A) further provides, in part, that a CHP property must produce at least 20 percent of its total useful energy in the form of thermal energy that is not used to produce electrical or mechanical power (or combination thereof), and at least 20 percent of its total useful energy in the form of electrical or mechanical power (or combination thereof), and that the energy efficiency percentage of the system must exceed 60 percent.

Section 48(c)(3)(B) provides that the credit for CHP property is reduced to the extent that a CHP property has an electrical or mechanical capacity in excess of applicable limits. Subject to the exception for CHP property that uses closed or open-loop biomass as feedstock, CHP property with capacity in excess of the applicable capacity limit (15 MW or a mechanical capacity of more than 20,000 horsepower or an equivalent combination of electrical and mechanical energy capacities) is eligible for only a fraction of the otherwise allowable section 48 credit. The fraction is equal to the applicable capacity limit divided by the capacity of the CHP property. However, CHP property with a capacity in excess of 50 MW or a mechanical energy capacity in excess of 67,000 horsepower or an equivalent combination of electrical and mechanical energy capacities does not qualify for the section 48 credit.

Section 48(c)(3)(C) provides that the energy efficiency percentage of a CHP property is the fraction (1) the numerator of which is the total useful electrical, thermal, and mechanical power produced by the system at normal operating rates, and expected to be consumed in its normal application, and (2) the denominator of which is the lower heating value of the fuel sources for the system. The energy efficiency percentage and the percentages under section 48(c)(3)(A)(ii) are determined on a British thermal unit (Btu) basis. Section 48(c)(3)(C)(iii) specifically provides that the term ''combined heat and power system property'' does not include property used to transport the energy source to the facility or to distribute energy produced by the facility.

Additionally, section 48(c)(3)(D) provides that a CHP property with a fuel source that is at least 90 percent from closed or open-loop biomass that would otherwise qualify for the section 48 credit but for the failure to meet the efficiency standard is eligible for a credit reduced in proportion to the degree to which the system fails to meet the efficiency standard. For example, a system that would otherwise be required to meet the 60-percent efficiency standard, but which only achieves 30-percent efficiency, would be permitted to claim a credit equal to one-half of the otherwise allowable credit (that is, a five percent credit).

In response to Notice 2015–70, several commenters requested that the definition of CHP property be modified by relaxing certain requirements. Specifically, commenters requested that the definition of CHP property be modified by eliminating or reducing the requirement that a facility produce at least 20 percent of its total useful energy in the form of electrical or mechanical power (or combination thereof). This modification would allow waste heat to power (WHP) property, which uses waste heat from industrial processes to generate electricity, to qualify as CHP property despite its inability to meet certain statutory requirements. Since the comments to Notice 2015–70 were received, Congress amended section 48 by adding waste energy recovery property (WERP) as a type of energy property in the Consolidated Appropriations Act, 2021, Public Law 116–260, 134 Stat. 1182 (Dec. 27, 2020). Additional information on requirements for WERP is provided in part I.C.9 of this Summary of Comments and Explanation of Provisions.

Proposed § 1.48–9(e)(6)(i) would adopt a simplified version of the statutory definition of CHP property. Additionally, proposed § 1.48–9(e)(6)(ii) would provide that CHP property does not include property used to transport the energy source to the generating facility or to distribute energy produced by the facility. The proposed regulations would also apply the functional interdependence test as described in part I.D.2 of this Summary of Comments and Explanation of Provisions to determine whether components are included as part of CHP property.

7. Qualified Small Wind Energy Property

Section 48(a)(3)(A)(vi) provides that energy property includes qualified small wind energy property. Section 48(c)(4) defines qualified small wind energy property as property using a qualifying small wind turbine (which has a nameplate capacity of not more than 100 kW) to generate electricity. The Treasury Department and the IRS received no comments regarding qualified small wind energy property in response to Notice 2015–70.

Accordingly, proposed § 1.48–9(e)(7) would adopt the statutory definition of qualified small wind energy property. The proposed regulations would apply the functional interdependence test as described in part I.D.2 of this Summary of Comments and Explanation of Provisions to determine whether components are included as part of qualified small wind energy property.

8. Geothermal Heat Pump Equipment

Section 48(a)(3)(A)(vii) provides that energy property includes geothermal heat pump equipment. The statute provides, in part, that geothermal heat pump equipment is equipment that uses the ground or ground water as a thermal energy source to heat a structure or as a thermal energy sink to cool a structure. The Treasury Department and the IRS received no comments regarding geothermal heat pump equipment in response to Notice 2015–70. As a result, proposed § 1.48–9(e)(8) would adopt the statutory definition of qualified geothermal heat pump equipment while providing the modification that in addition to the ground and ground water, other underground working fluids may be used as a thermal energy source or as a thermal energy sink. The proposed regulations would apply the functional interdependence test as described in part I.D.2 of this Summary of Comments and Explanation of Provisions to determine whether components are included as part of geothermal heat pump equipment.

Additionally, while section 48(a)(3)(A)(vii) does not specify energy distribution equipment and components of a building's heating and/or cooling system as components of geothermal heat pump equipment, such equipment may be integral to the function of the geothermal heat pump equipment, to heat or cool a structure. Thus, energy distribution equipment may be considered geothermal heat pump equipment. See section I.E.3. of this preamble for a discussion of an integral part of energy property.

9. Waste Energy Recovery Property (WERP)

Section 48(a)(3)(A)(viii) provides that energy property includes WERP. Section 48(c)(5)(A) defines WERP as property (with a capacity not in excess of 50 MW) that generates electricity solely from heat from buildings or equipment if the primary purpose of such building or equipment is not the generation of electricity. Additionally, section 48(c)(5)(C) prevents taxpayers from claiming a double benefit by providing that any property that could be treated as WERP (determined without regard to section 48(c)(5)), which is part of a CHP property is not treated as WERP for purposes of section 48 unless the taxpayer elects not to treat such system as a CHP property for purposes of section 48.

Proposed § 1.48–9(e)(9), would adopt the statutory definition of WERP. The proposed regulations would also apply the functional interdependence test as described in part I.D.2 of this Summary of Comments and Explanation of Provisions to determine whether components are included as part of WERP. Additionally, after consultation with the Department of Energy, proposed § 1.48–9(e)(9) would provide examples of buildings or equipment the primary purpose of which is not the generation of electricity including, but not limited to, manufacturing plants, medical care facilities, facilities on college campuses, pipeline compressor stations, and associated equipment.

10. Energy Storage Technology

Section 48(a)(3)(A)(ix) was added by the IRA to provide that energy property includes energy storage technology. Section 48(c)(6)(A)(i) defines energy storage technology to mean property (other than property primarily used in the transportation of goods or individuals and not for the production of electricity) that receives, stores, and delivers energy for conversion to electricity (or, in the case of hydrogen, that stores energy), and has a nameplate capacity of not less than 5 kWh. Section 48(c)(6)(A)(ii) provides that thermal energy storage property is also energy storage technology.

Section 48(c)(6)(B) provides a rule for modifications of energy storage technology. In the case of any property that either was placed in service before August 16, 2022, and would be described in section 48(c)(6)(A)(i), except that such property has a capacity of less than 5 kWh and is modified in a manner that such property (after such modification) has a nameplate capacity of not less than 5 kWh, or is energy storage technology (as described in section 48(c)(6)(A)(i)) and is modified in a manner that such property (after such modification) has an increase in nameplate capacity of not less than 5 kWh, such property is treated as energy storage technology (as described in section 48(c)(6)(A)(i)) except that the basis of any existing property prior to such modification is not taken into account for purposes of section 48.

Section 48(c)(6)(C) defines thermal energy storage property, for purposes of section 48(c)(6) as property comprising a system that: is directly connected to a heating, ventilation, or air conditioning system; removes heat from, or adds heat to, a storage medium for subsequent use; and provides energy for the heating or cooling of the interior of a residential or commercial building. Section 48(c)(6)(C)(ii) provides that thermal energy storage property does not include a swimming pool, a combined heat and power system property, or a building or its structural components.

The Treasury Department and the IRS received comments addressing energy storage technologies in response to Notice 2022–49. Some comments discussed the definition of energy storage technology and how broadly energy storage technology should be interpreted in the regulations. For example, a commenter requested that guidance define energy storage broadly based on its characteristics and capabilities, rather than using a technology-based definition that could unintentionally exclude developing technologies. Some commenters requested that the definition of energy storage technology focus more on capability and less on a particular technology. Other commenters requested confirmation that certain specific technologies would be included within the definition of energy storage technology and that the definition be based on the underlying definition for the technology provided in section 48(c)(6), as opposed to the specific functionalities of the energy storage technology. After consideration of these comments, proposed § 1.48–9(e)(10) would adopt the statutory definition of energy storage technology.

Commenters also provided input on hydrogen storage, including a variety of recommendations on what the definition of hydrogen storage property should include. For example, one commenter suggested that ''energy storage technology'' with respect to hydrogen storage includes all equipment, facilities, storage receptacles, dedicated vehicles and vessels used to compress, liquify, store, and distribute hydrogen and hydrogen carriers, such as ammonia, methanol, and other forms of hydrogen carriers. Another commenter requested that regulations include a broad list of components of energy storage technologies including the storage receptacle itself and all pressure vessels, piping, valves, and tanks among many other components. This commenter also suggested that property that facilitates use of ammonia, methanol and other hydrogen carriers be included as hydrogen energy storage technology. Another commenter noted that the regulations should provide specific use limitations for stored hydrogen such as

for use solely in energy-related activities.

Section 48(c)(6)(A) already defines energy storage technology (including hydrogen storage) and thermal energy storage property based on the general functions of the relevant energy storage technology. Hydrogen energy storage property must store hydrogen that is solely used for the production of energy and not for the production of end products, such as fertilizer. For example, this would include, but is not limited to, hydrogen used to produce heat, to generate electricity, or to be used in a fuel cell vehicle. The type of hydrogen storage medium (for example, physical based or material based), is not limited. Proposed § 1.48–9(e)(10)(iv) therefore would adopt that rule. The Treasury Department and the IRS request comments on alternative approaches to assessing limitations on the use of hydrogen energy storage property, including whether additional clarification is needed regarding the production of energy from hydrogen, and what type of documentation would be needed to demonstrate that a hydrogen energy storage property was used to store hydrogen solely used for the production of energy.

Proposed § 1.48–9(e)(10) would apply the functional interdependence test as described in part I.D.2 of this Summary of Comments and Explanation of Provisions to determine whether components are included as part of an energy storage technology. This approach provides a technology-neutral way to determine what is considered energy storage technology and is broad enough to encompass technological changes. The proposed regulations would, however, provide additional guidance in the form of a non-exclusive list of examples of different types of energy storage technologies. The list is non-exclusive because it would be impossible to list all the types of technologies that could qualify currently, and the Treasury Department and the IRS acknowledge the importance of leaving the language broad to allow future technological advances in energy storage technologies to qualify.

Additionally, rechargeable electrochemical batteries of all types meet the functional definition by receiving energy in the form of electricity, storing electro-chemical energy, and producing electricity. A commenter requested that re-used or ''second life'' batteries should be considered ''new energy property.'' Generally, used property cannot be considered ''new property'' for purposes of the 80/20 Rule, which is described in part III.A. of this Summary of Comments and Explanation of Provisions. However, proposed § 1.48–9(e)(10)(v) would provide that recycled components may be used to meet the modification rule for energy storage technology. The Treasury Department and the IRS request comments on whether ''second life'' batteries should be considered new components for purposes of the 80/20 Rule. Additionally, the Treasury Department and the IRS request comment on what types of components may be used to modify an existing energy storage technology, and whether there are any challenges with recycled components being used to meet the modification rule.

Energy storage technology excludes property primarily used in the transportation of goods or individuals and not for the production of electricity under section 48(c)(6)(A)(i). The Treasury Department and the IRS understand that this exclusion, at a minimum, would apply to batteries and other energy storage technology that are incorporated into or otherwise physically integrated within motor vehicles and other modes of transportation of goods or individuals and from which an electric motor of such vehicle or other mode of transportation draws electricity for propulsion. The Treasury Department and the IRS do not intend that this exclusion apply to batteries and other energy storage technology that may be used to charge or recharge such vehicles or other modes of transportation, if the batteries and other energy storage technologies are physically separate from such vehicles or other modes of transportation. The Treasury Department and the IRS request comments as to how the exclusion for property primarily used in the transportation of goods or individuals and not for the production of electricity should be defined and the specific types of property that may be covered or not covered by this exclusion.

Although the list of examples of energy storage technologies that proposed § 1.48–9(e)(10) would provide is nonexclusive, and therefore many other technologies that are not addressed would meet these functional definitions, there are some examples that do not meet the functional definition. For example, some technologies are marketed as ''virtual batteries,'' which are aggregations of controllable electricity demand providing similar electrical grid services to an electrical grid battery. Such ''virtual batteries'' receive energy in the form of electricity, but they do not store it for later discharge as electricity. The function of ''virtual batteries'' is to shift demand to different points in time. Because such demand shifting is not a storage activity for purposes of section 48(c)(6), this technology is not an energy storage technology. There are other technologies for which the determination of whether they meet the statutory requirements of section 48(c)(6) is less clear. The Treasury Department and the IRS request comments on whether these other types of technologies should be considered energy storage technologies.

11. Qualified Biogas Property

Section 48(a)(3)(A)(x) was added by the IRA to provide that energy property includes qualified biogas property. Section 48(c)(7)(A) defines qualified biogas property as property comprising a system that converts biomass (as defined in section 45K(c)(3), as in effect on the date of enactment of section 48(a)(3)(A) (August 16, 2022)) into a gas that consists of not less than 52 percent methane by volume, or is concentrated by such system into a gas that consists of not less than 52 percent methane, and captures such gas for sale or productive use, and not for disposal via combustion. Section 48(c)(7)(B) provides that qualified biogas property includes any property that is part of such system that cleans or conditions such gas.

In response to Notice 2022–49, the Treasury Department and the IRS received several comments regarding qualified biogas property. Many commenters supported adopting a broad definition of qualified biogas property to include all the related technologies that commenters stated could be utilized in qualified biogas property. After consideration of these comments, proposed § 1.48–9(e)(11) would adopt the statutory definition of qualified biogas property.

Additionally, at least one commenter stated that when gas is being upgraded and injected into a pipeline, upgrading equipment is necessary to condition the gas into the appropriate mixture for injection into the pipeline and should be part of the qualified biogas property. In the commenter's view, the eligibility of this upgrading equipment hinges on the meaning of the phrase ''captures such gas for sale or productive use.'' The commenter asserted that the statute should encompass such conversion of biogas to a more portable product such as a compressed or liquified gas. Therefore, the commenter asserted that upgrading equipment be included in a qualified biogas property because it captures such biogas for sale or

productive use and includes any property that is part of such qualified biogas property that cleans or conditions such gas.

After consideration of these comments, proposed § 1.48–9(e)(11) would provide that components of property are considered qualified biogas property if they are functionally interdependent, that is, if the placing in service of each component is dependent upon the placing in service of each of the other components in order to perform the intended function of the qualified biogas property as described in proposed § 1.48–9(e)(11)(i). This approach would provide a technology-neutral way to determine what is considered included in a qualified biogas property and is broad enough to encompass technological changes. Additionally, proposed § 1.48–9(e)(11)(i) provides examples of functionally interdependent components of the qualified biogas property including, but not limited to, a waste feedstock collection system, a landfill gas collection system, mixing or pumping equipment, and an anaerobic digester.

Regarding the upgrading equipment that is necessary to condition biogas into the appropriate mixture for injection into the pipeline, this equipment is not functionally interdependent with the qualified biogas property that converts biomass into a gas containing not less than 52 percent methane and captures such gas for sale or productive use as specified in the statute. While this upgrading equipment makes the injection of biogas into a pipeline possible, such upgrading equipment is not necessary to satisfy the statutory requirements that the biogas converted from biomass contain not less than 52 percent methane, and that it be captured for sale or productive use. In support of including upgrading equipment necessary to prepare the biogas for injection into the pipeline, commenters point to the statutory language that qualified biogas property includes any property that is part of such system that *cleans or conditions such gas.* However, unlike upgrading equipment that is necessary for injection of the biogas into the pipeline, cleaning and conditioning equipment is part of the necessary process to convert biomass into gas that is not less than 52 percent methane and capture gas for sale or productive use. Therefore, proposed § 1.48–9(e)(11)(i) would clarify that upgrading equipment is not a functionally interdependent component of qualified biogas property. The Treasury Department and the IRS request comments regarding what types of components may be included within the definition of cleaning and conditioning property provided in the definition of qualified biogas property in section 48(c)(7)(B).

One commenter had recommendations about the application of the requirement in section 48(c)(7)(A)(ii) that a qualified biogas property captures such gas for sale or productive use, and not for disposal via combustion. This commenter noted that some properties that produce electricity from gas using a combustion process, may flare waste or tail gas, including during commissioning or maintenance periods. The commenter recommended a *de minimis* exception so that sale or use of gas in this manner will not prevent a property that produced such gas from being a qualified biogas property. The Treasury Department and the IRS request additional comments on whether such an exception is necessary and what should be considered *de minimis* for this purpose.

Lastly, several comments addressed the methane requirements in the statutory definition by commenting on how and when methane content should be measured and whether methane monitoring is required. After consideration and coordination with the Department of Energy, the proposed regulations would adopt a rule addressing the production point at which methane content must be measured. Proposed § 1.48–9(e)(11)(ii) would provide that the methane requirements described in section 48(c)(7)(A)(i)(I) and section 48(c)(7)(A)(i)(II) are measured at the point at which gas exits the biogas production system (which may include an anerobic digester, landfill gas collectors, or thermal gasification equipment) of a qualified biogas property. This is the point at which a taxpayer generally must determine whether it will convert the biogas to fuel for sale or use it directly to generate heat or fuel an electricity generation unit.

12. Microgrid Controllers

Section 48(a)(3)(A)(xi) was added by the IRA to provide that energy property includes microgrid controllers. Section 48(c)(8)(A) defines a microgrid controller as equipment that is part of a qualified microgrid and designed and used to monitor and control the energy resources and loads on such microgrid. Section 48(c)(8)(B) defines a qualified microgrid as an electrical system that includes equipment that is capable of generating not less than 4 kW and not greater than 20 MW of electricity; is capable of operating in connection with the electrical grid and as a single controllable entity with respect to such electrical grid, and independently (and disconnected) from such electrical grid; and is not part of a bulk-power system (as defined in section 215 of the Federal Power Act (16 U.S.C. 824o)).

In response to Notice 2022–49, the Treasury Department and the IRS received several comments requesting clarification on the definition of microgrid controllers, with some commenters suggesting a broad interpretation and others suggesting a narrow interpretation. Additionally, several commenters identified certain components that should be included as part of an eligible microgrid controller.

Several commenters asserted that the focus of the microgrid controller definition should be on capability and not the availability of an interconnection with the utility grid. In response to these comments, proposed § 1.48–9(e)(12)(ii) would clarify that an eligible microgrid includes an electrical system that is capable of operating in connection with the larger electrical grid whether or not the microgrid is physically connected to the electrical grid. For example, a microgrid located in a remote area that does not have a larger electrical grid to which it can physically connect can still be a qualified microgrid.

After consideration of these comments, proposed § 1.48–9(e)(12)(i) would adopt the statutory definition of a microgrid controller. The Treasury Department and the IRS request comments on whether the rules for functionally interdependent property provided in proposed § 1.48–9(f)(2)(ii) would be sufficient to determine the components that should be included as part of a microgrid controller, or whether another test is needed due to the specific role of microgrid controllers and their components.

13. Other Property Included in Section 48

Because future legislation may add additional types of energy property to section 48, proposed § 1.48–9(e)(13) would provide that any other property specified by section 48 as energy property is treated as energy property for purposes of these proposed regulations. The general rules and requirements applicable to energy property provided in these proposed regulations would also apply to such property.

D. Definition of Energy Property and Scope of Included Components

Since shortly after the enactment of section 48, energy property eligible for the section 48 credit has been

interpreted by the Treasury Department and the IRS to include, in addition to energy generation property, costs related to components such as power conditioning equipment, transfer equipment, and parts related to the functioning of that equipment.

On November 9, 1978, the Energy Tax Act of 1978, amended section 48 by adding a new subsection (then section 48(l)) to define ''energy property.'' Public Law 95–816, 92 Stat. 2174. On January 23, 1981, the Treasury Department and the IRS promulgated T.D. 7765 to provide additional guidance regarding the definition of energy property. 46 FR 7287–01. The preamble to T.D. 7765 states that ''[i]n response to comments, the definition of solar energy property was expanded to make it clear that it includes storage devices, power conditioning equipment, transfer equipment, and property solely related to the functioning of those items. However, such equipment does not include transmission equipment.''

The preamble to T.D. 7765 also provides that ''[a] number of comments cited specific legislative history to the effect that wind energy property includes 'transfer equipment.' '' The preamble to T.D. 7765 defines ''transfer equipment'' as including equipment that permits the aggregation of electricity generated by several windmills and equipment that alters voltage in order to permit transfer to a transmission line. The preamble to T.D. 7765 concludes that transfer equipment is specifically added to the definition of wind energy property, however, transfer equipment does not include transmission lines.

Existing § 1.48–9(d)(3) defines ''solar energy property'' as equipment that uses solar energy to generate electricity, and includes storage devices, power conditioning equipment, transfer equipment, and parts solely related to the functioning of those items. This section also provides that solar energy property used to generate electricity includes only equipment up to (but not including) the stage that transmits or uses electricity.

Existing § 1.48–9(e) defines ''wind energy property'' as consisting of a windmill, wind-driven generator, storage devices, power conditioning equipment, transfer equipment, and parts solely related to the functioning of those items. Section 48(a)(3) no longer includes wind energy property as a type of energy property. However, qualified wind facilities (including qualified offshore wind facilities) may be qualified investment credit facilities that a taxpayer may elect to treat as energy property if they meet all the requirements provided in section 48(a)(5).

While not specifically addressed in section 48, Internal Revenue Bulletin guidance interpreting section 48 has provided that functionally interdependent components, are considered components of energy property eligible for the section 48 credit. In Notice 2018–59, 2018–28 I.R.B. 196, the Treasury Department and the IRS clarified what components are considered part of an energy property. Section 7.01(1) of Notice 2018–59 states that an energy property generally includes all components of property that are functionally interdependent (unless such equipment is an addition or modification to an energy property). Notice 2018–59 provides that components of property are functionally interdependent if the placing in service of each component is dependent upon the placing in service of each of the other components in order to generate electricity. Further, Notice 2018–59 relies upon the rationale provided in Revenue Ruling 94–31, 1994–1 C.B. 16, to provide that functionally interdependent components of property that can be operated and metered together and can begin producing electricity separately from other components of property within a larger energy project will be considered an energy property.

In the context of defining ''section 38 property,'' § 1.48–1(d)(4) provides that ''section 38 property'' is ''used as an integral part of one of the specified activities if it is used directly in the activity and is essential to the completeness of the activity.'' Section 1.48–1(d)(4) also provides that ''[p]roperty shall be considered used as an integral part of one of the specified activities if so used either by the owner of the property or by the lessee of the property.'' Notice 2018–59 incorporates the concept of integral property from § 1.48–1(d) to provide that certain property that is an integral part of an energy property is included in energy property for purposes of the section 48 credit. While Notice 2018–59 explained that property that is ''functionally interdependent'' to the generation of electricity was treated as a unit of energy property, it also provided that certain other property that was integral to the production of electricity are included in determining what costs to include in the basis of energy property and the date on which construction began. Section 7.02(1) of Notice 2018–59 includes an example illustrating that, while a transmission tower located at a site where energy property is located is not energy property because transmission is not an integral part of the activity performed by the energy property, a custom-designed transformer that steps up the voltage of electricity produced at an energy property to the voltage needed for transmission is power conditioning equipment, which is an integral part of the activity performed. In addition, section 7.02(2) of Notice 2018–59 explains that onsite roads used to operate and maintain the energy property are integral to the production of electricity, but not roads used primarily to access the site or primarily for employee or visitor vehicles. Similarly, sections 7.02(3) and (4) of Notice 2018–59 explain that fences are not integral to the production of electricity nor are buildings, unless the building is essentially an item of machinery or equipment, or a structure that houses property that is integral to the activity of an energy property if the use of the structure is so closely related to the use of the housed energy property that the structure clearly can be expected to be replaced when the energy property it initially houses is replaced.

In response to a request for comments regarding the definition and scope of energy property in Notice 2015–70, several commenters requested that the regulations provide a specific list of eligible components and define each type of component. Commenters specifically requested that the regulations provide definitions for conversion equipment, power conditioning equipment, transfer equipment, and other property commonly used in conjunction with energy property. Further, some commenters requested that the regulations include safety equipment such as electrical panels, rapid shut-down equipment, and utility disconnection equipment as eligible components when used in conjunction with energy property. Conversely, several commenters recommended that the regulations not provide a technical definition or list of components because innovations in energy property may require that such a definition would need to be continually updated.

Commenters requested that the regulations be clarified to include as energy property all components located *before* the point at which voltage of the electricity is increased to the voltage of the transmission line, referred to as the ''separation point,'' such as step-up transformers, dead end structures, switches, switch gear buildings, voltage regulators, and hardware and software used to monitor, operate, and protect such property. Additionally, one commenter requested that the

regulations be clarified to include as energy property all components located beyond the separation point, such as switches, circuit breakers, lighting or surge arrestors, and metering equipment, if the use of such components is primarily related to the functioning or protection of components located at or before the separation point.

One challenge in providing definitions of what components to include in energy property is in determining what components are common to all energy property, without limiting or constraining future technological advances. To avoid limiting future energy technologies, the Treasury Department and the IRS consulted with the Department of Energy and determined that the best option is to adopt a function-oriented approach to describe the types of components that are considered energy property. Accordingly, proposed § 1.48–9(f) would adopt the concepts of functional interdependence and property that is an integral part of an energy property as provided in Internal Revenue Bulletin guidance issued previously by the Treasury Department and the IRS.

1. Unit of Energy Property

Proposed § 1.48–9(f)(2)(i) would provide that a unit of energy property consists of all functionally interdependent components of property (as defined in proposed § 1.48–9(f)(2)(ii)) owned by the taxpayer that are operated together and that can operate apart from other energy properties within a larger energy project (as defined in proposed § 1.48–13(d) and discussed in part II.C of this Summary of Comments and Explanation of Provisions).

2. Functional Interdependence

Proposed § 1.48–9(f)(2)(ii) would provide that components of property are functionally interdependent if the placing in service of each component is dependent upon the placing in service of each of the other components in order to generate or to store electricity, thermal energy, or hydrogen, or otherwise perform its intended function as provided in section 48(c) and as described in proposed § 1.48–9(e). Energy property, with certain exceptions, includes all components necessary to generate or store electricity or thermal energy for transmission, distribution, or use up to (but not including) the stage that transmits, distributes, or uses electricity or thermal energy. In the case of qualified biogas property, microgrid controllers, electrochromic glass property, and fiber-optic solar energy property, components of such energy property are functionally interdependent if the placing in service of each component is dependent upon the placing in service of each of the other components in order to perform the intended function of the energy property as provided by section 48(c) and as described in proposed § 1.48–9(e). Additionally, energy property generally would not include equipment that is an addition or modification to an existing energy property unless the rules regarding retrofitted energy property described in proposed § 1.48–14(a) and part III.A. of this Summary of Comments and Explanation of Provisions apply.

3. Integral Part of an Energy Property

Proposed § 1.48–9(f)(3)(i) would provide that property owned by a taxpayer that is an integral part of an energy property owned by that same taxpayer is energy property. To be part of an energy property, such property must be used directly in the intended function of the energy property as provided by section 48(c) and as described in § 1.48–9(e) and be essential to the completeness of the intended function. Proposed § 1.48–9(f)(3)(ii) would describe power conditioning equipment and transfer equipment, and would provide that such components, and parts related to the functioning of those components, are energy property when they meet the definition of integral part provided in § 1.48–9(f)(3)(i).

Many commenters requested clarification on the eligible components of an offshore wind facility. Proposed § 1.48–9(f)(5)(iii) would provide an example that applies the integral part rule to include power conditioning and transfer equipment as part of a qualified offshore wind facility but excludes transmission and distribution equipment from being part of the qualified offshore wind facility. This example is consistent with the view of the Joint Committee on Taxation in the *General Explanation of Tax Legislation Enacted in the 116th Congress,* JCS 1–22 (February 2022). According to that document, ''[q]ualified offshore wind facilities are qualified wind facilities . . . and include property owned by the taxpayer necessary to condition electricity for use on the electrical grid such as subsea cables and voltage transformers.'' *Id.* at 498.

Furthermore, consistent with Notice 2018–59, proposed § 1.48–9(f)(3)(iii) would provide as further examples of integral property onsite roads that are used for equipment to operate and maintain the energy property. Section 1.48–9(f)(3)(iii) would also clarify that roads primarily for access to the site, or roads used primarily for employee or visitor vehicles, are not integral parts of an energy property. Proposed § 1.48–9(f)(3)(iv) and (v) would also provide that fences and buildings (also referred to as structures) are generally not integral parts of an energy property because they are not integral to the activity of the energy property. However, a building may be an integral part of a unit of energy property if it is essentially an item of machinery or equipment, or a structure that houses property that is integral to the activity of an energy property, if the use of the structure is so closely related to the use of the housed energy property that the structure clearly can be expected to be replaced when the energy property it initially houses is replaced. The Treasury Department and the IRS request comments on whether additional types of property meet the requirements provided in proposed § 1.48–9(f)(3) and could be considered an integral part of an energy property.

4. Location of Energy Property

Section 48 and the existing regulations thereunder are silent regarding the credit eligibility of components of an energy property located in different locations. However, the Treasury Department and the IRS have provided analogous guidance regarding the credit eligibility of offsite components for the residential energy efficient property tax credit under section 25D of the Code (section 25D credit).

In Notice 2013–70, 2013–47 I.R.B. 528, the Treasury Department and the IRS provided guidance addressing the eligibility for the section 25D credit for offsite components of solar electric property. Specifically, Q&A #25 of Notice 2013–70 addressed the issue of whether a taxpayer that installs solar panels as part of solar electric property other than directly on the taxpayer's home may claim the section 25D credit. Q&A #25 concluded that the taxpayer would be able to claim the section 25D credit because the solar electric property expenditure was made for property that, consistent with the requirements of the section 25D credit, uses solar energy to generate electricity for use in a dwelling unit that is used as a residence by the taxpayer. The fact that the solar panels were not directly located on the taxpayer's home did not change the analysis or the eligibility of the taxpayer's expenditure for purposes of the section 25D credit.

Similarly, Q&A #26 of Notice 2013–70 addressed a scenario in which a taxpayer purchases solar panels that are

placed on an offsite solar array (community solar project) and connected to the local public utility's electrical grid that supplies electricity to the taxpayer's residence. The taxpayer enters into a direct contractual arrangement with the utility to allow the taxpayer to provide electricity to the electrical grid using a net metering system that measures the amount of electricity produced by the taxpayer's solar panels and transmitted to the electrical grid and the amount of electricity used by the taxpayer's residence and drawn from the electrical grid. The contract states that the taxpayer owns the electricity transmitted by the solar panels to the electrical grid until drawn from the electrical grid at his residence. Q&A #26 determined that offsite solar panels under this type of contractual arrangement with a utility that supplies electricity to the taxpayer's residence also meet the definition of a solar electric property expenditure eligible to claim the section 25D credit. In response to Notice 2015–70, many commenters referenced Notice 2013–70 when requesting that existing § 1.48–9 be modified to allow components of energy property to be situated in different locations without affecting the eligibility of the energy property for the section 48 credit.

After consideration of the comments received, the Treasury Department and the IRS have determined that if property is a functionally interdependent part of an energy property (as defined in § 1.48–9(f)(2)(ii)), or an integral part of an energy property (as defined in § 1.48–9(f)(3)(i)), such property is part of an energy property regardless of where it is located. Proposed § 1.48–9(f)(4) would adopt this position.

5. Property Excluded From Energy Property

Proposed § 1.48–9(d)(2) would also clarify that certain types of intangible property, such as power purchase agreements, renewable energy certificates, goodwill, and going concern value, are not energy property because they are not functionally interdependent with other components of an energy property as defined in proposed § 1.48–9(f)(2)(ii) and are not an integral part of an energy property as defined in proposed § 1.48–9(f)(3)(i).

II. Rules Relating to the Increased Credit Amount for Prevailing Wages and Apprenticeships

The IRA amended several sections of the Code including section 48 to provide increased credit amounts for taxpayers who satisfy certain requirements, including an increased credit amount for satisfying prevailing wage and apprenticeship (PWA) requirements. This same increased credit amount is also generally available under certain sections of the Code including section 48 with respect to energy projects with a maximum net output of less than one megawatt (One-Megawatt Exception). Additionally, this same increased credit amount is available under certain sections of the Code including section 48 if beginning of installation or beginning of construction (BOC) occurs before January 29, 2023 (BOC Exception).

The Treasury Department and the IRS issued proposed § 1.48–13 as part of the August Proposed Regulations to provide guidance concerning the increased credit amount available for taxpayers satisfying the PWA requirements. This notice of proposed rulemaking withdraws § 1.48–13 as proposed in the August Proposed Regulations and reproposes in a new § 1.48–13 (proposed § 1.48–13) the substance of the withdrawn rules with minor changes and additional rules with respect to the increased credit amount available for taxpayers under section 48(a)(9).

Proposed § 1.48–13 would provide special rules affecting the basis of energy property that include: (i) the definition of an energy project for purposes of the PWA requirements as well as other delineated purposes discussed in part II.C of this Summary of Comments and Explanation of Provisions and (ii) guidance concerning the One-Megawatt Exception discussed in part II.D of this Summary of Comments and Explanation of Provisions. These proposed regulations also provide guidance on the recapture rules under section 48(a)(10)(C) applicable to failures to satisfy the PWA requirements.

A. General Rules

For properties placed in service after December 31, 2022, the section 48 credit is generally six percent of the basis of energy property described in section 48(a)(2)(A)(i) and two percent of the basis of energy property described in section 48(a)(2)(A)(ii). If a taxpayer satisfies the PWA requirements, the One-Megawatt Exception, or the BOC Exception, then the section 48 credit for the basis of each energy property placed in service during the taxable year is multiplied by five.

To satisfy the prevailing wage requirements under section 48(a)(10)(A) and (B) (Prevailing Wage Requirements), a taxpayer must ensure that any laborers and mechanics employed by the taxpayer or any contractor or subcontractor in: (i) the construction of any energy project, and (ii) the alteration or repair of that energy project (for the five-year period beginning on the date such project is originally placed in service), are paid wages at rates not less than the prevailing rates for construction, alteration, or repair of a similar character in the locality in which that energy project is located as most recently determined by the Secretary of Labor, in accordance with subchapter IV of chapter 31 of title 40, United States Code (Davis-Bacon Act). Section 48(a)(10)(B) provides that rules similar to the rules of section 45(b)(7)(B) apply for purposes of the correction and penalty related to the failure to satisfy the Prevailing Wage Requirements.

Section 48(a)(10)(C) provides a recapture rule applicable to failures to satisfy the Prevailing Wage Requirements with respect to alterations or repairs that occur during the five-year period after the energy project is placed in service (section 48(a)(10)(C) recapture). Specifically, section 48(a)(10)(C) instructs the Secretary, by regulations or other guidance, to provide for recapturing the benefit of any increase in the credit allowed by the Prevailing Wage Requirements with respect to failures to satisfy the Prevailing Wage Requirements during the five-year period after the energy project is placed in service. Section 48(a)(10)(C) clarifies that the failures during the five-year period remain subject to the correction and penalty provisions in section 45(b)(7)(B) (as referenced in section 48(a)(10)(B)) and provides that the period and percentage of the credit that is recaptured is determined under rules similar to the rules in section 50(a). Subject to the section 48(a)(10)(C) recapture (including the correction and penalty provisions in section 45(b)(7)(B)), the taxpayer is deemed at the time the energy project is placed in service to satisfy the Prevailing Wage Requirements for alterations or repairs for the five-year period beginning after such project is originally placed in service. Section 48(a)(11) provides that rules similar to the rules of section 45(b)(8) apply for purposes of the apprenticeship requirements.

The August Proposed Regulations provided guidance for taxpayers claiming an increased credit amount under section 48(a)(9)(A)(i) with respect to an energy project that satisfies the PWA requirements, the One-Megawatt Exception, or the BOC Exception. The August Proposed Regulations provided that to satisfy the PWA requirements, the energy project must meet the

Prevailing Wage Requirements of section 48(a)(10)(A) and proposed § 1.45–7(b)–(d), the apprenticeship requirements of section 45(b)(8) and proposed § 1.45–8, and the recordkeeping and reporting requirements of proposed § 1.45–12. In addition, under the August Proposed Regulations, to satisfy the Prevailing Wage Requirements with respect to section 48(a)(10)(A)(ii), a taxpayer also would be required to ensure that any laborer and mechanic employed by the taxpayer or any contractor or subcontractor in the construction of any energy project, as well any alteration or repair of an energy project in the five-year period beginning on the date a project is placed in service, are paid wages at rates not less than the prevailing rates for construction, alteration, or repair of a similar character in the locality in which the energy project is located in accordance with the Davis-Bacon Act. The August Proposed Regulations also provided that the increased credit amount was subject to section 48(a)(10)(C) recapture for any project that failed to satisfy the Prevailing Wage Requirements in proposed § 1.45–7 with respect to an alteration or repair of such project for the five-year period beginning on the date such project is originally placed in service (but that does not cease to be investment credit property within the meaning of section 50(a) of the Code).

B. Section 48(a)(10)(C) Recapture Rules

The Treasury Department and the IRS have determined that additional guidance on the section 48(a)(10)(C) recapture rules is necessary. Proposed § 1.48–13 would provide additional guidance on the section 48(a)(10)(C) recapture rules related to the Prevailing Wage Requirements. The proposed regulations also provide other minor technical corrections to the August Proposed Regulations.

In addition to largely restating the general rules in the August Proposed Regulations, proposed § 1.48–13 would clarify that a taxpayer that has claimed an increased credit amount under section 48(a)(9)(A)(i) and 48(a)(9)(B)(iii) but failed to satisfy the Prevailing Wage Requirements set forth in proposed § 1.45–7(b)–(d) with respect to any period during the five-year period beginning on the date a project is placed in service is subject to section 48(a)(10)(C) recapture of a portion (up to 100 percent) of the increased credit amount. Proposed § 1.48–13 would also clarify that the failure to satisfy the Prevailing Wage Requirements in proposed § 1.45–7(b)–(d) with respect to any period during the five-year period beginning on the date a project is placed in service remains subject to the correction and penalty provisions in proposed § 1.45–7(c)(1).

Section 48(a)(10)(C) requires that the recapture period and percentage of such recapture be determined under rules similar to the rules of section 50(a). Consistent with that requirement, proposed § 1.48–13 would also clarify that the five-year recapture period under section 48(a)(10)(C) would begin on the day an energy project is placed in service and end on the day that is five full years after the placed-in-service date. Proposed § 1.48–13 would also provide that each 365-day period (366-day period in case of a leap year) within the recapture period is a separate recapture year. The proposed regulations would provide that the recapture amount is determined consistent with the percentages set forth in section 50(a) based on the year in which the section 48(a)(10)(C) recapture event is determined to have occurred.

The Treasury Department and the IRS understand that the five-year recapture period is unlikely to align with a taxpayer's taxable year. The proposed regulations would provide that whether a section 48(a)(10)(C) recapture event has occurred is determined at the close of taxable year that begins or ends within the five-year recapture period. In addition to the reporting and recordkeeping requirements contained in proposed § 1.45–12, the proposed regulations would provide for an annual information reporting requirement that verifies compliance with the Prevailing Wage Requirements following the close of each recapture year consistent with the forms and instructions prescribed by the IRS. The IRS anticipates that the annual compliance reporting obligation will be made at the time the taxpayer files its income tax or other annual return following the close of each recapture year.

Under proposed § 1.48–13, if the increased credit amount is subject to section 48(a)(10)(C) recapture, then the increase in tax under chapter 1 for the recapture of the increased credit amount would be assessed with respect to the taxable year in which the section 48(a)(10)(C) recapture event occurred. The proposed regulations also clarify that a taxpayer whose increased credit amount is subject to section 48(a)(10)(C) recapture may still be entitled to the base amount of the energy credit under section 48(a) if they meet the requirements to claim the credit. Additionally, the proposed regulations clarify the application of the transferability rules under section 6418 to a section 48(a)(10)(C) recapture event and include a proposed addition to § 1.6418–5 confirming the notification requirements for an eligible taxpayer and that a transferee taxpayer is responsible for any amount of tax increase under section 48(a)(10)(C).

C. Definition of Energy Project

Under section 48(a)(9)(A)(ii), an energy project is a project consisting of one or more energy properties that are part of a single project. Proposed § 1.48–13(d) would provide a definition of ''energy project'' for purposes of the increased credit amount for the PWA requirements (provided by section 48(a)(9)), the domestic content bonus credit amount (provided by section 48(a)(12)), and the increase in credit rate for energy communities (provided in section 48(a)(14)). For these purposes, the term *energy project* means one or more energy properties that are operated as part of a single project. Section 45 qualified facilities that are co-located with section 48 energy property will not be considered part of an energy project (unless they elect under section 48(a)(5) to be treated as energy property). Multiple energy properties would be treated as one energy project, if at any point during the construction of the multiple energy properties, they are owned by a single taxpayer (subject to the related taxpayer rule discussed later in this part) and any two or more of the following factors (also set forth in section 7.01(2)(a) of Notice 2018–59 as factors indicating that multiple energy properties are operated as part of a single project) are present:

1. The energy properties are constructed on contiguous pieces of land;
2. The energy properties are described in a common power purchase, thermal energy, or other off-take agreement or agreements;
3. The energy properties have a common intertie;
4. The energy properties share a common substation, or thermal energy off-take point;
5. The energy properties are described in one or more common environmental or other regulatory permits;
6. The energy properties are constructed pursuant to a single master construction contract; or
7. The construction of the energy properties are financed pursuant to the same loan agreement.

Under proposed § 1.48–13(d)(2), related taxpayers would be treated as one taxpayer in determining whether multiple energy properties are treated as an energy project. Related taxpayers would be defined as members of a group of trades or businesses that are under

common control (as defined in § 1.52–1(b)).

Proposed § 1.48–13(d)(3) would also provide that if multiple energy properties are treated as a single project for beginning of construction purposes with respect to the section 48 credit, the multiple energy properties would also be treated as one energy project for purposes of the PWA requirements, the domestic content bonus credit amount, and the increase in section 48 credit rate for energy communities. This rule would apply to an energy project for which construction begins after the date final regulations are published in the **Federal Register**.

D. One-Megawatt Exception

Section 48(a)(9)(B)(i) and § 1.48–13 of the August Proposed Regulations would provide that the increased credit amount is also available under section 48 with respect to energy projects with a maximum net output of less than 1 MW of electrical (as measured in alternating current) or thermal energy. The August Proposed Regulations do not address how to determine the maximum net output of a project.

The Department of Energy has advised the Treasury Department and the IRS that for energy projects that generate electricity, the determination of an energy project's nameplate capacity will provide the necessary guidance to determine the maximum electrical generating output in MWs of electrical (as measured in alternating current) or thermal energy that the unit is capable of producing on a steady state basis and during continuous operation under standard conditions. Proposed § 1.48–13(e) would thus provide a rule for the determination of nameplate capacity as expressed in MWs of electrical (as measured in alternating current) or thermal energy. Because electrochromic glass property, fiber-optic solar, and microgrid controllers do not generate electricity or thermal energy, these energy properties are not eligible for the One-Megawatt Exception. The Treasury Department and the IRS request comments on whether other methods of measurement may allow these energy properties to use the One-Megawatt Exception.

Under proposed § 1.48–13(e)(1), the nameplate capacity for an electrical generating unit would mean the maximum electrical generating output in MWs that the unit is capable of producing on a steady-state basis and during continuous operation under standard conditions, as measured by the manufacturer and consistent with the definition provided in 40 CFR 96.202. Where applicable, those rules provide that the International Standard Organization (ISO) conditions are used to measure the maximum electrical generating output.

Proposed § 1.48–13(e)(2) through (4) would provide rules for energy storage technologies. Generally, electrical energy storage property would look to the storage device's nameplate capacity in MWs under proposed § 1.48–13(e)(2). As with energy properties that generate electricity, nameplate capacity for an electrical energy storage property would mean the maximum electrical generating output in MWs that the unit is capable of producing on a steady state basis and during continuous operation under standard conditions, as measured by the manufacturer and consistent with the definition provided in 40 CFR 96.202.

Proposed § 1.48–13(e)(3) would provide that for thermal energy storage property, taxpayers must use the equivalent value of 3.4 million British Thermal Units per hour (mmBtu/hour) for heating and 284 tons for cooling to determine whether the thermal energy storage property satisfies the One-Megawatt Exception (Btu per hour/3,412,140 = MW). The Treasury Department and the IRS request comments on whether these tests are suitable or whether another test should apply for measuring the One-Megawatt Exception for thermal energy storage property.

Proposed § 1.48–13(e)(4) would provide that for hydrogen energy storage property, 1 MW is equivalent to 3.4 mmBtu/hour, and using the higher heating value of hydrogen, this can be converted to 10,500 scf per hour. Therefore, proposed § 1.48–13(e)(4) would provide that for a hydrogen energy storage property to satisfy the One-Megawatt Exception, an eligible hydrogen producing, or hydrogen storage energy property must be designed to have a maximum net output of less than 3.4 mmBtu/hour of hydrogen or equivalently 10,500 scf per hour of hydrogen.

Proposed § 1.48–13(e)(3) through (5) would provide that to apply the One-Megawatt Exception to energy projects that produce thermal energy or fuels, taxpayers must use the equivalent value of 3.4 million British thermal units (mmBtus) per hour (Btu per hour/3,412,140 = MW). For certain technologies that produce fuels, such as qualified biogas property (proposed § 1.48–13(e)(5)), hydrogen energy storage property (proposed § 1.48–13(e)(4)), and specified hydrogen production facilities (as defined in section 48(a)(15)(C)) (proposed § 1.48–13(e)(4)), taxpayers may use equivalent maximum fuel volume flows in standard cubic feet (scf) per hour to assess the One-Megawatt Exception. Taxpayers can use equivalent volume flows using the default high heat value conversion factors found in *Table C–1 to Subpart C of Part 98, Title 40 of the Greenhouse Gas Reporting Rule* promulgated by the Environmental Protection Agency. Otherwise, taxpayers may calculate their own equivalent volumetric flow if the heat content of the gas is known.

For property generating thermal energy, proposed § 1.48–13(e)(3) would provide that the equivalents for 1 MW that should be used are 3.4 mmBtu/hour for heating and equivalently 284 tons for cooling should be used to determine whether the energy property satisfies the One-Megawatt Exception. Proposed § 1.48–13(e)(3) would also specify that for projects delivering thermal energy to a building or buildings, the One-Megawatt Exception can be assessed as either the aggregate maximum thermal output of all individual heating or cooling elements within the building or buildings or as the maximum thermal output that the entire project is capable of delivering to a building or buildings at any given moment.

III. Rules Applicable to Energy Property

A. Retrofitted Energy Property (80/20 Rule)

The Treasury Department and the IRS have published several pieces of Internal Revenue Bulletin guidance regarding the eligibility of retrofitted equipment added to qualified facilities and energy property for purposes of the section 45 and 48 credits. In Notice 2016–31, 2016–23 I.R.B. 1025, the Treasury Department and the IRS considered the application of the Five Percent Safe Harbor provided in section 5.01 of Notice 2013–29, 2013–20 I.R.B. 1085, to retrofitted qualified facilities for purposes of applying the beginning of construction requirement to the section 45 credit. Section 6.01 of Notice 2016–31 cites to Revenue Ruling 94–31 and Notice 2008–60, 2008–2 C.B. 178, for the concept that a qualified facility may qualify as originally placed in service even though it contains some used property, provided the fair market value of the used property is not more than 20 percent of the qualified facility's total value (that is, the cost of the new property plus the value of the used property). This concept has become known as the ''80/20 Rule.''

Similarly, Notice 2018–59 addressed the application of the 80/20 Rule to retrofitted energy property for purposes

of the applying the beginning of construction rules to the section 48 credit. Section 7.05(1) of Notice 2018–59 provides that retrofitted energy property may qualify as originally placed in service even though it contains some used components of property, provided it satisfies the 80/20 Rule. Further, this section of the notice provided that, for purposes of the 80/20 Rule, the cost of the new energy property includes all properly capitalized costs of the new energy property.

In response to requests for comment in Notice 2015–70 and Notice 2022–49, several commenters requested that the regulations address the applicability of the 80/20 Rule to energy property for purposes of the section 48 credit. After consideration of the comments, proposed § 1.48–14(a) would apply the 80/20 Rule to energy property for purposes of the section 48 credit.

B. Dual Use Property

Existing § 1.48–9 includes a dual use equipment rule (Dual Use Rule). The preamble to T.D. 8147 notes that the regulations prior to amendment by T.D. 8147 required that equipment must use only energy from a single qualifying source (solar energy property, wind energy property, or geothermal equipment) to qualify as energy property. In changing from a single source rule to the Dual Use Rule, the preamble to T.D. 8147 explained that the Treasury Department and the IRS reconsidered the legislative history of the investment tax credit and determined that, ''while Congress did not intend that property that does not use qualified energy be eligible for the business energy credit as solar, wind, or geothermal property, Congress also did not intend to adopt an all or nothing rule for dual use solar, wind, or geothermal energy property.''

Accordingly, the Dual Use Rule in existing § 1.48–9 provides that a solar energy property, wind energy property, and geothermal equipment are eligible for the section 48 credit to the extent of the property's basis or cost allocable to its annual use of energy from a qualified source, provided the use of energy from ''non-qualifying'' sources does not exceed 25 percent of the total energy input of the property during an annual measuring period. Notably, the Dual Use Rule provided in § 1.48–9 also precludes an energy property from receiving and aggregating energy from a combination of qualifying sources (solar energy property, wind energy property, and geothermal equipment). Because the Dual Use Rule requires that a solar energy property, wind energy property, or geothermal equipment must use a minimum of 75 percent of energy from a qualified source during an annual measuring period to qualify for a section 48 credit. This rule became known as the ''75-percent Cliff.''

The Dual Use Rule provided in existing § 1.48–9 also provides that, if in the first annual measuring period, the applicable percentage (based on usage from a qualifying source) is between 75 percent and 100 percent, only a proportionate amount of the eligible basis of the energy property should be taken into account in computing the amount of the section 48 credit. If less than 75 percent of the energy used is from qualifying sources, then the eligible basis is zero, and the property is not eligible for the section 48 credit.

1. Alternatives to the 75-Percent Cliff

In response to Notice 2015–70, many commenters requested that the regulations be modified to reduce the Dual Use Rule's current 75-percent Cliff to a 50-percent Cliff. Commenters cited as support for this proposal the statutory language of section 25D(d)(1), which allows for full credit eligibility if a solar water heating property receives at least 50 percent of its energy inputs from the sun. Applying this premise to the investment tax credit under section 48 would allow an energy property to be eligible for 100 percent of the section 48 credit if it receives at least 50 percent of its energy input from a qualifying source but would render the energy property ineligible for the section 48 credit if less than 50 percent of its energy input is from a qualifying source. Commenters asserted that a 50-percent Cliff would be more equitable than the 75-percent Cliff.

Several commenters also recommended that the regulations be modified to provide that if greater than 50 percent of energy received by an energy property is from a qualifying source that the energy property is eligible for a full section 48 credit. Conversely, if the energy property receives less than 50 percent of its energy input from a qualifying source, the qualifying basis of the energy property is reduced incrementally for the annual measuring period. Importantly, this rule would reduce the credit but not disqualify the energy property entirely from credit eligibility. The benefit of adopting this rule is that it would eliminate the ''all or nothing'' dynamic of the current 75-percent Cliff and, as a result, would provide certainty that an energy property will remain credit eligible. The main obstacle to adopting this rule is that it would be expensive for taxpayers to measure with great accuracy the relative amounts of energy input from different qualifying sources.

Many commenters suggested changing the Dual Use Rule to a ''Primary Use Rule'' modeled on the ''Primary Use'' Test for asset class depreciation determinations, changes in use, and for asset disposition purposes. According to commenters, this approach is popular because the Primary Use Test could be performed at the same time (on the placed in service date) and manner in which the taxpayer determines the primary use of the asset for depreciation purposes. The challenge of this approach is that it also depends upon taxpayers correctly using the depreciation asset class determination procedures and reporting any changes in primary use to the IRS for recapture. Moreover, the scope of the Primary Use Test seems inappropriate for the section 48 credit because the Primary Use Test merely serves to determine how the property is depreciated rather than whether the property can be depreciated. Applying this test to determine credit eligibility may increase, beyond what was intended, the credit available to a taxpayer.

After consideration of the comments, the Treasury Department and the IRS have determined it would be most consistent with statutory intent to reduce the applicable threshold of the Dual Use Rule to 50 percent resulting in the adoption of a 50-percent Cliff. Therefore, proposed § 1.48–14(b)(2)(i) would require an energy property to derive a minimum of 50 percent of energy from a qualifying source during an annual measuring period. Similar to the operation of the 75-percent Cliff in existing § 1.48–9, if the energy used from qualifying sources is between 50 percent and 100 percent, only a proportionate amount of the eligible basis of the energy property will be taken into account in computing the amount of the section 48 credit. If less than 50 percent of the energy used is from qualifying sources, then the eligible basis is zero, and the property is not eligible for the section 48 credit. The Treasury Department and the IRS recognize that the Dual Use Rule is no longer relevant to determining the eligibility of energy storage technology placed in service after December 31, 2022, because the IRA added energy storage technology as an energy property effective for property placed in service after December 31, 2022. However, the Dual Use Rule may still have other applications under section 48. The Treasury Department and the IRS request comments on the application of the Dual Use Rule to

section 48 after its amendment by the IRA.

2. Aggregation of Energy Inputs

While T.D. 8147 significantly amended existing § 1.48–9 to permit 25 percent of energy used by energy property from non-qualifying sources, it did not allow the aggregation of energy from multiple energy properties to be treated as energy from qualifying sources for purposes of the Dual Use Rule.

In response to Notice 2015–70, several commenters requested a revised rule to permit taxpayers to calculate credit basis by aggregating all inputs from qualifying sources that would otherwise individually qualify for the section 48 credit (all types of energy property and any qualified facilities for which an election is made to claim the section 48 credit as a ''qualified investment credit facility'' under section 48(a)(5)). After consideration of the comments received, proposed § 1.48–14(b)(2)(ii) would revise the Dual Use Rule to permit the aggregation of energy inputs from more than one energy property.

3. Measurement Period

Existing § 1.48–9(c)(10)(iv) and (d)(6) provides that an annual measuring period is the period during which the portion of dual use property's basis or cost allocable to use of energy from a qualified source is measured. An annual measuring period for an item of dual use property is defined as the 365-day period beginning with the day it is placed in service or a 365-day period beginning the day after the last day of the immediately preceding annual measuring period.

In response to Notice 2015–70, several commenters requested that the regulations provide a clarification of the annual measurement rules applicable to dual use property. Several of these commenters' concerns were tied to energy storage technology. Because the IRA now includes energy storage technology as eligible property, many of these specific concerns may have been eliminated. However, the proposed regulations would still address these concerns by adopting these annual measurement rules for application to the Dual Use Rule. Accordingly, a taxpayer may claim the section 48 credit when it places an energy property in service, and all relevant time periods, including depreciation and recapture, begin on that date. After consideration of the comments, proposed § 1.48–14(b)(2)(iii) would provide that an annual measuring period for an item of dual use property is any period of 365 consecutive days (366 days in a leap year) beginning with the day the dual use property is placed in service.

4. Dual Use Property and Microgrid Controllers

Certain equipment is necessary for a microgrid controller to perform its functions, but such equipment may also have been required to be installed even without the presence of a microgrid. An example is a communications system (for example, a local ethernet network or a commercial wireless network). A microgrid controller must be connected to a communications system to operate properly. Such a communications system could be considered part of the microgrid controller itself. However, the communications system could also be used for other purposes and may not be dedicated to the microgrid system. The Dual Use Rule would be inapplicable in this scenario because the scenario does not involve the use of energy derived from both a qualifying source and from sources other than a qualifying source (non-qualifying source). The Treasury Department and the IRS request comments on whether a rule is needed to address this situation for microgrid controllers or other potentially similar situations for which the Dual Use Rule would not apply.

C. Energy Property That Could Be Eligible for Multiple Credits

Section 48 and the existing regulations thereunder are silent regarding the eligibility of components of energy property for multiple credits. However, in Notice 2013–70, the Treasury Department and the IRS considered the ability of a single taxpayer to claim section 25D and section 48 credits for different uses of the same energy property. In Q&A #27 of Notice 2013–70, a taxpayer purchased and installed solar electric property to generate electricity for the taxpayer's residence. The taxpayer also expected the solar electric property to generate excess electricity that would be sold to a utility. Q&A #27 determined that the taxpayer may not claim the section 25D credit for the full amount of the solar electric property expenditure because the property not only generates electricity for use in the taxpayer's residence, but it also generates electricity for sale by the taxpayer. As a result, the taxpayer may only claim the section 25D credit for the portion of the solar electric property expenditure that relates to the electricity generated for use in the taxpayer's home. However, the taxpayer may be able to claim the section 48 credit for a portion of the solar electric property expenditure if the requirements of section 48 are satisfied. Notice 2013–70 did not separately analyze whether the taxpayer had met the requirements to claim the section 48 credit.

Several commenters requested a modification of the regulations to allow section 48 credit eligibility in scenarios involving different taxpayers that claim different credits related to different components of an energy property. This may also occur in situations in which different taxpayers own components of energy property as discussed in part III.E.1 of this Summary of Comments and Explanation of Provisions. After consideration of these comments, proposed § 1.48–14(c)(1) would provide that the same energy property may be eligible for both the section 48 credit and another credit subject to certain limitations that proposed § 1.48–14(c)(2) would provide.

D. Incremental Cost

Existing guidance under section 48 provides that only the incremental cost of energy property is included in the eligible basis for purposes of determining the section 48 credit. Existing § 1.48–9(k) defines incremental cost as the excess of the total cost of equipment over the amount that would have been expended for the equipment if the equipment were not used for a qualifying purpose related to the section 48 credit. The existing regulations provide as an example, a scenario in which energy property costing $100 performs a pollution control function as well as a non-qualifying function. The example states that it would cost $60 solely to perform the non-qualifying function, thus the incremental cost to the energy property would be $40.

The Treasury Department and the IRS received no comments regarding the incremental cost rule in response to Notice 2015–70. Thus, proposed § 1.48–14(d)(1) would continue to apply this incremental cost approach and would provide that only the incremental cost of energy property is included in the eligible basis of the energy property for purposes of computing the section 48 credit.

E. Special Rules Concerning Ownership

1. Separate Ownership of Energy Property

Section 48 and the existing regulations thereunder are silent regarding whether the components of an energy property can be owned by multiple taxpayers. In Revenue Ruling 78–268, 1978–2 C.B. 10, the Treasury Department and the IRS addressed a situation involving four owners that shared a common tenancy in an electric

generating facility: two investor-owned utilities, a tax-exempt cooperative, and a tax-exempt municipality-owned utility. The specific issue raised in this Revenue Ruling was whether ownership by the tax-exempt entities disqualified the entire electric generating facility from the investment tax credit. Former section 48(a)(4) effectively stated that property owned by a tax-exempt entity could not be investment tax credit property. Revenue Ruling 78–268 concluded that the two investor-owned utilities were eligible for the investment tax credit despite the fact that the electric generating facility was not credit-eligible property in the hands of the tax-exempt entities. This revenue ruling has been interpreted to stand for the proposition that fractional interests in common tenancies should be treated as separate assets for Federal income tax purposes.

Several commenters requested the adoption of a rule that separate parties that own an interest in energy property are eligible for the section 48 credit to the extent of their fractional ownership interests. Further, these commenters also requested the adoption of a rule that, if components of energy property are owned by separate taxpayers, each taxpayer would be eligible for the section 48 credit to the extent of their cost basis in the components of energy property that they own. These commenters cite Revenue Ruling 78–268 as support for the proposition that fractional interests in common tenancies should be treated as separate assets for Federal income tax purposes.

Many commenters requested that the regulations address situations involving energy property with multiple owners, such as solar condos and community solar facilities. These commenters requested that the regulations be clarified to state that shared ownership does not affect the credit eligibility of an energy property, regardless of the ownership structure. To support this position, several commenters cite to section 25C(e)(1) (redesignated as section 25C(f)(1) of the Code by the IRA) and section 25D(e)(5) that treat a tenant-stockholder (as defined in section 216 of the Code) in a cooperative housing corporation (as defined in section 216) as making his or her proportionate share (as defined in section 216(b)(3)) of any expenditures of such corporation. Similarly, sections 25C(f)(1) and 25D(e)(6) treat an individual member of a condominium management association as having made the individual's proportionate share of any expenditures of such association. As a result, a tenant-stockholder in a cooperative or a member of a condominium association may claim a section 25C or 25D credit for their proportional share of the expenditure of the cooperative or condominium association for credit eligible property.

Several commenters expressed concerns about credit eligibility and the ownership of offshore wind property. For example, a group of commenters requested confirmation that certain transfer and power conditioning equipment necessary to deploy offshore wind is eligible for a section 48 credit, but also that the transfer and power conditioning equipment is eligible for section 48 even if owned by a separate entity from the entity that owns the offshore wind turbines or if the transfer and power conditioning equipment is shared between multiple offshore wind facilities as part of a shared transmission solution.

The Treasury Department and the IRS have determined that a taxpayer that owns an energy property is eligible for the section 48 credit only to the extent of the taxpayer's eligible basis in the energy property. In the case of multiple parties that hold ownership shares in an energy property, each party is eligible for the section 48 credit to the extent of the party's fractional ownership interest. Proposed § 1.48–14(e)(2) would adopt this position. Proposed § 1.48–14(e)(4) also would provide examples illustrating the treatment of multiple owners of an energy property.

As described in part I.D.3 of this Summary of Comments and Explanation of Provisions with regard to qualified offshore wind property, functionally interdependent components do not include power conditioning and transfer equipment such as subsea cables and voltage transformers necessary to condition electricity for use on the electrical grid. However, the power conditioning and transfer equipment are integral parts of the qualified offshore wind property, and thus, are energy property. In contrast, transmission and distribution equipment are not functionally interdependent components of an energy property nor are they an integral part of an energy property. If the taxpayer owns both the unit of energy property and at least a portion of the related power conditioning and transfer equipment, that taxpayer would be able to calculate the section 48 credit on the eligible basis of the energy property, including the taxpayer's basis in the integral power conditioning and transfer equipment. In the case of multiple parties that hold ownership shares in an energy property, each party is eligible for the section 48 credit to the extent of its fractional ownership interest. If power conditioning and transfer equipment owned by one taxpayer is an integral part of an energy property owned by an unrelated taxpayer, the taxpayer that owns the power conditioning and transfer equipment would not be eligible for the section 48 credit but the taxpayer that owns the energy property would be eligible for the section 48 credit.

For example, if Taxpayer A owns only power conditioning and transfer equipment that is an integral part of an energy property owned by unrelated Taxpayer B, Taxpayer A would not be eligible for the section 48 credit. However, this would not prevent Taxpayer B from claiming a section 48 credit on the basis of the energy property that it owns. In addition, if unrelated taxpayers Taxpayer A and Taxpayer B jointly own power conditioning and transfer equipment that is an integral part of a qualified offshore wind facility, but only Taxpayer B owns the unit of energy property (that is, the qualified offshore wind facility), only Taxpayer B may claim the section 48 credit. The amount of Taxpayer B's section 48 credit is calculated by taking into account both Taxpayer B's share of the basis in the power conditioning and transfer equipment and Taxpayer B's basis in the unit of energy property (that is, Taxpayer B's basis in qualified offshore wind facility).

2. Related Taxpayers

Section 48 does not define the term ''related taxpayers.'' This term was defined in existing § 1.48–9(q)(10)(i) in the context of qualified intercity buses. This provision states that related taxpayers are treated as one taxpayer in determining the increase in operating capacity of qualifying intercity buses and in determining the qualified investment in qualified intercity buses for the energy credit. Existing § 1.48–9(q)(10)(i) also provides that related taxpayers are members of a group of trades or businesses that are under common control (as defined in § 1.52–1(b)). The Treasury Department and the IRS received no comments regarding the related taxpayer rule in response to Notice 2015–70. As a result, proposed § 1.48–14(e)(3) would incorporate the rule provided in the existing regulations.

F. Coordination With Other Code Provisions

1. Election To Treat Qualified Facilities as Energy Property

Section 48(a)(5) allows a taxpayer that owns a qualified facility (as defined in

section 45(d)) to elect to claim the section 48 credit in lieu of the section 45 credit. Section 48(a)(5)(A) provides that if the taxpayer makes an election, the qualified facility will be treated as part of a qualified investment credit facility, and therefore deemed energy property eligible for a section 48 credit. A qualified investment credit facility is defined in section 48(a)(5)(C) as a qualified facility described in section 45(d)(1)–(4), (6), (7), (9), or (11), with respect to which no credit has been allowed under section 45, and for which the taxpayer makes an irrevocable election to claim the section 48 credit in lieu of any section 45 credit. Qualified facilities for which a taxpayer is eligible to make an election under section 48(a)(5) include wind, closed- and open-loop biomass, geothermal, solar, landfill gas, trash, hydropower, marine and hydrokinetic facilities.

Only with respect to a qualified investment credit facility, section 48(a)(5)(D) defines ''qualified property'' as tangible personal property or other tangible property (not including a building or its structural components), but only if such property is used as an integral part of the qualified investment credit facility; with respect to which depreciation (or amortization in lieu of depreciation) is allowable; that is constructed, reconstructed, erected, or acquired by the taxpayer; and the original use of the property commences with the taxpayer.

Notice 2009–52, 2009–25 I.R.B. 1094, provides taxpayers with procedures to make an election under section 48(a)(5). Proposed § 1.48–14(f)(6) would adopt the procedures in Notice 2009–52 and, as a result, Notice 2009–52 will be obsoleted upon the publication of the final regulations in the **Federal Register**.

a. Interaction of Section 45 Credit Requirements With Section 48 Credit

In response to Notice 2015–70, several commenters requested that the regulations address whether and to what extent the definition of ''qualified investment credit facility'' provided in section 48(a)(5)(C) makes the rules that generally apply for determining a taxpayer's section 45 credit applicable to qualified facilities for which the taxpayer makes an election. Additionally, Notice 2022–49 requested comments on whether guidance is needed to determine whether a qualified investment credit facility that elects to claim the section 48 credit in lieu of the section 45 credit is subject to all of the requirements of section 45, including the requirement that electricity generated by the qualified investment credit facility be sold to an unrelated person, and what factors the Treasury Department and the IRS should consider regarding such guidance. Several commenters responded and generally were not supportive of imposing the requirements of section 45 on a qualified investment credit facility that elects to claim the section 48 credit in lieu of the section 45 credit. One commenter pointed out, for example, that section 48 only cross-references specific provisions of section 45(d) and not all of section 45(d) nor all of section 45. This commenter noted that because section 48 is an investment tax credit rather than a production tax credit, the rationale for requiring sales of energy from a qualified investment credit facility to unrelated persons is inapplicable.

Section 45(a) sets forth the amount of the production tax credit for a taxable year. It does not determine whether a facility is a ''qualified facility'' (that definition is set forth in section 45(d)). Section 45(a) specifies the amount of the credit for a qualified facility by formula (0.3 cents (increased credit amount under section 45(a)(6) if the requirements of 45(a)(6)(B) are met) multiplied by the kWh of electricity generated and sold to an unrelated person. This statutory structure appears to make the requirement that electricity be sold to an unrelated person relevant only for determining the amount of the section 45 tax credit, not eligibility for the section 48 tax credit. Therefore, after consideration of these comments, the Treasury Department and the IRS have determined that the requirements of section 45 are not imposed on a qualified investment credit facility that elects to claim the section 48 credit in lieu of the section 45 credit. Proposed § 1.48–14(f)(1) would adopt this position.

b. Time and Manner of Making Election

Section 2 of Notice 2009–52 provides that, to make the election with respect to a qualified facility, a taxpayer must claim the energy credit on a completed Form 3468, *Investment Credit,* and file such form with the taxpayer's income tax return for the year in which the property is placed in service. The taxpayer must make a separate election for each qualified facility that is to be treated as a qualified investment credit facility. Proposed § 1.48–14(f)(6)(i) would adopt this procedure with some modifications. If any taxpayer owning an interest in a qualified investment credit facility makes an election under section 48(a)(5), that election would be binding on all taxpayers that directly or indirectly own an interest in the facility.

Additionally, proposed § 1.48–14(f)(6)(ii) would provide a similar special rule for partnerships and S corporations, which would require that the election be made at the entity level and is binding on all ultimate credit claimants (as defined in § 1.50–1(b)(3)(ii)) who must claim the credit in proportion to their respective qualified investment in the energy property. The credit is claimed on each claimant's completed Form 3468, or any successor form(s), and filed with a timely filed (including extensions) return for the taxable year in which the partnership or S corporation makes the election.

2. Coordination Between Section 42 and 48 Credits

Section 50(c)(3)(A) provides the general rule that a taxpayer's basis in an energy property is reduced by 50 percent of the amount of a section 48 credit determined with respect to the taxpayer's investment in the energy property. Section 13102(i) of the IRA amended section 50(c) to provide an exception to that rule for property placed in service after December 31, 2022. As a result, a taxpayer that has claimed a section 48 credit with respect to its basis in an energy property is not required to reduce its basis in the energy property when determining eligible basis for purposes of calculating a low-income housing credit under section 42 of the Code (section 42 credit). Accordingly, the basis of energy property may be used to determine a section 48 credit and may also be included in eligible basis when determining a section 42 credit.

G. Rules for Certain Lower-Output Energy Properties To Include Qualified Interconnection Costs in the Basis of Associated Energy Property

Section 13102(j) of the IRA added section 48(a)(8)(A) to the Code, which provides that, for purposes of determining the section 48 credit with respect to energy property (as defined in section 48(a)(3)) that has a maximum net output of not greater than 5 MW (as measured in alternating current) (Five-Megawatt Limitation), a taxpayer may include amounts paid or incurred by the taxpayer for qualified interconnection property in connection with the installation of the energy property to provide for the transmission or distribution of the electricity produced or stored by such energy property. Additionally, these costs must be properly chargeable to the capital account of the taxpayer.

Section 48(a)(8)(B) defines ''qualified interconnection property'' to mean, with respect to an energy project that is not

a microgrid controller, any tangible property that is part of an addition, modification, or upgrade to a transmission or distribution system that is required at or beyond the point at which the energy project interconnects to such transmission or distribution system in order to accommodate such interconnection; either that is constructed, reconstructed, or erected by the taxpayer, or for which the cost with respect to the construction, reconstruction, or erection of such property is paid or incurred by such taxpayer; and the original use of which, pursuant to an interconnection agreement, commences with a utility.

Section 48(a)(8)(C) defines an ''interconnection agreement'' as an agreement with a utility for the purposes of interconnecting the energy property owned by such taxpayer to the transmission or distribution system of such utility.

Section 48(a)(8)(D) defines the term ''utility'' for purposes of section 48(a)(8) as the owner or operator of an electrical transmission or distribution system that is subject to the regulatory authority of a State or political subdivision thereof, any agency or instrumentality of the United States, a public service or public utility commission or other similar body of any State or political subdivision thereof, or the governing or ratemaking body of an electric cooperative.

Section 48(a)(8)(E) provides a special rule for interconnection property. In the case of expenses paid or incurred for interconnection property, amounts otherwise chargeable to capital account with respect to such expenses must be reduced under rules similar to the rules of section 50(c).

1. Qualified Interconnection Property

Notice 2022–49 requested comments on several aspects of the treatment of qualified interconnection property, specifically the types of eligible costs, the required documentation, and the Five-Megawatt Limitation.

Qualified interconnection property costs arise from installation of tangible property that is part of an addition, modification, or upgrade to a transmission or distribution system at or beyond the point of interconnection. Energy property includes all functionally interdependent property owned by the taxpayer. Additionally, property owned by the taxpayer that is an integral part of such energy property is energy property. This may include power conditioning equipment owned by the taxpayer and used to condition electricity into a form suitable for use or transmission. However, qualified interconnection property, which is most similar in function to transmission and distribution property, is neither property that is a functionally interdependent component of an energy property nor an integral part of an energy property. Therefore, qualified interconnection property is not energy property. Accordingly, proposed § 1.48–14(g)(2) would clarify that qualified interconnection property is not taken into account in determining whether an energy property satisfies the requirements for the domestic content bonus credit amount referenced in section 48(a)(12)(B) and the increase in credit rate for energy communities provided in section 48(a)(14).

Consistent with section 48(a)(8)(A), however, proposed § 1.48–14(g) would clarify that, in connection with the installation by a taxpayer of energy property (as defined in section 48(a)(3)) that has a maximum net output of not greater than 5 MW (as measured in alternating current), amounts paid or incurred by the taxpayer for qualified interconnection property that is required to accommodate the interconnection are included in the basis of a related energy property. Additionally, proposed § 1.48–14(g)(3) would provide that the maximum net output of an energy property is measured only by nameplate generating capacity of the unit of energy property (or, in the case of energy storage technology, the nameplate capacity of such energy storage technology) at the time the energy property is placed in service.

2. Costs Included in Basis of Related Energy Property

Proposed § 1.48–14(g)(1) would provide that only amounts paid or incurred by a taxpayer for property that is constructed, reconstructed, or erected by the taxpayer, or for which the cost with respect to the construction, reconstruction, or erection of such property is paid or incurred by such taxpayer, will be included in the basis of a related energy property. A taxpayer that is reimbursed for these costs may not include such reimbursed costs in the amount paid or incurred by the taxpayer for qualified interconnection property. Proposed § 1.48–14(g)(6) would adopt this rule. In the case of a utility reimbursing a taxpayer for costs the taxpayer pays or incurs for qualified interconnection property, the utility should provide the taxpayer with information regarding such costs by the date on which the project is placed in service.

The Treasury Department and the IRS are aware of common situations where a taxpayer could ultimately receive a payment, credit, or service from another entity, including a utility, related to the costs the taxpayer pays or incurs for qualified interconnection property. For example, one taxpayer may place in service energy property and make payments to a utility with respect to qualified interconnection property involving the addition, modification, or upgrade to the utility's transmission system related to such energy property. Subsequently, a different taxpayer may, at a later date, place in service energy property and make payments to the same utility related to the same additions, modifications, or upgrades to the utility's transmission system that were made in response to the first taxpayer's interconnection. The utility may pay, credit, or provide services to the first taxpayer in an amount related to the costs paid by the second taxpayer. The likely amount or timing of any such payment, credit, or service would not be known at the time the first taxpayer interconnects to the utility's transmission system.

The Treasury and the IRS request comment on whether such payment, credit, or service received by the first taxpayer, as the result of subsequent payments made to a utility by other parties, should be treated as a reimbursement to the first taxpayer and impact the amount of the costs of qualified interconnection property that the first taxpayer may include in its basis for purposes of the section 48 credit. The Treasury and the IRS also request comment on whether the costs paid by the second taxpayer should be treated as amounts paid or incurred for qualified interconnection property in connection with the installation of the second taxpayer's energy property. The Treasury and IRS request comment on industry practices relevant to the determination of costs paid or incurred for qualified interconnection property, including the accounting treatment of costs paid or incurred for qualified interconnection property. The Treasury and the IRS also request comment on whether any clarifications are needed regarding the tax treatment of amounts paid or incurred for qualified interconnection property, including reimbursement of costs paid or incurred by a taxpayer for qualified interconnection costs.

In section 3.02(1)(b)(ii) of Notice 2022–49, the Treasury Department and the IRS requested comments concerning what type of documentation, in addition to interconnection agreements and cost certification reports, is readily available for a taxpayer to demonstrate that they have paid or incurred interconnection costs. Taxpayers must retain

documentation in compliance with section 6001 of the Code. The proposed regulations do not provide any specific type of required documentation, and any documentation that satisfies section 6001 will suffice to substantiate that a taxpayer has paid or incurred qualified interconnection costs. Commenters to Notice 2022–49 provided feedback on the documentation that taxpayers may use to substantiate costs paid or incurred for qualified interconnection property.

Qualified interconnection property is either constructed, reconstructed, or erected by the taxpayer, or the taxpayer pays or incurs the cost with respect to the construction, reconstruction, or erection of such property; and the original use of which, pursuant to an interconnection agreement, commences with a utility. Therefore, in some cases, taxpayers will have the necessary information and documentation on these costs. In other cases, the taxpayers will need to receive this information from the utility, which, the Treasury Department and the IRS understand, will be a common scenario. For situations in which property is constructed, reconstructed, or erected by a party other than the taxpayer, final information with conclusive details such as a true-up report with the actual costs, final invoices, proof of payment or reimbursement, and permission to operate documentation or any other final project accounting documentation should be maintained. Other examples of cost documentation records include, but are not limited to, the interconnection agreement, interconnection study, signed customer contracts, and cost certification reports.

3. Five-Megawatt Limitation

Under section 48(a)(8)(A), energy property includes amounts paid or incurred by the taxpayer for qualified interconnection property in connection with the installation of energy property only if it has a maximum net output of not greater than 5 MW (as measured in alternating current). The addition of amounts paid or incurred by the taxpayer for qualified interconnection property in section 48(a)(8)(A) is tied to the installation of ''energy property.'' The statute clearly ties the 5 MW limitation to the energy property; therefore, as long as an energy property is 5 MW or less, the statute is satisfied. Additionally, measurement at the level of the energy property provides certainty for taxpayers and the IRS because it is measured by the energy property's maximum net output when it is placed in service. Therefore, proposed § 1.48–14(g)(3) would provide that the Five-Megawatt Limitation must be measured at the level of the energy property. Proposed § 1.48–14(g)(7) also would provide examples illustrating the application of this rule.

In accordance with proposed § 1.48–14(g)(3), if an energy project comprised of multiple energy properties has a combined nameplate capacity in excess of 5 MW, each of the energy properties would nonetheless be eligible to include amounts paid or incurred by the taxpayer for qualified interconnection property if each energy property satisfies the Five-Megawatt Limitation. The Treasury Department and the IRS request comments regarding the application of the Five-Megawatt Limitation to a single energy property, including whether the definition of an energy property is sufficiently clear for this purpose. In addition, the Treasury Department and the IRS request comments regarding the circumstances under which multiple energy properties each with a nameplate capacity of less than 5 MW would utilize common power conditioning equipment for economic or regulatory reasons and/or common interconnection agreements, or would instead utilize separate power conditioning equipment and/or interconnection agreements.

4. Non-Application to Certain Types of Energy Properties

The definition of qualified interconnection property specifically excludes interconnection property installed with respect to an energy project that is a microgrid controller. Additionally, taxpayers may not include the costs of qualified interconnection property in the basis of electrochromic glass property and fiber optic solar energy property because these types of energy property do not require additions, modifications, or upgrades to a transmission or distribution system. Similarly, in the case of energy properties that generate thermal energy, such as certain geothermal property and qualified biogas property, this provision is inapplicable.

Effect on Other Documents

Notice 2009–52 will be obsoleted upon publication of the final regulations in the **Federal Register**. Notice 2009–52, in relevant part, provides procedures for taxpayers to make an irrevocable election under section 48(a)(5) to treat qualified property that is part of a qualified investment credit facility as energy property eligible for a section 48 credit in lieu of a section 45 credit.

Proposed Applicability Dates

Except for the provisions of proposed §§ 1.48–13 and 1.6418–5(f), these regulations generally are proposed to apply with respect to property that is placed in service after December 31, 2022, and during a taxable year beginning after the date final regulations are published in the **Federal Register**. Proposed § 1.6418–5(f) is proposed to apply to taxable years ending on or after the date final regulations are published in the **Federal Register**. A taxpayer may rely on proposed §§ 1.48–9, 1.48–14, and 1.6418–5(f) with respect to property that is placed in service after December 31, 2022, and during a taxable year beginning on or before the date final regulations are published in the **Federal Register**, provided the taxpayer and all related persons (within the meaning of sections 267(b) and 707(b) of the Code) apply proposed §§ 1.48–9 and 1.48–14 in their entirety and in a consistent manner.

Proposed § 1.48–13 is proposed to apply to projects placed in service in taxable years ending after the date final regulations are published in the **Federal Register**, and the construction of which begins after the date final regulations are published in the **Federal Register**. However, proposed § 1.48–13(d) is proposed to apply to energy projects the construction of which begins after November 22, 2023. Taxpayers may rely on § 1.48–13 with respect to construction of a property or project beginning on or after January 29, 2023, and on or before the date these regulations are published as final regulations in the **Federal Register**, provided, that beginning after the date that is 60 days after August 29, 2023, taxpayers follow proposed § 1.48–13 in its entirety and in a consistent manner.

Special Analyses

I. Regulatory Planning and Review—Economic Analysis

Pursuant to the Memorandum of Agreement, Review of Treasury Regulations under Executive Order 12866 (June 9, 2023), tax regulatory actions issued by the IRS are not subject to the requirements of section 6 of Executive Order 12866, as amended. Therefore, a regulatory impact assessment is not required.

II. Paperwork Reduction Act

The Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520) (PRA) requires that a Federal agency obtain the approval of Office of Management and Budget (OMB) before collecting information from the public, whether such collection of information is

mandatory, voluntary, or required to obtain or retain a benefit. A Federal agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection of information displays a valid control number.

The collections of information in these proposed regulations contain reporting and recordkeeping requirements that are required to verify the eligibility of the property for the credit. These collections of information would generally be used by the IRS for tax compliance purposes and by taxpayers to facilitate proper reporting and compliance.

The reporting requirement mentioned within this proposed regulations with respect to section 48 are in proposed § 1.48–14(f)(6), which provides the time and manner for a taxpayer to make a section 48(a)(5)(C) an election to have qualified investment credit facility property that was placed in service after December 31, 2008, treated as a qualified investment credit facility for purposes of claiming the section 48 credit. These requirements are considered general tax records under § 1.6001–1.

A taxpayer must make a section 48(a)(5)(C) election on a completed Form 3468 (Investment Credit) (or successor forms, or pursuant to instructions and other guidance) with the taxpayer's timely filed return (including extensions) for the taxable year in which the energy property is placed in service. The taxpayer must make a separate section 48(a)(5)(C) election for each qualified facility that is to be treated as a qualified investment credit facility. These collections are included in Notice 2009–52, 2009–1 C.B. 1094, which is already approved under OMB Control Number 1545–2145 for all filers. Also, the election selection is included on, Form 3468, which is already approved in OMB Control Numbers 1545–0155 for trust and estate filers, 1545–0074 for individual filers, and 1545–0123 for business filers. This proposed regulation is not changing the collection requirements already approved by OMB.

These proposed regulations would also include reporting requirements, in addition to the general reporting requirements set forth in in § 1.45–12 of the August Proposed Regulations, for taxpayers that claim an increased credit amount under section 48(a)(9)(B)(iii). These proposed regulations would require taxpayers to verify compliance with the Prevailing Wage Requirements by providing information that includes the aggregate information detailed in § 1.45–12 of the August Proposed Regulations during the five-year recapture period after an energy project is placed in service. The Secretary may issue forms and instructions in future guidance for the purpose of meeting these reporting requirements. As set forth in the preamble to the August Proposed Regulations, these reporting requirements will be covered under OMB control numbers 1545–0074 for individuals/sole proprietors and 1545–0123 for business entities. The IRS has solicited public comments on these requirements and the associated burdens for trusts and estates and has sought OMB approval under a new OMB control number (1545–NEW) for trust and estate filers. This proposed regulation is not changing or creating new collection requirements not already approved by, or will be approved by, OMB for the § 1.45–12.

These proposed regulations also describe recapture procedures as detailed in proposed § 1.6418–5. The reporting of a section 48(a)(10)(C) recapture event will still be required to be reported using Form 4255, *Recapture of Investment Credit.* This form is approved under OMB control numbers 1545–0074 for individuals, 1545–0123 for business entities, and 1545–0166 for trust and estate filers. The proposed regulation is not changing or creating new collection requirements not already approved by OMB.

III. Regulatory Flexibility Act

The Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) (RFA) imposes certain requirements with respect to Federal rules that are subject to the notice and comment requirements of section 553(b) of the Administrative Procedure Act (5 U.S.C. 551 *et seq.*) and that are likely to have a significant economic impact on a substantial number of small entities. Unless an agency determines that a proposal is not likely to have a significant economic impact on a substantial number of small entities, section 603 of the RFA requires the agency to present an initial regulatory flexibility analysis (IRFA) of the proposed rule.

The Treasury Department and the IRS have not determined whether the proposed rule, when finalized, will likely have a significant economic impact on a substantial number of small entities. This determination requires further study. However, because there is a possibility of significant economic impact on a substantial number of small entities, an IRFA is provided in these proposed regulations. The Treasury Department and the IRS invite comments on both the number of entities affected and the economic impact on small entities.

Pursuant to section 7805(f), this notice of proposed rulemaking has been submitted to the Chief Counsel of Advocacy of the Small Business Administration for comment on its impact on small business.

A. Need for and Objectives of the Rule

The proposed regulations will provide greater clarity to taxpayers for purposes of claiming the section 48 credit for energy property. The proposed rule is expected to encourage taxpayers to invest in developing new energy properties, including qualified facilities otherwise eligible for the section 45 credit for which a taxpayer makes a section 48(a)(5)(C) election. Thus, the Treasury Department and the IRS intend and expect that the proposed rule will deliver benefits across the economy that will beneficially impact various industries.

B. Affected Small Entities

The Small Business Administration estimated in its 2018 Small Business Profile that 99.9 percent of United States businesses meet its definition of a small business. The applicability of these proposed regulations does not depend on the size of the business, as defined by the Small Business Administration. As described more fully in the preamble to these proposed regulations and in this IRFA, these rules may affect a variety of different businesses across several different industries.

The section 48 credit incentivizes the development of energy property. Because the potential credit claimants can vary widely, it is difficult to estimate at this time the impact of these proposed regulations, if any, on small businesses.

The Treasury Department and the IRS expect to receive more information on the impact on small businesses through comments on this proposed rule and again when taxpayers start to claim the section 48 credit using the guidance and procedures provided in these proposed regulations.

C. Impact of the Rule

The proposed regulations will allow taxpayers to plan investments and transactions based on the ability to claim the section 48 credit. The increased use of the section 48 credit will incentivize the development of technologies for energy generation and storage. The use of the section 48 credit may also lead to additional investment in electrical grid infrastructure to transport electricity.

Because the statutory changes that are reflected in the proposed rules have already been accounted for by Form 3468, the recordkeeping and reporting requirements should not increase for taxpayers that already claim the section 48 credit. The Form 3468 already provides the procedures for taxpayers to make a section 48(a)(5)(C) election. To make the election, a taxpayer must claim the energy credit with respect to a qualified investment credit facility property on a completed Form 3468 (Investment Credit) (or successor forms, or pursuant to instructions and other guidance) and file such form with the taxpayer's timely filed return (including extensions) for the taxable year in which the property is placed in service. Although the Treasury Department and the IRS do not have sufficient data to precisely determine the likely extent of the increased costs of compliance, the estimated burden of complying with the recordkeeping and reporting requirements are described in the Paperwork Reduction Act section of the preamble.

D. Duplicative, Overlapping, or Conflicting Federal Rules

The proposed rule would not duplicate, overlap, or conflict with any relevant Federal rules. As discussed above, the proposed rule would merely provide procedures and definitions to allow taxpayers to claim the section 48 credit.

IV. Unfunded Mandates Reform Act

Section 202 of the Unfunded Mandate Reform Act of 1995 (UMRA) requires that agencies assess anticipated costs and benefits and take certain other actions before issuing a final rule that includes any Federal mandate that may result in expenditures in any one year by a State, local, or Tribal government, in the aggregate, or by the private sector, of $100 million (updated annually for inflation). These proposed regulations do not include any Federal mandate that may result in expenditures by State, local, or Tribal governments or by the private sector in excess of that threshold.

V. Executive Order 13132: Federalism

Executive Order 13132 (Federalism) prohibits an agency from publishing any rule that has federalism implications if the rule either imposes substantial, direct compliance costs on State and local governments, and is not required by statute, or preempts State law, unless the agency meets the consultation and funding requirements of section 6 of the Executive order. These proposed regulations do not have federalism implications and do not impose substantial, direct compliance costs on State and local governments or preempt State law within the meaning of the Executive order.

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

Executive Order 13175 (Consultation and Coordination With Indian Tribal Governments) prohibits an agency from publishing any rule that has Tribal implications if the rule either imposes substantial, direct compliance costs on Indian Tribal governments, and is not required by statute, or preempts Tribal law, unless the agency meets the consultation and funding requirements of section 5 of the Executive order. This proposed rule does not have substantial direct effects on one or more Federally recognized Indian Tribes and does not impose substantial direct compliance costs on Indian Tribal governments within the meaning of the Executive order.

Statement of Availability of IRS Documents

IRS notices and other guidance cited in this preamble are published in the Internal Revenue Bulletin (or Cumulative Bulletin) and are available from the Superintendent of Documents, U.S. Government Publishing Office, Washington, DC 20402, or by visiting the IRS website at *https://www.irs.gov.*

Comments and Public Hearing

Before these proposed amendments to the regulations are adopted as final regulations, consideration will be given to any comments regarding the notice of proposed rulemaking and partial withdrawal of notice of proposed rulemaking that are submitted timely to the IRS in the preamble under the **ADDRESSES** section. The Treasury Department and the IRS request comments on all aspects of the proposed regulations. All comments submitted will be made available at *http://www.regulations.gov* or upon request for public inspection and copying.

A public hearing has been scheduled for February 20, 2024, at 10 a.m. ET, in the Auditorium at the Internal Revenue Building, 1111 Constitution Ave. NW, Washington, DC. Because of access restrictions, visitors will not be admitted beyond the immediate entrance area more than 30 minutes before the hearing starts. Participants may alternatively attend the public hearing by telephone.

The rules of 26 CFR 601.601(a)(3) apply to the public hearing. Persons who wish to present oral comments at the public hearing must submit an outline of the topics to be discussed and the time to be devoted to each topic by January 22, 2024. A period of 10 minutes will be allotted to each person for making comments. An agenda showing the scheduling of the speakers will be prepared after the deadline for receiving outlines has passed. Copies of the agenda will be available free of charge at the public hearing. If no outline of the topics to be discussed at the public hearing is received by January 22, 2024, the public hearing will be cancelled. If the public hearing is cancelled, a notice of cancellation of the public hearing will be published in the **Federal Register**.

Individuals who want to testify in person at the public hearing must send an email to *publichearings@irs.gov* to have your name added to the building access list. The subject line of the email must contain the regulation number REG–132569–17 and the language TESTIFY In Person. For example, the subject line may say: Request to TESTIFY In Person at Hearing for regulation number REG–132569–17.

Individuals who want to testify by telephone at the public hearing must send an email to *publichearings@irs.gov* to receive the telephone number and access code for the hearing. The subject line of the email must contain the regulation number REG–132569–17 and the language TESTIFY Telephonically. For example, the subject line may say: Request to TESTIFY Telephonically at Hearing for REG–132569–17.

Individuals who want to attend the public hearing in person without testifying must also send an email to *publichearings@irs.gov* to have your name added to the building access list. The subject line of the email must contain the regulation number REG–132569–17 and the language ATTEND In Person. For example, the subject line may say: Request to ATTEND Hearing in Person for REG–132569–17. Requests to attend the public hearing must be received by 5:00 p.m. on February 15, 2024.

Hearings will be made accessible to people with disabilities. To request special assistance during a hearing please contact the Publications and Regulations Branch of the Office of Associate Chief Counsel (Procedure and Administration) by sending an email to *publichearings@irs.gov* (preferred) or by telephone at (202) 317–6901 (not a toll-free number) by at least 5:00 p.m. on February 14, 2024.

Drafting Information

The principal authors of these proposed rules are Martha M. Garcia

and Boris Kukso of the Office of Associate Chief Counsel (Passthroughs & Special Industries). However, other personnel from the Treasury Department and the IRS participated in their development.

List of Subjects in 26 CFR Part 1

Income taxes, Reporting and recordkeeping requirements.

Partial Withdrawal of Notice of Proposed Rulemaking

Under the authority of 26 U.S.C. 7805, proposed § 1.48–13 contained in the notice of proposed rulemaking (REG–100908–23) that was published in the **Federal Register** on August 30, 2023 (88 FR 60018), is withdrawn.

Proposed Amendments to the Regulations

Accordingly, the Treasury Department and the IRS propose to amend 26 CFR part 1 as follows:

PART 1—INCOME TAXES

■ **Paragraph 1.** The authority citation for part 1 is amended by:
■ a. Revising the entry for § 1.48–9; and
■ b. Adding entries in numerical order for §§ 1.48–13, 1.48–14, and 1.6418–5.

The revision and additions read in part as follows:

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

* * * * *

Section 1.48–9 also issued under 26 U.S.C. 48(a)(3)(D)(i) and (16). * * *

Section 1.48–13 also issued under 26 U.S.C. 48(a)(10)(C) and (16). * * *

Section 1.48–14 also issued under 26 U.S.C. 48(a)(16). * * *

* * * * *

Section 1.6418–5 also issued under 26 U.S.C. 48(a)(10)(C) and 6418(g) and (h).

* * * * *

■ **Par. 2.** Revise § 1.48–9 to read as follows:

§ 1.48–9 Definition of energy property.

(a) *In general.* For purposes of the energy credit determined under section 48 of the Internal Revenue Code (Code), the term *energy property* means property that, taking into account the definition of the term *unit of energy property* (defined in paragraph (f)(2)(i) of this section) and of other terms defined in paragraph (b) and other provisions of this section, meets the requirements of paragraph (c) of this section and is of a type of energy property set forth in paragraph (e) of this section. Paragraph (d) of this section provides rules for property excluded from energy property. Paragraph (f) of this section provides rules for components included in an energy property. Paragraph (g) of this section provides the applicability date for this section.

(b) *Definitions related to requirements for energy property.* For purposes of section 48 of the Code, this section, §§ 1.48–13 and 1.48–14, and any provision of the Code or this chapter that expressly refers to any of the foregoing, the following definitions apply:

(1) *Construction, reconstruction, or erection of energy property.* The term *construction, reconstruction, or erection of energy property* means work performed to construct, reconstruct, or erect energy property either by the taxpayer or for the taxpayer in accordance with the taxpayer's specifications.

(2) *Acquisition of energy property.* The term *acquisition of energy property* means a transaction by which a taxpayer obtains rights and obligations with respect to energy property, including—

(i) Title to the energy property under the law of the jurisdiction in which the energy property is placed in service, unless the property is possessed or controlled by the taxpayer as a lessee, and

(ii) Physical possession or control of the energy property.

(3) *Original use of energy property*—(i) *In general.* The term *original use of energy property* means the first use to which a unit of energy property is put, whether or not such use is by the taxpayer.

(ii) *Retrofitted units of energy property.* A retrofitted unit of energy property acquired by the taxpayer will not be treated as being put to original use by the taxpayer unless the rules in § 1.48–14(a) regarding retrofitted energy property (80/20 Rule) or paragraph (e)(10)(v) of this section regarding modifications of certain energy storage technology apply. The question of whether a unit of energy property meets the 80/20 Rule or is modified (as described in paragraph (e)(10)(v) of this section) is a facts and circumstances determination.

(4) *Allowable*—(i) *In general.* For purposes of applying paragraph (c)(1)(ii) of this section, depreciation (or amortization in lieu of depreciation) is *allowable* with respect to energy property if such property is of a character subject to the allowance for depreciation under section 167 of the Code and the basis or cost of such property is recovered using a method of depreciation (for example, the straight line method), which includes any additional first year depreciation deduction method of depreciation (for example, under section 168(k) of the Code). Further, if an Internal Revenue Service adjustment with respect to the Federal income tax or information return for such taxable year requires the basis or cost of such energy property to be recovered using a method of depreciation, depreciation is allowable to the taxpayer with respect to energy property.

(ii) *Exclusions from allowable.* For purposes of paragraph (b)(4)(i) of this section, depreciation is not allowable with respect to energy property if the basis or cost of such property is not recovered through a method of depreciation but, instead, such basis or cost is recovered through a deduction of the full basis or cost of the energy property in one taxable year (for example, under section 179 of the Code).

(5) *Placed in service*—(i) *In general.* Energy property is considered placed in service in the earlier of:

(A) The taxable year in which, under the taxpayer's depreciation practice, the period for depreciation with respect to such energy property begins; or

(B) The taxable year in which the energy property is placed in a condition or state of readiness and availability for a specifically assigned function, whether in a trade or business or in the production of income. Energy property in a condition or state of readiness and availability for a specifically assigned function includes, but is not limited to, components that are acquired and set aside during the taxable year for use as replacements for a particular energy property (or energy properties) in order to avoid operational time loss and equipment that is acquired for a specifically assigned function and is operational but is undergoing testing to eliminate any defects. However, components acquired to be used in the construction of an energy property will not be considered in a condition or state of readiness and availability for a specifically assigned function.

(ii) *Energy property subject to § 1.48–4 election to treat lessee as purchaser.* Notwithstanding paragraph (b)(5)(i) of this section, energy property with respect to which an election is made under § 1.48–4 to treat the lessee as having purchased such energy property is considered placed in service by the lessor in the taxable year in which possession is transferred to such lessee.

(6) *Unit of energy property.* The term *unit of energy property* is defined in paragraph (f)(2)(i) of this section. No provision of this section or § 1.48–13 or § 1.48–14 uses the term *unit* in respect of energy property with any meaning other than that provided in paragraph (f)(2)(i) of this section.

(7) *Claim.* With respect to a section 48 credit determined with respect to energy property of a taxpayer, the term *claim* means filing a completing Form 3468, *Investment Credit,* or any successor form(s), with the taxpayer's timely filed (including extensions) Federal income tax return for the taxable year in which the energy property is placed in service, and includes the making of an election under section 6417 or 6418 of the Code and corresponding regulations with respect to such section 48 credit and made on the taxpayer's Federal income tax return or annual information return.

(c) *Requirements for energy property*—(1) *In general.* Energy property must satisfy each of the requirements of paragraphs (c)(1)(i) through (v) of this section:

(i) The taxpayer constructs, reconstructs, or erects the property, or, if the original use of the property commences with the taxpayer, acquires the property;

(ii) Depreciation (or amortization in lieu of depreciation) is allowable with respect to the property;

(iii) The property meets the performance and quality standards as provided in paragraph (c)(2) of this section;

(iv) The construction of the property begins before the date provided in section 48 of the Code (if any such date is provided); and

(v) The property is placed in service by the taxpayer by the date provided in section 48 (if any such date is provided).

(2) *Performance and quality standards*—(i) *In general.* Energy property must meet performance and quality standards, if any, which have been prescribed by the Secretary of the Treasury or her delegate (after consultation with the Secretary of Energy) and are in effect at the time of acquisition of the energy property.

(ii) *Special rules for performance and quality standards*—(A) *Small wind energy property.* Small wind energy property must meet the performance and quality standards in effect at the time of acquisition of the small wind turbine set forth in the American Wind Energy Association Small Wind Turbine Performance and Safety Standard 9.1–2009, or subsequent revisions (AWEA); International Electrotechnical Commission 61400–1, 61400–2, 61400–11, 61400–12, or subsequent revisions (IEC); or the ANSI/ACP 101–1–2021, the Small Wind Turbine Standard, or subsequent revisions (ACP). The certification requirements applicable to such performance and quality standards are provided in guidance published in the Internal Revenue Bulletin. *See* § 601.601 of this chapter.

(B) *Electrochromic glass property.* To be eligible for the section 48 credit, electrochromic windows must be rated in accordance with the National Fenestration Rating Council (NFRC) and secondary glazing systems must be rated in accordance with the Attachments Energy Rating Council (AERC) Rating and Certification Process, or subsequent revisions. *See* paragraph (e)(2)(ii) of this section for the definition of electrochromic glass property.

(iii) *Time of acquisition.* For purposes of applying performance and quality standards, the time of acquisition is the date the taxpayer enters into a binding contract (as defined in paragraph (c)(2)(iv) of this section) to acquire the property, or, in the case of property constructed, reconstructed, or erected by the taxpayer, the earlier of the date that—

(A) The taxpayer begins construction, reconstruction, or erection of the property, or

(B) The taxpayer and another person enter into a binding contract (as defined in paragraph (c)(2)(iv) of this section) requiring the other person to construct, reconstruct, or erect property and to place the property in service for an agreed upon use.

(iv) *Binding contract.* For purposes of this paragraph (c)(2), a contract is binding only if it is enforceable under State law against the taxpayer or a predecessor and does not limit damages to a specified amount (for example, by use of a liquidated damages provision). For this purpose, a contractual provision that limits damages to an amount equal to at least five percent of the total contract price will not be treated as limiting damages to a specified amount. For additional guidance regarding the definition of a binding contract, see § 1.168(k)–2(b)(5)(iii)(A).

(d) *Property that is not energy property*—(1) *Interaction with section 45.* Energy property does not include any property that is part of a qualified facility the production from which is allowed as a credit determined under section 45 of the Code (section 45 credit) for the taxable year or any prior taxable year. However, see paragraph (f)(3) of this section for rules regarding property that is an integral part of an energy property that is also used by a qualified facility. *See* § 1.48–14(f)(1) for rules regarding making an election under section 48(a)(5) of the Code to treat a qualified facility as an energy property.

(2) *Other property.* Energy property also does not include power purchase agreements, goodwill, going concern value, or renewable energy certificates.

(e) *Types of energy property.* The types of energy property eligible for a section 48 credit are:

(1) *Solar energy property*—(i) *In general. Solar energy property* is equipment that uses solar energy to generate electricity, to heat or cool (or provide hot water for use in) a structure, or to provide solar process heat, excepting property used to generate energy for the purposes of heating a swimming pool. Solar energy property includes solar electric generation equipment (as defined in paragraph (e)(1)(ii) of this section), solar process heat equipment (as defined in paragraph (e)(1)(iii) of this section), and equipment that uses solar energy to heat or cool a structure or provide hot water for use in a structure, and parts related to the functioning of all such equipment.

(ii) *Solar electric generation equipment. Solar electric generation equipment* is equipment that converts sunlight into electricity through the use of devices such as solar cells or other collectors.

(iii) *Solar process heat equipment. Solar process heat equipment* is equipment that uses solar energy to generate steam at high temperatures for use in industrial or commercial processes.

(2) *Fiber-optic solar energy property and electrochromic glass property*—(i) *Fiber-optic solar energy property. Fiber-optic solar energy property* is equipment that uses solar energy to illuminate the inside of a structure using fiber-optic distributed sunlight.

(ii) *Electrochromic glass property. Electrochromic glass energy property* uses electricity to change its light transmittance properties (both visible and near infrared light) in order to heat or cool a structure. For purposes of section 48, windows, including secondary windows (also referred to as secondary glazings), that incorporate electrochromic glass are treated as electrochromic glass property.

(3) *Geothermal energy property*—(i) *In general. Geothermal energy property* is equipment used to produce, distribute, or use energy derived from a geothermal deposit (within the meaning of section 613(e)(2) of the Code), but only, in the case of electricity generated by geothermal power, up to (but not including) the electrical transmission stage. Geothermal equipment includes production equipment (as defined in paragraph (e)(3)(ii) of this section) and distribution equipment (as defined in paragraph (e)(3)(iii) of this section).

(ii) *Production equipment.* For purposes of paragraph (e)(3)(i) of this section, *production equipment* is equipment necessary to bring

geothermal energy from the subterranean deposit to the surface, including well-head and downhole equipment (such as screening or slotting liners, tubing, downhole pumps, and associated equipment). Production, injection, and monitoring wells required for production of the geothermal deposit qualify as production equipment. If geothermal energy is used to generate electricity, production equipment also includes the property necessary to produce electricity. Production equipment does not include equipment used for exploration and development of geothermal deposits.

(iii) *Distribution equipment.* For purposes of paragraph (e)(3)(i) of this section, *distribution equipment* is equipment that transports geothermal energy from a geothermal deposit to the site of ultimate use. If geothermal energy is used to generate electricity, distribution equipment includes equipment that transports geothermal fluids between the geothermal deposit and the power plant. Distribution equipment also includes components of a building's heating and/or cooling system, such as pipes and ductwork that distribute within a building the energy derived from the geothermal deposit.

(4) *Qualified fuel cell property. Qualified fuel cell property* is a fuel cell power plant that has a nameplate capacity of at least 0.5 kilowatts (kW) (1 kW in the case of a fuel cell power plant with a linear generator assembly) of electricity using an electrochemical or electromechanical process, and an electricity-only generation efficiency greater than 30 percent. For this purpose, electricity-only generation efficiency may be calculated by dividing the heat rate of the fuel cell (for example, kilowatt-hours (kWh) electricity produced per kilogram (kg) of fuel consumed) by the higher heating value of the fuel (for example, kWh per kg). A fuel cell power plant is an integrated system comprised of a fuel cell stack assembly, or linear generator assembly, and associated balance of plant components that converts a fuel into electricity using electrochemical or electromechanical means. A linear generator assembly does not include any assembly that contains rotating parts.

(5) *Qualified microturbine property. Qualified microturbine property* is a stationary microturbine power plant that has a nameplate capacity of less than 2,000 kW and an electricity-only generation efficiency of not less than 26 percent at International Standard Organization conditions. A stationary microturbine power plant is an integrated system comprised of a gas turbine engine, a combustor, a recuperator or regenerator, a generator or alternator, and associated balance of plant components that converts a fuel into electricity and thermal energy. A stationary microturbine power plant also includes all secondary components located between the existing infrastructure for fuel delivery and the existing infrastructure for power distribution, including equipment and controls for meeting relevant power standards, such as voltage, frequency, and power factors.

(6) *Combined heat and power system (CHP) property*—(i) *In general. CHP property* is property comprising a system that uses the same energy source for the simultaneous or sequential generation of electrical power, mechanical shaft power, or both, in combination with the generation of steam or other forms of useful thermal energy (including heating and cooling applications). CHP property must produce at least 20 percent of its total useful energy in the form of thermal energy that is not used to produce electrical or mechanical power (or combination thereof), and at least 20 percent of its total useful energy in the form of electrical or mechanical power (or combination thereof). The energy efficiency percentage of CHP property must exceed 60 percent (except in the case of CHP systems that use biomass within the meaning of section 45 of the Code). CHP property does not include any property comprising a system if such system has a capacity in excess of 50 MW or a mechanical energy capacity in excess of 67,000 horsepower or an equivalent combination of electrical and mechanical energy capacities.

(ii) *Components excluded.* CHP property does not include property used to transport the energy source to the generating facility or to distribute energy produced by the facility.

(7) *Qualified small wind energy property.* Qualified small wind energy property is property that uses a qualifying small wind turbine to generate electricity. A qualifying small wind turbine means a wind turbine that has a nameplate capacity of not more than 100 kW.

(8) *Geothermal heat pump equipment.* Geothermal heat pump equipment is equipment that uses the ground, ground water, or other underground fluids as a thermal energy source to heat a structure or as a thermal energy sink to cool a structure.

(9) *Waste energy recovery property (WERP)*—(i) *In general.* WERP is property that generates electricity solely from heat from buildings or equipment if the primary purpose of such building or equipment is not the generation of electricity. Examples of buildings or equipment the primary purpose of which is not the generation of electricity include, but are not limited to, manufacturing plants, medical care facilities, facilities on college campuses, pipeline compressor stations, and associated equipment. WERP does not include any property that has a capacity in excess of 50 MW.

(ii) *Coordination with CHP property.* Any WERP that is part of a system that is a CHP property is not treated as WERP for purposes of section 48 of the Code unless the taxpayer elects to not treat such system as a CHP property for purposes of section 48.

(10) *Energy storage technology*—(i) *In general.* Energy storage technology includes electrical energy storage property described in paragraph (e)(10)(ii) of this section, thermal energy storage property described in paragraph (e)(10)(iii) of this section, and hydrogen energy storage property described in paragraph (e)(10)(iv) of this section.

(ii) *Electrical energy storage property.* Electrical energy storage property is property (other than property primarily used in the transportation of goods or individuals and not for the production of electricity) that receives, stores, and delivers energy for conversion to electricity, and has a nameplate capacity of not less than 5 kWh. For example, subject to the exclusion for property primarily used in the transportation of goods or individuals, electrical energy storage property includes but is not limited to rechargeable electrochemical batteries of all types (such as lithium ion, vanadium flow, sodium sulfur, and lead-acid); ultracapacitors; physical storage such as pumped storage hydropower, compressed air storage, flywheels; and reversible fuel cells.

(iii) *Thermal energy storage property.* Thermal energy storage property is property comprising a system that is directly connected to a heating, ventilation, or air conditioning (HVAC) system; removes heat from, or adds heat to, a storage medium for subsequent use; and provides energy for the heating or cooling of the interior of a residential or commercial building. Thermal energy storage property includes equipment and materials, and parts related to the functioning of such equipment, to store thermal energy for later use to heat or cool, or to provide hot water for use in heating a residential or commercial building. It does not include a swimming pool, CHP property, or a building or its structural components. For example, thermal energy storage includes, but is not limited to, thermal ice storage systems that use electricity to run a refrigeration cycle to produce ice

that is later connected to the HVAC system as an exchange medium for air conditioning the building, heat pump systems that store thermal energy in an underground tank or borehole field to be extracted for later use for heating and/or cooling, and electric furnaces that use electricity to heat bricks to high temperatures and later use this stored energy to heat a building through the HVAC system.

(iv) *Hydrogen energy storage property.* Hydrogen energy storage property is property (other than property primarily used in the transportation of goods or individuals and not for the production of electricity) that stores hydrogen and has a nameplate capacity of not less than 5 kWh, equivalent to 0.127 kg of hydrogen or 52.7 standard cubic feet (scf) of hydrogen. Hydrogen energy storage property must store hydrogen that is solely used as energy and not for other purposes such as for the production of end products such as fertilizer. For example, hydrogen energy storage property includes, but is not limited to, a hydrogen compressor and associated storage tank and an underground storage facility and associated compressors.

(v) *Modifications of energy storage energy property.* With respect to electrical energy storage property and hydrogen energy storage property placed in service after December 31, 2022, energy storage technology that is modified as set forth in this paragraph (e)(10)(v) is treated as electrical energy storage property described in paragraph (e)(10)(ii) of this section or hydrogen energy storage property described in paragraph (e)(10)(iv) of this section, except that the basis of any existing property prior to such modification is not taken into account for purposes of this section and section 48. This paragraph (e)(10)(v) applies to any electrical energy storage property and hydrogen energy storage property that either:

(A) Was placed in service before August 16, 2022, and would be described in section 48(c)(6)(A)(i) of the Code, except that such property had a capacity of less than 5 kWh and is modified in a manner that such property (after such modification) has a nameplate capacity (after such modification) of not less than 5 kWh; or

(B) Is described in section 48(c)(6)(A)(i) of the Code and is modified in a manner that such property (after such modification) has an increase in nameplate capacity of not less than 5 kWh.

(11) *Qualified biogas property*—(i) *In general.* Qualified biogas property is property comprising a system that converts biomass (as defined in section 45K(c)(3) of the Code, as in effect on August 16, 2022) into a gas that consists of not less than 52 percent methane by volume (tested at the point described in paragraph (e)(11)(ii) of this section), or is concentrated by such system into a gas that consists of not less than 52 percent methane (tested at the point described in paragraph (e)(11)(ii) of this section), and captures such gas for sale or productive use and not for disposal via combustion. Qualified biogas property also includes any property that is part of such system that cleans or conditions such gas. For example, qualified biogas property includes, but is not limited to, a waste feedstock collection system, a landfill gas collection system, mixing or pumping equipment, and an anaerobic digester. However, gas upgrading equipment necessary to concentrate the gas into the appropriate mixture for injection into a pipeline through removal of other gases such as carbon dioxide, nitrogen, or oxygen is not included in qualified biogas property.

(ii) *Methane content requirement.* The methane content requirement described in section 48(c)(7)(A)(i) of the Code and paragraph (e)(11)(i) of this section is measured at the point at which gas exits the biogas production system, which may include an anerobic digester, landfill gas collection system, or thermal gasification equipment. This is the point at which a taxpayer generally must determine whether it will convert the biogas to fuel for sale or use it directly to generate heat or to fuel an electricity generation unit.

(12) *Microgrid controllers*—(i) *In general.* A microgrid controller is equipment that is part of a qualified microgrid and is designed and used to monitor and control the energy resources and loads on such microgrid. A qualified microgrid is an electrical system that includes equipment that is capable of generating not less than 4 kW and not greater than 20 MW of electricity; is capable of operating in connection with the electrical grid and as a single controllable entity with respect to such electrical grid, and independently (and disconnected) from such electrical grid; and is not part of a bulk-power system (as defined in section 215 of the Federal Power Act (16 U.S.C. 824o)).

(ii) *Capable of operating in connection with the electrical grid.* For purposes of this paragraph, a qualified microgrid includes an electrical system that is capable of operating in connection with the larger electrical grid, regardless of whether a connection to the larger electrical grid exists.

(13) *Other property included in section 48.* Any other property specified by section 48 as energy property is energy property for purposes of this section and §§ 1.48–13 and § 1.48–14.

(f) *Property included in energy property*—(1) *In general.* An energy property includes a unit of energy property (as defined in paragraph (f)(2)(i) of this section) that meets the requirements of paragraph (c) of this section, that is not excluded from energy property as provided in paragraph (d) of this section, and is of a type of energy property included in paragraph (e) of this section. Property owned by the taxpayer that is an integral part of an energy property (as defined in paragraph (f)(3) of this section) is treated as energy property. Energy property does not include any electrical transmission equipment, such as transmission lines and towers, or any equipment beyond the electrical transmission stage. Energy property also generally does not include equipment that is an addition or modification to an existing energy property. However, see § 1.48–14(a) for rules regarding retrofitted energy property (80/20 Rule) and paragraph (e)(10)(v) of this section for rules regarding modifications of certain types of energy storage technology.

(2) *Unit of energy property*—(i) *Definition.* The term *unit of energy property* means all functionally interdependent components of property (as defined in paragraph (f)(2)(ii) of this section) owned by the taxpayer that are operated together and that can operate apart from other energy properties within a larger energy project (as defined in § 1.48–13(d)). For rooftop solar energy property, all components of property that are installed on a single rooftop are considered a single unit of energy property. *See* § 1.48–13(d) for rules regarding when multiple energy properties will be treated as an energy project for certain purposes.

(ii) *Functionally interdependent*—(A) *In general.* Except as provided in paragraph (f)(3)(ii)(B) of this section, with respect to components of a unit of energy property, the term *functionally interdependent* means that the placing in service of each component is dependent upon the placing in service of each of the other components in order to generate or store electricity, thermal energy, or hydrogen as provided by section 48(c) of the Code and as described in paragraph (e) of this section.

(B) *Components of certain energy property.* In the case of solar process heat equipment, fiber-optic solar energy property, electrochromic glass property,

geothermal heat pump equipment, qualified biogas property, and microgrid controllers, with respect to components of such property, the term *functionally interdependent* means that the placing in service of each component is dependent upon the placing in service of each of the other components in order to perform the intended function of the energy property as provided by section 48(c) of the Code and as described in paragraph (e) of this section.

(3) *Integral part*—(i) *In general.* For purposes of the section 48 credit, property owned by a taxpayer is an integral part of an energy property owned by the same taxpayer if it is used directly in the intended function of the energy property as provided by section 48(c) of the Code and as described in paragraph (e) of this section and is essential to the completeness of the intended function. Property that is an integral part of an energy property is energy property. A taxpayer may not claim the section 48 credit for any property that is an integral part of the taxpayer's energy property that is not owned by the taxpayer. Multiple energy properties (whether owned by one or more taxpayers) may include shared property that may be considered an integral part of each energy property so long as the cost basis for the shared property is properly allocated to each energy property. The total cost basis of such shared property divided among the energy properties may not exceed 100 percent of the cost of such shared property. In addition, property that is shared by a qualified facility (as defined in section 45(d) of the Code) and an energy property that is an integral part of the energy property will not be considered property that is not energy property under paragraph (d) of this section.

(ii) *Power conditioning and transfer equipment.* Property that is an integral part of energy property includes power conditioning equipment and transfer equipment used to perform the intended function of the energy property as provided by section 48(c) and as described in paragraph (e) of this section. Power conditioning equipment includes, but is not limited to, transformers, inverters, and converters, which modify the characteristics of electricity or thermal energy into a form suitable for use or transmission or distribution. Parts related to the functioning or protection of power conditioning equipment are also treated as power conditioning equipment and include, but are not limited to, switches, circuit breakers, arrestors, and hardware and software used to monitor, operate, and protect power conditioning equipment. Transfer equipment includes equipment that permits the aggregation of energy generated by components of energy properties and equipment that alters voltage in order to permit transfer to a transmission or distribution line. Transfer equipment does not include transmission or distribution lines. Examples of transfer equipment include, but are not limited to, wires, cables, and combiner boxes that conduct electricity. Parts related to the functioning or protection of transfer equipment are also treated as transfer equipment and may include items such as current transformers used for metering, electrical interrupters (such as circuit breakers, fuses, and other switches), and hardware and software used to monitor, operate, and protect transfer equipment. Power conditioning equipment and transfer equipment that are integral to an energy property may be integral to another energy property or used by a qualified facility (as defined in section 45(d) of the Code), so long as the total cost basis of the integral property is properly allocated across the energy property and qualified facility that share such property.

(iii) *Roads.* Roads that are an integral part of an energy property are integral to the activity performed by the energy property such as onsite roads that are used for equipment to operate and maintain the energy property. Roads primarily for access to the site, or roads used primarily for employee or visitor vehicles, are not integral to the activity performed by an energy property.

(iv) *Fences.* Fencing is not an integral part of an energy property because it is not integral to the activity performed by the energy property.

(v) *Buildings.* Generally, buildings are not integral parts of an energy property because they are not integral to the activity of the energy property. However, the following structures are not treated as buildings for this purpose:

(A) A structure that is essentially an item of machinery or equipment; and

(B) A structure that houses property that is integral to the activity of an energy property if the use of the structure is so closely related to the use of the housed energy property that the structure clearly can be expected to be replaced when the energy property it initially houses is replaced.

(4) *Location of energy property.* Any property that meets the requirements of paragraphs (f)(2) and (3) of this section is part of an energy property regardless of where such property is located.

(5) *Examples.* This paragraph provides examples illustrating property included in energy property.

(i) *Example 1. Solar energy property.* X constructs a solar energy property (Property) comprised of 500 separate solar panels. The solar panels are connected by wires, cables, and combiner boxes. Generated electricity is conditioned for subsequent use through an inverter and eventually carried to a substation that houses a transformer where the electricity is stepped up to electrical grid voltage before being transmitted to the electrical grid through an intertie. All components of the Property, up to and including the transformer are either functionally interdependent components of the Property or are integral parts of the Property. Therefore, the Property is an energy property for purposes of the section 48 credit. When X places the Property in service, the cost of the components up to and including the transformer is included in the basis of the Property for purposes of computing the section 48 credit.

(ii) *Example 2. Co-located energy properties.* Assume the same facts as in Example 1, except that Y constructs a wind energy property (Wind Property) near X's solar energy property (Solar Property). X's Solar Property and Y's Wind Property each connect to a substation that houses a transformer where the electricity is stepped up to electrical grid voltage before being transmitted to the electrical grid through the intertie. X and Y each pay 50% of the cost of the transformer and related power conditioning equipment housed therein. X's Solar Property and Y's Wind Property are separate energy properties. When X and Y place their respective energy properties in service, the cost of the components up to and including 50% of the cost of the transformer and related power conditioning equipment is included in X's and Y's basis in their respective energy properties for purposes of computing the section 48 credit.

(iii) *Example 3. Qualified offshore wind facility.* Z constructs a qualified offshore wind facility (Offshore Wind Facility) comprised of 150 turbines for which Z makes a valid election under section 48(a)(5) of the Code to claim the section 48 credit in lieu of the section 45 credit. The alternating current electricity generated by the individual wind turbines will be carried by inter-array cables to an offshore substation where a transformer will step up the voltage of the electricity and a converter will convert it to direct current so it may be transported by subsea export cables to an onshore substation adjacent to the point of interconnection with the electrical grid. When the electricity reaches the onshore substation, it will

flow into another converter where it will be converted back to alternating current, and then through a transformer and associated switchgear where it will be converted to electrical grid voltage and where the Offshore Wind Facility can be electrically isolated from the grid. The electricity will then pass through an intertie that will take the electricity from the substation to the point of interconnection with the electrical grid. All components of the Offshore Wind Facility, up to and including the transformer and switchgear housed in the onshore substation, are either functionally interdependent components of an energy property or integral parts of an energy property. Therefore, the Offshore Wind Facility is an energy property, and when Z places the Offshore Wind Facility in service, the cost of the components up to and including the transformer and switchgear housed in the onshore substation are included in the basis of the Offshore Wind Facility for purposes of computing the section 48 credit.

(iv) *Example 4. Co-located energy property and qualified facility.* X constructs a wind facility (Wind Facility) that is co-located with an energy storage technology (Energy Storage). The Wind Facility and Energy Storage share power conditioning and transfer equipment. X assigns 50% of the cost of the shared power conditioning and transfer equipment to the Wind Facility and 50% of the cost to the Energy Storage. The power conditioning and transfer equipment are integral parts of the Energy Storage, and are therefore, considered energy property. Therefore, X will include 50% of the cost of the power conditioning and transfer equipment when determining the section 48 credit for the Energy Storage. Because the shared power conditioning and transfer equipment are not considered part of the Wind Facility, if the Wind Facility otherwise satisfies the requirements of the section 45 credit, X can claim the section 45 credit for the Wind Facility.

(g) *Applicability date.* This section applies with respect to property placed in service after December 31, 2022, and during a taxable year beginning after [DATE OF PUBLICATION OF FINAL RULE].

■ **Par. 3.** Section 1.48–13 is added to read as follows:

§ 1.48–13 Rules relating to the increased credit amount for prevailing wage and apprenticeship.

(a) *In general.* If a qualified energy project satisfies the requirements in paragraph (b) of this section, the amount of the energy credit determined under section 48(a) of the Internal Revenue Code (Code), after the application of sections 48(a)(1) through (8), and 48(a)(15), is equal to the credit determined under section 48(a) (section 48 credit) multiplied by five.

(b) *Requirements.* A qualified energy project satisfies the requirements of this paragraph (b) if it is one of the following—

(1) A project with a maximum net output of less than one megawatt (MW) of electrical (as measured in alternating current) or thermal energy determined based on the nameplate capacity as provided in paragraph (e) of this section (One-Megawatt Exception);

(2) A project the construction of which began prior to January 29, 2023; or

(3) A project that meets the prevailing wage requirements of section 48(a)(10)(A) of the Code, § 1.45–7(b)–(d), and paragraph (c) of this section, the apprenticeship requirements of section 45(b)(8) of the Code and § 1.45–8, and the recordkeeping and reporting requirements of § 1.45–12.

(c) *Special rule applicable to general prevailing wage requirements*—(1) *In general.* In addition to satisfying the prevailing wage requirements under § 1.45–7(b) through (d), a taxpayer must ensure that any laborers and mechanics employed (within the meaning of § 1.45–7) by the taxpayer or any contractor or subcontractor in the construction of such energy project, and for the five-year period beginning on the date such project is placed in service, the alteration or repair of such project, are paid wages at rates not less than the prevailing rates for construction, alteration, or repair of a similar character in the locality in which such project is located as most recently determined by the Secretary of Labor, in accordance with 40 U.S.C. chapter 31, subchapter IV. Subject to section 48(a)(10)(C) of the Code and this paragraph (c), for purposes of determining the increased credit amount under section 48(a)(9)(B)(iii) of the Code, the taxpayer is deemed to satisfy the prevailing wage requirements of section 48(a)(10)(A)(ii) of the Code at the time such project is placed in service.

(2) *Exception.* For purposes of satisfying the prevailing wage requirements of paragraph (b)(3) of this section, § 1.45–7(a) does not apply.

(3) *Recapture*—(i) *In general.* The increased credit amount under paragraph (b)(3) of this section is subject to recapture for any project that does not satisfy the prevailing wage requirements in § 1.45–7(b) through (d) and paragraph (c)(1) of this section for any period with respect to an alteration or repair of such project during the five-year period beginning on the date such project is originally placed in service (five-year recapture period) (but that does not cease to be investment credit property within the meaning of section 50(a) of the Code).

(ii) *Recapture event*—(A) *In general.* Any failure to satisfy the prevailing wage requirements in § 1.45–7(b) through (d) and paragraph (c)(1) of this section for any period with respect to the alteration or repair of any project during the five-year recapture period is a recapture event. Any failure to satisfy the prevailing wage requirements in § 1.45–7(b) through (d) and paragraph (c)(1) of this section for any period remain subject to the correction and penalty provisions in § 1.45–7(c), including the waiver provisions in § 1.45–7(c)(6). Subject to § 1.45–7(c)(5) and (6), if the correction and penalty payments described in § 1.45–7(c) are not made by the taxpayer on or before the date that is 180 days after the date of a final determination by the IRS (as defined in § 1.45–7(c)(4)(ii)), the cure provision in § 1.45–7(c) does not apply and the increased credit amount is subject to recapture.

(B) *Yearly determination.* A determination of whether a recapture event has occurred under paragraph (c)(3)(ii) of this section must be made for each taxable year (or portion thereof) occurring within the five-year recapture period, beginning with the taxable year ending after the date the energy project is placed in service. Thus, for each taxable year beginning or ending within the five-year recapture period, the taxpayer must determine whether the prevailing wage requirements of section 48(a)(10)(A) of the Code, § 1.45–7(b)–(d), and paragraph (c)(1) of this section are satisfied for the recapture year(s) occurring during each taxable year.

(C) *Carrybacks and carryforward adjusted.* In the case of any recapture event described in paragraph (c)(3)(ii)(A) of this section, the carrybacks and carryforwards under section 39 must be adjusted by reason of such recapture event.

(iii) *Correction and penalty payments not required if taxpayer is subject to recapture under section 48(a)(10)(C) of the Code.* If the IRS determines that a taxpayer that claimed the increased credit amount under section 48(a)(9)(B)(iii) of the Code or transferred a specified credit portion under section 6418 of the Code that includes the increased credit amount under section 48(a)(9)(B)(iii) failed to satisfy the prevailing wage requirements in § 1.45–

7(b) through (d) and paragraph (c)(1) of this section for any period with respect to the alteration or repair of any project during the five-year recapture period and the taxpayer does not make the correction and penalty payments provided in § 1.45–7(c), then no penalty is assessed under § 1.45–7, and the increased credit amount is subject to recapture. Taxpayers whose increased credit amount is subject to recapture under this section may still be entitled to the base amount of the energy credit under section 48(a) of the Code if such taxpayers meet the requirements to claim the credit.

(4) *Recapture amount*—(i) *In general.* If a recapture event has occurred as described in paragraph (c)(3)(ii) of this section and the taxpayer fails to make the correction and penalty payments described in § 1.45–7(c)(1) within 180 days after the date of a final determination by the IRS, the tax under chapter 1 of the Code for the taxable year in which the recapture event occurs is increased by the applicable recapture percentage multiplied by the increased credit amount that was claimed by the taxpayer under paragraph (b)(3) of this section.

(ii) *Applicable recapture percentage.* If the recapture event occurs:

(A) Within one full year after the property is placed in service, the recapture percentage is 100;

(B) Within one full year after the close of the period described in paragraph (c)(4)(ii)(A) of this section, the recapture percentage is 80;

(C) Within one full year after the close of the period described in paragraph (c)(4)(ii)(B) of this section, the recapture percentage is 60;

(D) Within one full year after the close of the period described in paragraph (c)(4)(ii)(C) of this section, the recapture percentage is 40;

(E) Within one full year after the close of the period described in paragraph (c)(4)(ii)(D) of this section, the recapture percentage is 20.

(5) *Recapture period.* The five-year recapture period begins on the date the project is placed in service and ends on the date that is five full years after the placed-in-service date. Each 365-day period (366-day period in case of a leap year) within the five-year recapture period is a separate recapture year for recapture purposes.

(6) *Increase in tax for recapture.* The increase in tax under chapter 1 of the Code for the recapture of an increased credit amount claimed under paragraph (b)(3) occurs in the year of the recapture event.

(7) *Annual prevailing wage compliance report.* In addition to the general reporting requirements in § 1.45–12, a taxpayer that has claimed an increased credit amount under paragraph (b)(3) of this section or transferred a specified credit portion under section 6418 of the Code that includes an increased credit amount under paragraph (b)(3) of this section is required to provide to the IRS, information on the payment of prevailing wages with respect to any alteration or repair of the project during the recapture period at the time and in the form and manner prescribed in IRS forms or instructions or in publications or guidance published in the Internal Revenue Bulletin. *See* § 601.601 of this chapter.

(8) *Transferred specified credit portions.* In the case of a transferred specified credit portion under section 6418, to which recapture of an increased credit amount under this paragraph (c) applies, the eligible taxpayer is required to notify the transferee taxpayer of the recapture event in accordance with the provisions of § 1.6418–5(f)(2) and the transferee taxpayer is responsible for any amount of increase in tax under section 48(a)(10)(C) of the Code and this paragraph (c) in accordance with the provisions of § 1.6418–5(f)(3).

(9) *Coordination with recapture rules under section 50(a).* If any increased credit amount was recaptured with respect to investment credit property in a prior year under section 48(a)(10)(C) of the Code and this paragraph (c), then, such increased credit amount is not included in determining the aggregate decrease in the credits allowed under section 38 of the Code for all prior taxable years which would have resulted solely from reducing to zero the credit determined under subparts D and E of part IV of subchapter A of chapter 1 of the Code (that is, sections 38–50 of the Code) with respect to the property.

(d) *Energy project defined*—(1) *In general.* For purposes of the increased credit amount provided by section 48(a)(9) of the Code and paragraphs (b) and (c) of this section, the domestic content bonus credit amount provided by section 48(a)(12) of the Code, and the increase in credit rate for energy communities provided in section 48(a)(14) of the Code, the term *energy project* means one or more energy properties (multiple energy properties) that are operated as part of a single energy project. Multiple energy properties will be treated as one energy project if, at any point during the construction of the multiple energy properties, they are owned by a single taxpayer (subject to the related taxpayer rule provided in paragraph (d)(2) of this section) and any two or more of the following factors are present:

(i) The energy properties are constructed on contiguous pieces of land;

(ii) The energy properties are described in a common power purchase, thermal energy, or other off-take agreement or agreements;

(iii) The energy properties have a common intertie;

(iv) The energy properties share a common substation, or thermal energy off-take point;

(v) The energy properties are described in one or more common environmental or other regulatory permits;

(vi) The energy properties are constructed pursuant to a single master construction contract; or

(vii) The construction of the energy properties are financed pursuant to the same loan agreement.

(2) *Related taxpayers*—(i) *Definition.* For purposes of this section, the term *related taxpayers* means members of a group of trades or businesses that are under common control (as defined in § 1.52–1(b)).

(ii) *Related taxpayer rule.* For purposes of this section, related taxpayers are treated as one taxpayer in determining whether multiple energy properties are treated as an energy project with respect to which a section 48 credit may be determined.

(3) *Consistent treatment as an energy project.* If multiple energy properties are treated as a single energy project for beginning of construction purposes with respect to the section 48 credit, the multiple energy properties will also be treated as a single energy project for purposes of the prevailing wage and apprenticeship requirements, the domestic content bonus credit amount, and the increase in section 48 credit rate for energy communities.

(e) *Nameplate capacity for purposes of the One-Megawatt Exception.* For purposes of paragraph (b)(1) of this section, the determination of whether an energy project has a maximum net output of less than 1 MW of electrical (as measured in alternating current) or thermal energy is determined based on the nameplate capacity. Where applicable, taxpayers should use the International Standard Organization (ISO) conditions to measure the maximum electrical generating output or usable energy capacity of an energy project. Paragraphs (e)(1) through (5) of this section provide rules for applying the One-Megawatt Exception (as provided in paragraph (b)(1) of this section) to different types of energy properties. Because electrochromic glass

property (as defined in § 1.48–9(e)(2)(ii)), fiber-optic solar energy property (as defined in § 1.48–9(e)(2)(i)), and microgrid controllers (as defined in § 1.48–9(e)(12)) do not generate electricity or thermal energy, these energy properties are not eligible for the One-Megawatt Exception.

(1) *Electrical generating energy property.* In the case of an electrical generating energy property, the maximum electrical generating output in MW that the unit of energy property is capable of producing on a steady state basis and during continuous operation under standard conditions, as measured by the manufacturer and consistent with the definition of nameplate capacity provided in 40 CFR 96.202.

(2) *Electrical energy storage property.* In the case of electrical energy storage property (as defined in § 1.48–9(e)(10)(ii)), the storage device's maximum net output.

(3) *Thermal energy storage property and other property generating thermal energy.* In the case of thermal energy storage property (as defined in § 1.48–9(e)(10)(iii)) and other energy property that generates thermal energy for productive use (for example, direct geothermal use, geothermal heat pumps, solar process heating), a taxpayer must use the equivalent of 3.4 million British Thermal Units per hour (mmBtu/hour) for heating and 284 tons for cooling can be used to determine if the thermal storage property satisfies the One-Megawatt Exception (Btu per hour/3,412,140 = MW). For projects delivering thermal energy to a building or buildings, this can be assessed as either the aggregate maximum thermal output of all individual heating or cooling elements within the building or buildings, or as the maximum thermal output that the entire project is capable of delivering to a building or buildings at any given moment.

(4) *Hydrogen energy storage property and specified clean hydrogen production facilities.* A hydrogen energy storage property (as defined in § 1.48–9(e)(10)(iv)) or a specified clean hydrogen production facility (as defined in section 48(a)(15)(C) of the Code) must have a maximum net output of less than 3.4 mmBtu/hour of hydrogen or equivalently 10,500 standard cubic feet (scf) per hour of hydrogen to satisfy the One-Megawatt Exception.

(5) *Qualified biogas property.* In the case of qualified biogas property, 3.4 mmBtu/hour can be used as equivalent to the One-Megawatt Exception. Taxpayers may convert the maximum net output of 3.4 mmBtu/hour into an equivalent maximum net volume flow in scf per hour using the appropriate high heat value conversion factors found in the EPA GHGRR at table C–1 to subpart C of part 98 (40 CFR part 98). Otherwise, taxpayers may calculate their own equivalent volumetric flow if the heat content of the gas is known.

(f) *Applicability date*—(1) *In general.* Except as provided in paragraph (f)(2) of this section, this section applies to projects placed in service in taxable years ending on or after the date final regulations are published in the **Federal Register**, and the construction of which begins after the date final regulations are published in the **Federal Register**.

(2) *Exception.* Paragraph (d) of this section applies to energy projects the construction of which begins after November 22, 2023.

■ **Par. 4.** Section 1.48–14 is added to read as follows:

§ 1.48–14 Rules applicable to energy property.

(a) *Retrofitted energy property*—(1) *In general.* For purposes of section 48(a)(3)(B)(ii), (a)(5)(D)(iv), and (a)(8)(B)(iii) of the Internal Revenue Code (Code), a retrofitted energy property may be originally placed in service even though it contains some used components of the unit of energy property only if the fair market value of the used components of the unit of energy property is not more than 20 percent of the total value of the unit of energy property taking into account the cost of the new components of property plus the value of the used components of the unit of energy property (80/20 Rule). Only expenditures paid or incurred that relate to the new components of the unit of energy property are taken into account for purposes of computing the energy credit determined under section 48 (section 48 credit) with respect to the unit of energy property. The cost of new components of the unit of energy property includes all costs properly included in the depreciable basis of the new components. If the taxpayer satisfies the 80/20 Rule with regard to the unit of energy property and the taxpayer pays or incurs new costs for property that is an integral part of the energy property (as defined in § 1.48–9(f)(3)(i)), the taxpayer may include the new costs paid or incurred for property that is an integral part of the energy property (as defined in § 1.48–9(f)(3)(i)) in the basis of the energy property for purpose of the section 48 energy credit. Further, in the case of an energy project (as defined in § 1.48–13(d)), the 80/20 Rule is applied to each unit of energy property comprising an energy project.

(2) *Excluded costs.* Costs incurred for new components of property added to used components of a unit of energy property may not be taken into account for purposes of the section 48 credit unless the taxpayer satisfies the 80/20 Rule (as provided in paragraph (a)(1) of this section) by placing into service a unit of energy property for which the fair market value of the used components of property is not more than 20 percent of the total value of the unit of energy property taking into account the cost of the new components of property plus the value of the used components of property.

(3) *Examples.* This paragraph (a)(3) provides examples illustrating the provisions of this paragraph (a):

(i) *Example 1. Retrofitted solar energy property that satisfies the 80/20 Rule.* Z owns an existing solar energy property for which the section 48 credit has been claimed and the recapture period for the section 48 credit has elapsed. Z replaces used components of the solar energy property with new components of property at a cost of $1.4 million. The retrofitted solar energy property constitutes a unit of energy property. The fair market value of the remaining original components of the retrofitted solar energy property is $100,000, which is not more than 20% of the retrofitted solar energy property's total value of $1.5 million (the cost of the new components ($1.4 million) + the value of the remaining original components ($100,000)). The value of the old components of the retrofitted solar energy property is $100,000/$1.5 million (7% of the value of total value of the retrofitted solar energy property), thus the retrofitted solar energy property will be considered newly placed in service for purposes of section 48, and Z will be able to claim a section 48 credit based on the cost of the new components ($1.4 million).

(ii) *Example 2. Capital improvements to an existing energy property that do not satisfy the 80/20 Rule.* X owns an existing unit of energy property for which the section 48 credit has been claimed and the recapture period for the section 48 credit has elapsed. The fair market value of the unit of energy property is $1 million. During the tax year, X makes capital improvements to the unit of energy property. The expenditures for such capital improvements total $300,000. X may not claim a section 48 credit for the $300,000 spent on capital improvements during the tax year because the capital improvements did not satisfy the 80/20 Rule.

(b) *Dual use property*—(1) *Definition.* For purposes of section 48, the term *dual use property* means property that uses energy derived from both a

qualifying source (that is, from an energy property defined in § 1.48–9(a) (including a qualified facility for which an election has been made as provided by paragraph (f)(1) of this section)) and from a non-qualifying source (that is, sources other than an energy property defined in § 1.48–9(a) (including a qualified facility for which an election has been made as provided by paragraph (f)(1) of this section)).

(2) *Qualification as energy property*—(i) *In general.* If dual use property meets each of the requirements of this paragraph (b), it will qualify as energy property if its use of energy from non-qualifying sources does not exceed 50 percent of its total energy input (as determined under the rules of paragraph (b)(2)(ii) of this section) during an annual measuring period (as defined in paragraph (b)(2)(iii) of this section). If the energy used from qualifying sources is between 50 percent and 100 percent, only a proportionate amount of the eligible basis of the energy property will be taken into account in computing the amount of the section 48 credit (for example, if 80 percent of the energy used by a dual use property is from qualifying sources, 80 percent of the basis of the dual use property will be taken into account in computing the amount of the section 48 credit).

(ii) *Aggregation of energy inputs.* The measurement of energy use required for purposes of paragraph (b)(2)(i) of this section may be made by comparing, on the basis of British thermal units (Btus), energy input to dual use property from all qualifying sources with energy input from all non-qualifying sources. The Commissioner may also accept any other method that accurately establishes the relative annual use of energy derived from all qualifying sources and of energy input from all non-qualifying sources by dual use property.

(iii) *Annual measuring period.* For purposes of paragraph (b)(2)(i) of this section, the term *annual measuring period* means with respect to an item of dual use property the 365-day period (366-day period in case of a leap year) beginning with the day the dual use property is placed in service or a 365-day period (366-day period in case of a leap year) beginning the day after the last day of the immediately preceding annual measuring period.

(iv) *Recapture.* If, for a taxable year (within the recapture period specified in section 50(a) of the Code) subsequent to the taxable year that a dual use property was placed in service, the equipment's use of energy from all qualifying sources is reduced below 50 percent of its total energy input (as determined under the rules of paragraph (b)(2)(i) of this section), then recapture of the section 48 credit is required under section 50(a).

(c) *Energy property eligible for multiple Federal income tax credits*—(1) *In general.* For purposes of this section, the basis of energy property may be eligible for calculating both the section 48 credit and another Federal income tax credit, subject to the limitation provided in paragraph (c)(2) of this section.

(2) *Limitation.* A taxpayer that owns energy property that is eligible for both the section 48 credit and another Federal income tax credit is eligible for the section 48 credit only to the extent the other Federal income tax credit was not claimed with respect to the taxpayer's eligible basis in the energy property. Except as provided in paragraph (f)(2) of this section, in no event may a taxpayer claim both a section 48 credit and another Federal income tax credit with respect to the same eligible basis in an energy property. See paragraph (e) of this section for special rules regarding ownership of energy property.

(d) *Incremental cost*—(1) *In general.* For purposes of this section, only the incremental cost of energy property is included in the eligible basis of the energy property. The term *incremental cost* means the excess of the total cost of energy property over the amount that would have been expended for the energy property if the energy property were not used for a qualifying purpose.

(2) *Example.* A installs solar energy property above the surface of an existing roof of a building that A owns. The solar energy property uses bifacial panels that convert to energy the light that strikes both the front and back of the panels if installed over a highly reflective surface that is affixed to a roof (reflective roof). The cost of the reflective roof is $15,000 whereas the cost of a standard roof for the building would be $10,000. The reflective roof does not include the portions of the existing roof that will be replaced, and any features of the roof not directly related to establishing, improving, and maintaining the efficiency of the reflective roof. Accordingly, the reflective roof, if installed in connection with the solar energy property, constitutes energy property under section 48. The incremental cost of the reflective roof is $5,000, and that amount is A's eligible basis in the solar energy property for purposes of the section 48 credit.

(e) *Special rules concerning ownership*—(1) *Eligible basis.* For purposes of this section, a taxpayer that owns an energy property is eligible for the section 48 credit only to the extent of the taxpayer's eligible basis in the energy property. In the case of multiple taxpayers holding direct ownership in an energy property, each taxpayer determines its eligible basis based on its fractional ownership interest in the energy property.

(2) *Multiple owners.* A taxpayer must directly own at least a fractional interest in the entire unit of energy property for a section 48 credit to be determined with respect to such taxpayer's interest. No section 48 credit may be determined with respect to a taxpayer's ownership of one or more separate components of an energy property if the components do not constitute a unit of energy property. However, the use of property owned by one taxpayer that is an integral part of an energy property owned by a second taxpayer will not prevent a section 48 credit from being determined with respect to the second taxpayer's energy property.

(3) *Related taxpayers*—(i) *Definition.* For purposes of this section, the term *related taxpayers* means members of a group of trades or businesses that are under common control (as defined in § 1.52–1(b)).

(ii) *Related taxpayer rule.* For purposes of this section, related taxpayers are treated as one taxpayer in determining whether a taxpayer has made an investment in an energy property with respect to which a section 48 credit may be determined.

(4) *Examples.* The following examples illustrate the rules in this paragraph (e). In each example, X and Y are unrelated taxpayers.

(i) *Example 1. Fractional ownership required to satisfy section 48.* X and Y own fractional ownership interests in a geothermal heat pump equipment that is a unit of energy property. Because X and Y each own a fractional ownership interest in a unit of energy property, a section 48 credit may be determined with respect to X's and Y's fractional ownership interests in the unit of energy property.

(ii) *Example 2. Ownership of separate components.* X and Y own separate components of a geothermal heat pump equipment, which taken together is a unit of energy property. X owns the coils in the ground and Y owns the heat pump. No section 48 credit may be determined with respect to either X or Y because each owns a separate component of energy property that does not constitute a unit of energy property as defined in § 1.48–9(f)(2).

(iii) *Example 3. Shared ownership of property that is an integral part of separate energy properties.* X owns a wind energy property that is a unit of energy property and Y owns a solar energy property that is a unit of energy

property that are co-located. Both X's wind energy property and Y's solar energy property connect to a substation that houses a step-up transformer where the electricity is stepped up to electrical grid voltage before being transmitted to the electrical grid through an intertie. X and Y each own a 50% fractional ownership interest in the step-up transformer. The step-up transformer is an integral part of both the wind energy property and the solar energy property (as defined in § 1.48–9(f)(3)(i). As a result, X and Y may both compute a section 48 credit for their respective energy properties by including 50% of the costs of the step-up transformer.

(iv) *Example 4. Separate ownership of property that is an integral part of separate energy property.* X owns a wind energy property that is a unit of energy property and property that is an integral part of the wind energy property, specifically a transformer where the electricity is stepped up to electrical grid voltage before being transmitted to the electrical grid through an intertie. Y owns a solar energy property that is a unit of energy property that connects to X's transformer. Because Y does not hold an ownership interest in the transformer, Y may compute its section 48 credit for its solar energy property but it will not include any costs relating to the transformer.

(f) *Coordination with other Code provisions.* Paragraphs (f)(1) through (7) of this section provide rules applicable to the election under section 48(a)(5)(C) to treat certain facilities as energy property eligible for a section 48 credit in lieu of a renewable electricity production credit under section 45 of the Code (section 45 credit). Paragraph (f)(8) of this section provides a coordination rule for property with respect to which both a section 48 credit and a low-income housing credit under section 42 of the Code (section 42 credit) may be determined.

(1) *Election to treat qualified facilities as energy property.* If a taxpayer makes an election under section 48(a)(5)(C) of the Code (pursuant to the requirements in paragraph (f)(6) of this section) to treat qualified property (as defined in paragraph (f)(2) of this section) that is part of a qualified investment credit facility (as defined in paragraph (f)(4) of this section) as energy property with respect to which a section 48 credit may be determined, such property will be treated as energy property for purposes of section 48. No section 45 credit may be determined with respect to any such qualified investment credit facility and the requirements of section 45 are not imposed on a qualified investment credit facility. No credit under sections 45Q or 45V of the Code may be determined with respect to either any carbon capture equipment included in a qualified investment credit facility or any specified clean hydrogen production facility.

(2) *Qualified property.* For purposes of this paragraph (f), the term *qualified property* means property that meets each of the requirements of paragraphs (f)(2)(i) through (iii) of this section:

(i) The property is tangible personal property (as defined in paragraph (f)(3)(i) of this section) or other tangible property (not including a building or its structural components) (as defined in paragraph (f)(3)(ii) of this section), but only if such other tangible property is used as an integral part (as defined paragraph (f)(3)(iii) of this section) of the qualified investment credit facility (as defined in paragraph (f)(4) of this section).

(ii) Depreciation (or amortization in lieu of depreciation) is allowable (as defined in § 1.48–9(b)(4)) with respect to the property.

(iii) The taxpayer constructs, reconstructs, or erects the property (as defined in § 1.48–9(b)(1)) or acquires the property (as defined in § 1.48–9(b)(2)) if the original use of the property (as defined in § 1.48–9(b)(3)) commences with the taxpayer.

(3) *Definitions related to requirements for qualified property.* For purposes of section 48 of the Code and this paragraph (f), the definitions of this paragraph (f)(3) apply:

(i) *Tangible personal property.* The term *tangible personal property* means any tangible property except land and improvements thereto, such as buildings or other inherently permanent structures (including items that are structural components of such buildings or structures). Tangible personal property includes all property (other than structural components) that is contained in or attached to a building. Further, all property that is in the nature of machinery (other than structural components of a building or other inherently permanent structure) is considered tangible personal property even though located outside a building. Local law is not controlling for purposes of determining whether property is or is not tangible property or tangible personal property. Thus, tangible property may be personal property for purposes of the energy credit even though under local law the property is considered to be a fixture and therefore real property.

(ii) *Other tangible property.* The term *other tangible property* means tangible property other than tangible personal property (not including a building and its structural components), that is used as an integral part of furnishing electrical energy by a person engaged in a trade or business of furnishing any such service.

(iii) *Integral part*—(A) *In general.* Property owned by a taxpayer is an integral part of a qualified investment credit facility owned by the same taxpayer if it is used directly in the intended function of the qualified investment credit facility and is essential to the completeness of the intended function of the qualified investment credit facility. A taxpayer may not claim the section 48 credit for any property that is an integral part of the taxpayer's qualified investment credit facility that is not owned by the taxpayer.

(B) *Power conditioning and transfer equipment.* Property that is an integral part of a qualified investment credit facility includes power conditioning equipment and transfer equipment used to perform the intended function of the qualified investment credit facility. Power conditioning equipment includes, but is not limited to, transformers, inverters, and converters, which modify the characteristics of electricity or thermal energy into a form suitable for use or transmission or distribution. Parts related to the functioning or protection of power conditioning equipment are also treated as power conditioning equipment and include, but are not limited to, switches, circuit breakers, arrestors, and hardware and software used to monitor, operate, and protect power conditioning equipment. Transfer equipment includes equipment that permits the aggregation of energy generated by components of energy properties and equipment that alters voltage in order to permit transfer to a transmission or distribution line. Transfer equipment does not include transmission or distribution lines. Examples of transfer equipment include, but are not limited to, wires, cables, and combiner boxes that conduct electricity. Parts related to the functioning or protection of transfer equipment are also treated as transfer equipment and may include items such as current transformers used for metering, electrical interrupters (such as circuit breakers, fuses, and other switches), and hardware and software used to monitor, operate, and protect transfer equipment.

(C) *Roads.* Roads that are an integral part of a qualified investment credit facility are integral to the activity performed by the qualified investment credit facility; these include onsite roads that are used for equipment to

operate and maintain the qualified investment credit facility. Roads primarily for access to the site, or roads used primarily for employee or visitor vehicles, are not integral to the activity performed by a qualified investment credit facility.

(D) *Fences.* Fencing is not an integral part of an energy property because it is not integral to the activity performed by the energy property.

(E) *Buildings.* Generally, buildings are not integral parts of a qualified investment credit facility because they are not integral to the activity of the qualified investment credit facility. However, the following structures are not treated as buildings for this purpose:

(*1*) A structure that is essentially an item of machinery or equipment.

(*2*) A structure that houses property that is integral to the activity of a qualified investment credit facility if the use of the structure is so closely related to the use of the housed qualified investment credit facility that the structure clearly can be expected to be replaced when the qualified investment credit facility it initially houses is replaced.

(4) *Qualified investment credit facility.* The term *qualified investment credit facility* means any facility—

(i) That is a qualified facility (within the meaning of section 45) described in section 45(d)(1) through (4), (6), (7), (9) or (11) of the Code;

(ii) That meets the placed in service and beginning of construction requirements (if any) provided in section 48 of the Code;

(iii) With respect to which no credit has been allowed under section 45 of the Code; and

(iv) For which the taxpayer makes an irrevocable election under section 48(a)(5) of the Code and paragraph (f)(1) of this section.

(5) *Intangibles excluded.* Intangible property is not qualified property for purposes of section 48(a)(5)(D) of the Code and paragraph (f) of this section.

(6) *Time and manner of making election*—(i) *In general.* To make an election under section 48(a)(5) of the Code and paragraph (f)(1) of this section to treat a qualified facility as a qualified investment credit facility, a taxpayer must claim the section 48 credit with respect to such qualified investment credit facility on a completed Form 3468, *Investment Credit,* or any successor form(s), and file such form with the taxpayer's timely filed (including extensions) Federal income tax return for the taxable year in which the qualified investment credit facility is placed in service. The taxpayer must also attach a statement to its Form 3468, or any successor forms(s), filed with its timely filed Federal income tax return (including extensions) that includes all of the information required by the instructions to Form 3468, or any successor form(s) for each qualified investment credit facility subject to an election under section 48(a)(5) and paragraph (f)(1) of this section. A separate election must be made for each qualified facility that meets the requirements provided in paragraph (f)(2) of this section to be treated as a qualified investment credit facility. If any taxpayer owning an interest in a qualified facility makes an election with respect to such qualified facility, that election is binding on all taxpayers that directly or indirectly own an interest in the qualified facility.

(ii) *Special rule for partnerships and S corporations.* In the case of a qualified facility owned by a partnership or an S corporation, the election under paragraph (f)(1) of this section is made by the partnership or S corporation and is binding on all ultimate section 48 credit claimants (as defined in § 1.50–1(b)(3)(ii)). The partnership or S corporation must file a Form 3468, or any successor forms(s), with its timely filed partnership or S corporation return (including extensions) with respect to Federal income tax for the taxable year in which the qualified investment credit facility is placed in service to indicate that it is making the election and attach a statement that includes all of the information required by the instructions to Form 3468, or any successor form(s) for each qualified facility subject to the election. The ultimate credit claimants must claim the section 48 credit on a completed Form 3468, or any successor form(s), and file such form with a timely filed (including extensions) Federal income tax return for the taxable year that ends with or within the taxable year in which the partnership or S corporation made the election. The partnership or S corporation making the election must provide the ultimate credit claimants with the necessary information to complete Form 3468, or any successor form(s), to claim the energy credit.

(7) *Election irrevocable.* The election under section 48(a)(5) of the Code and paragraph (f)(1) of this section to treat a qualified facility as an energy property is irrevocable.

(8) *Coordination rule for sections 42 and 48 credits.* As provided under section 50(c)(3)(C) of the Code, in the case of a taxpayer determining eligible basis for purposes of calculating a section 42 credit, a taxpayer is not required to reduce its basis in an energy property by the amount of the section 48 credit determined with respect to the property. The basis of an energy property may be used to determine a section 48 credit and may also be included in eligible basis when determining a section 42 credit. See paragraph (e) of this section for special rules regarding ownership of energy property.

(g) *Rules for certain lower-output energy properties to include qualified interconnection costs in the basis of associated energy property*—(1) *In general.* For purposes of determining the section 48 credit, energy property includes amounts paid or incurred by the taxpayer for qualified interconnection property (as defined in paragraph (g)(2) of this section), in connection with the installation of energy property (as defined in § 1.48–9(a)) that has a maximum net output of not greater than 5 MW (as measured in alternating current) (as described in paragraph (g)(3) of this section). The qualified interconnection property must provide for the transmission or distribution of the electricity produced or stored by such energy property and must be properly chargeable to the capital account of the taxpayer as reduced by paragraph (g)(6) of this section.

(2) *Qualified interconnection property.* The term *qualified interconnection property* means, with respect to an energy project that is not a microgrid controller, any tangible property that is part of an addition, modification, or upgrade to a transmission or distribution system that is required at or beyond the point at which the energy project interconnects to such transmission or distribution system in order to accommodate such interconnection; is either constructed, reconstructed, or erected by the taxpayer, (as defined in § 1.48–9(b)(1)), or for which the cost with respect to the construction, reconstruction, or erection of such property is paid or incurred by such taxpayer; and the original use (as defined in § 1.48–9(b)(3)), of which, pursuant to an interconnection agreement (as defined in paragraph (g)(4) of this section), commences with a utility (as defined in paragraph (g)(5) of this section). Qualified interconnection property is not part of an energy property. As a result, qualified interconnection property is not taken into account in determining whether an energy property satisfies the requirements for the domestic content bonus credit amount referenced in section 48(a)(12) of the Code and the increase in credit rate for energy communities provided in section 48(a)(14) of the Code.

(3) *Five-Megawatt Limitation*—(i) *In general.* The Five-Megawatt Limitation is measured at the level of the energy property in accordance with section 48(a)(8)(A) of the Code. The maximum net output of an energy property is measured only by nameplate generating capacity of the unit of energy property at the time the energy property is placed in service.

(ii) *Nameplate capacity for purposes of the Five-Megawatt Limitation.* The determination of whether an energy property has a maximum net output of not greater than 5 MW (as measured in alternating current) is based on the nameplate capacity for purposes of paragraph (g)(1) of this section. Where applicable, taxpayers should use the International Standard Organization (ISO) conditions to measure the maximum electrical generating output or usable energy capacity of an energy property. Paragraphs (g)(3)(i)(A) and (B) of this section, provide rules for applying the Five-Megawatt Limitation (as provided in paragraph (g)(1) of this section) to electrical generating energy property and electrical energy storage property, respectively.

(A) *Electrical generating energy property.* In the case of an electrical generating energy property, the maximum electrical generating output in MW that the unit of energy property is capable of producing on a steady state basis and during continuous operation under standard conditions, as measured by the manufacturer and consistent with the definition of nameplate capacity provided in 40 CFR 96.202.

(B) *Electrical energy storage property.* In the case of electrical energy storage property (as defined in § 1.48–9(e)(10)(ii)), the storage device's maximum net output is its nameplate capacity.

(4) *Interconnection agreement.* The term *interconnection agreement* means an agreement with a utility for the purposes of interconnecting the energy property owned by such taxpayer to the transmission or distribution system of the utility.

(5) *Utility.* For purposes of section 48(a)(8) of the Code and this paragraph (g), the term *utility* means the owner or operator of an electrical transmission or distribution system that is subject to the regulatory authority of a State or political subdivision thereof, any agency or instrumentality of the United States, a public service or public utility commission or other similar body of any State or political subdivision thereof, or the governing or ratemaking body of an electric cooperative.

(6) *Reduction to amounts chargeable to capital account.* In the case of expenses paid or incurred for qualified interconnection property as defined in paragraph (g)(2) of this section, amounts otherwise chargeable to capital account with respect to such expenses must be reduced under rules similar to the rules of section 50(c) of the Code. In addition, the taxpayer must pay or incur the interconnection property costs; therefore, any reimbursement, including by a utility, must be accounted for by reducing taxpayers' expenditure when determining eligible costs.

(7) *Examples.* This subparagraph provides examples illustrating the application of the Five-Megawatt Limitation provided in this paragraph (g).

(i) *Example 1. Application of Five-Megawatt Limitation to an interconnection agreement for energy properties owned by separate taxpayers.* X places in service a solar energy property (Solar Property) with a maximum net output of 5 MW (as measured in alternating current). Y places in service a qualified wind facility (Wind Facility), for which Y has made a valid election under section 48(a)(5) of the Code to elect the section 48 credit in lieu of the section 45 credit, with a maximum net output of 5 MW (as measured in alternating current). The Solar Property and the Wind Facility are separate units of energy property installed on contiguous pieces of land and connect to the grid through a common intertie. As part of the development of the Solar Property and Wind Facility, interconnection costs are required by the utility to modify and upgrade the transmission system at or beyond the common intertie to the utility's transmission system to accommodate such interconnection. X and Y are party to the same interconnection agreement with the utility that allows for a maximum output of 10 MW (as measured in alternating current). The interconnection agreement provides the total cost of the qualified interconnection property. X and Y may include the costs paid or incurred by X and Y, respectively, for qualified interconnection property subject to the terms of the interconnection agreement, when calculating their respective section 48 credits for the Solar Property and the Wind Facility because each has a maximum net output of not greater than 5 MW.

(ii) *Example 2. Application of Five-Megawatt Limitation to an interconnection agreement for a single energy property.* X develops three solar energy properties located in close proximity. The three solar energy properties are not considered an energy project pursuant to the definition in § 1.48–13(d). Each of the solar energy properties is a unit of energy property and has a maximum net output of 4 MW (as measured in alternating current). Electricity that is suitable for use or transmission (and is not further conditioned) from the three solar energy properties feeds into a single gen-tie line and a common intertie. X is party to a separate interconnection agreement with the utility for each solar energy property and each interconnection agreement allows for a maximum output of 4 MW (as measured in alternating current). X may include the costs it paid or incurred for qualified interconnection property for each solar energy property when calculating its section 48 credit for each of the three solar energy properties, subject to the terms of each interconnection agreement, because each of the solar energy properties has a maximum net output of not greater than 5 MW.

(iii) *Example 3. Application of Five-Megawatt Limitation to a single interconnection agreement for multiple energy properties.* The facts are the same as Example 2, except that X is party to one interconnection agreement with the utility with respect to the three solar energy properties and the interconnection agreement allows for a maximum output of 12 MW (as measured in alternating current). With respect to each of the three solar energy properties, X may include the costs it paid or incurred for qualified interconnection property for each solar energy property when calculating its section 48 credit for each of the three solar energy properties, subject to the terms of the interconnection agreement, because each of the solar energy properties has a maximum net output of not greater than 5 MW.

(iv) *Example 4. Application of Five-Megawatt Limitation to an Energy Project.* The facts are the same as Example 3, except that the three solar energy properties are also subject to a common power purchase agreement and as a result, are considered an energy project (as defined in § 1.48–13(d)). With respect to each of the three solar energy properties, X may include the costs it paid or incurred for qualified interconnection property when calculating its section 48 credit for each of the three solar energy properties, subject to the terms of the interconnection agreement, because each of the solar energy properties has a maximum net output of no greater than 5 MW.

(h) *Cross references.* (1) For rules regarding the coordination of the section

42 credit and section 48 credit, see section 50(c)(3) of the Code.

(2) For rules regarding the denial of double benefit for qualified biogas property, see section 45(e) of the Code.

(3) To determine applicable recapture rules, see section 50(a) of the Code.

(4) For rules regarding the credit eligibility of property used outside the United States, see section 50(b)(1) of the Code.

(5) For rules regarding the credit eligibility of property used by certain tax-exempt organizations, see section 50(b)(3) of the Code. See section 6417(d)(2) of the Code for an exception to this rule in the case of an applicable entity making an elective payment election.

(6) For application of the normalization rules to the section 48 credit when taken by certain regulated companies, including rules regarding the election not to apply the normalization rules to energy storage technology (as defined in section 48(c)(6) of the Code), see section 50(d)(2) of the Code.

(i) *Applicability date.* This section applies with respect to property placed in service after December 31, 2022, and during a taxable year beginning after [DATE OF PUBLICATION OF FINAL RULE].

■ **Par. 5.** Section 1.6418–5, as proposed to be added at 88 FR 40496, June 21, 2023, is amended by:

■ 1. Redesignating paragraphs (f) through (h) as paragraphs (g) through (i).

■ 2. Adding new paragraph (f).

The addition reads as follows:

§ 1.6418–5 Special rules.

* * * * *

(f) *Notification and impact of recapture under section 48(a)(10)(C) of the Code*—(1) *In general.* In the case of any election under § 1.6418–2 or § 1.6418–3 with respect to any specified credit portion described in § 1.6418–1(c)(2)(iii), if, during any taxable year, there is recapture under section 48(a)(10)(C) of the Code and § 1.48–13(c)(3) of any increased credit amount under section 48(a)(9)(B)(iii) before the close of the recapture period (as described in § 1.48–13(c)(3)(E)), such eligible taxpayer and the transferee taxpayer must follow the notification process in paragraph (f)(2) of this section with recapture impacting the transferee taxpayer as described in paragraph (f)(3) of this section.

(2) *Notification requirements.* The notification requirements for the eligible taxpayer are the same as for an eligible taxpayer that must report a recapture event as described in paragraph (d)(2)(i) of this section, except that the recapture amount that must be computed is defined in § 1.48–13(c)(3)(D).

(3) *Impact of recapture.* The transferee taxpayer is responsible for any amount of tax increase under section 48(a)(10)(C) of the Code and § 1.48–13(c)(3) upon the occurrence of a recapture event under § 1.48–13(c)(3)(B).

(4) *Applicability date.* This section applies to taxable years ending on or after [DATE OF PUBLICATION OF FINAL RULE].

* * * * *

Douglas W. O'Donnell,

Deputy Commissioner for Services and Enforcement.

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